

IN THE 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 FOR THE UNITED STATES AS *AMICUS CURIAE*
ON REHEARING *EN BANC*
IN SUPPORT OF NEITHER PARTY**

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August 2, 2010

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STATEMENT OF INTEREST

The U.S. Patent and Trademark Office (“PTO”) respectfully submits this *amicus* brief in response to the Court’s invitation and pursuant to Fed. R. App. P. 29(a). The PTO is the agency of the United States government “responsible for the granting and issuing of patents.” 35 U.S.C. § 2(a)(1). The PTO therefore appreciates the opportunity to provide its view because inequitable conduct before the agency hampers the PTO’s ability to fulfill its mission.

Over the years, this Court’s case law has developed multiple formulations for the materiality and intent prongs of inequitable conduct, causing the doctrine to be unclear. *See, e.g., Leviton Mfg. Co., Inc. v. Univ. Security Instruments, Inc.*, 606 F.3d 1353, 1358 (Fed. Cir. May 28, 2009) (characterizing materiality as having “scattered precedents”). The various formulations coupled with the severity of the sanction of unenforceability has led patent applicants with some regularity to minimize their exposure to material information by avoiding prior art searches, or to submit to the agency large numbers of prior art references of questionable materiality. Neither practice helps to further the agency’s mission, but instead harms the effectiveness of the examination process. The PTO consequently is deeply concerned about the current state of the inequitable conduct doctrine and believes that clear standards need to be established.

Apart from the problems caused by multiple standards, inequitable conduct appears to be alleged in patent litigation all too often. By one account, inequitable conduct is raised in approximately 80% of all the patent cases. *See* Benjamin Brown, *Inequitable Conduct: A Standard in Motion*, 19 *Fordham Intell. Prop. Media & Ent. L. J.* 593 (2009) (citation omitted). As now Chief Judge Rader explained: “The allegation of inequitable conduct opens new avenues of discovery; impugns the integrity of patentee, its counsel, and the patent itself; excludes the prosecuting attorney from trial participation (other than as a witness); and even offers the trial court a way to dispose of a case without the rigors of claim construction and other complex patent doctrines.” *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting). The PTO appreciates that these problems have far-reaching consequences not only for patent litigants but also the courts.¹

SUMMARY OF THE ARGUMENT

Inequitable conduct originates from the unclean hands doctrine and common law fraud. Inequitable conduct should not be adjusted in favor of either one, lest inequitable conduct become murkier or too rigid, respectively. Specifically, tying inequitable conduct to unclean hands would render it much more open-ended,

¹ The PTO takes no position on the specific facts of this case.

providing little guidance as to what conduct should merit unenforceability.

Likewise, tying inequitable conduct to common law fraud would render it overly narrow in light of Supreme Court precedent.

The proper standard for materiality should be the current version of Rule 56, which defines information as material if it either establishes a *prima facie* case of unpatentability, or contradicts any of the applicant's patentability arguments. *See* 37 C.F.R. § 1.56 (2009). The PTO, as the agency to which a duty of disclosure is owed, is in the best position to know what information is essential to determining the patentability of a claimed invention. Rule 56 reflects the agency's expertise and experience in this regard. Also, Rule 56 is consistent with Supreme Court precedent and provides clear guidance to applicants as to what information to submit to comply with the duty of disclosure.

The proper standard for intent should be an actual deceptive intent as judged by the single most reasonable inference to be drawn in light of all the evidence. A specific intent standard is consistent with Supreme Court precedent as well as this Court's only other *en banc* inequitable conduct decision. It also appropriate given the severe remedy of unenforceability. Moreover, intent should not be inferred from materiality alone. To do so would establish essentially a strict liability standard for inequitable conduct based exclusively on the materiality of the withheld,

misrepresented, or falsified information. While evidence of materiality may be used as circumstantial evidence of intent, each prong must be separately proven.

Once a court has found both materiality and intent, it should consider the equities of the case as a final step in the analysis, and may decline to render the patent unenforceable. However, this should be a rare case if both materiality under Rule 56 and specific deceptive intent are shown by clear and convincing evidence.

ARGUMENT

I. The Inequitable Conduct Doctrine Has Roots in Both Unclean Hands and Common Law Fraud

The inequitable conduct doctrine originated from the doctrine of unclean hands² as well as common law fraud.³ In a trilogy of cases, the Supreme Court used

² Unclean hands closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief. *See Bein v. Heath*, 6 How. 228, 247 (1848). It does not involve any specific elements, such as a “but for” standard, nor is it specific to patent law. Rather, it is a generalized defense based solely in equity. *See Precision Instrument Mfg. Co. v. Auto. Main. Mach. Co.*, 324 U.S. 806, 814-15 (1945) (observing that “[a]ny willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim”).

³ Common law fraud has five “indispensable” elements: “(1) a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation.” *Norton v. Curtiss*, 433 F.2d 779, 793 (CCPA 1971) (citing W. Prosser, *Law of Torts*, §§ 100-05 (3d ed. 1964); 37 C.J.S. *Fraud* § 3 (1943)).

either unclean hands or common law fraud to punish a patentee who procured a patent by essentially “lying, cheating, or stealing.”⁴ See The Honorable Randall R. Rader, Always at the Margin: Inequitable Conduct In Flux, 59 Am. U. L. Rev. 777, 780 (2010) (characterizing the Supreme Court cases dealing with fraud or unclean hands as involving situations “where applicants ‘lied, cheated, and stole’ to obtain a patent”).

More specifically, in *Keystone Driller Co. v. General Excavator Co.*, the Supreme Court reasoned that a patentee, who concealed the “possible prior art use” of the claimed invention from the PTO and contracted with the possible prior art user to remain silent, came to court in an infringement suit with unclean hands and thus was not entitled to enforce the patent. 290 U.S. 240, 247 (1933). The Court warned that “[t]he equitable powers of this court can never be exerted in behalf of one who has acted fraudulently, or who by deceit or any unfair means has gained an advantage.” *Id.* at 245.

The Court reached a similar conclusion based on unclean hands in *Precision Instrument Mfg. Co. v. Automotive Maintenance Machine Co.*, 324 U.S. 806 (1945).

⁴ The Supreme Court cases also illustrate that misconduct by a patentee during litigation can lead to a finding of inequitable conduct. See, e.g., *Keystone*, 290 U.S. at 240.

There, the patentee (i) learned of an inventor's perjury before the PTO regarding his claimed invention, (ii) used the perjury to force the inventor to assign over the application, and (iii) prosecuted the perjury-tainted application to issuance.

Id. at 810-814. The Supreme Court prevented the patentee from enforcing the perjury-tainted patent because it “[did] not display[] that standard of conduct requisite to the maintenance of th[e] suit in equity.” *Id.* at 819. The Court advised that “[t]hose who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible *fraud or inequitableness* underlying the applications in issue.” *Id.* at 818 (emphasis added). Further, it explained that “[t]he far-reaching social and economic consequences of a patent [] give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from *fraud or other inequitable conduct.*” *Id.* at 816 (emphasis added).

Finally, in *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, the Supreme Court prevented a patentee, who falsified an article touting the benefits of the claimed invention to overcome a rejection, from enforcing the patent based upon the finding of “a deliberately planned and carefully executed scheme to defraud not only the Patent Office but the Circuit Court of Appeals.” 322 U.S. 238, 245 (1944). The Court observed that “[t]he public welfare demands that the agencies of public

justice be not so impotent that they must always be mute and helpless victims of deception and fraud.” *Id.* at 246.

The Court of Customs and Patent Appeals confronted “fraud on the PTO” for the first time in *Norton v. Curtiss*, 433 F.2d 779 (CCPA 1970). Similar to the Supreme Court in *Keystone*, *Precision*, and *Hazel-Atlas*, the CCPA turned to unclean hands and common law fraud to resolve the case. It blended the two, borrowing the materiality and intent elements from common law fraud, but expanding the type of conduct swept into each to account for the unclean hands doctrine. In doing so, the Court explained that “in suits involving patents, today, the concept of ‘fraud’ on the Patent Office (at least where a patentee’s conduct pertaining to the relative merits of his invention is concerned), encompasses not only that which we have earlier termed ‘technical’ fraud, but also a wider range of ‘inequitable’ conduct found to justify holding a patent unenforceable.” *Id.* at 793. In that sense, the Court explained that “the concept of fraud becomes intermingled with the equitable doctrine of ‘unclean hands.’” *Id.* The CCPA justified this merger as an attempt to make an applicant’s duty of honesty and candor to the PTO meaningful, stating: “The highest standards of honesty and candor on the part of applicants in presenting such facts to the office are [] necessary elements in a working patent system. We would go so far as to say they are essential. It follows, therefore, that

we do approve of the indicated expansion of the types of misconduct for which applicants will be penalized.” *Id.* at 794.

The CCPA achieved an appropriate blend of unclean hands and common law fraud in *Norton*. Unclean hands and common law fraud are broad, generic doctrines that do not apply with any particularity to the specific problem of patent prosecution misconduct. In combining the two, the CCPA brought them into the patent prosecution context and did so in a way that encourages proper conduct before the agency and harmonizes the doctrine with Supreme Court precedent. Accordingly, the inequitable conduct framework is sound as it exists today.

II. The Proper Standard for Materiality Should Be Rule 56⁵

The Federal Circuit has identified five different standards for materiality: (i) the objective “but for” standard; (ii) the subjective “but for” standard; (iii) the “but it may have” standard; (iv) the “reasonable examiner” standard, 37 C.F.R. § 1.56 (1977-1991); and (v) the current version of Rule 56, 37 C.F.R. § 1.56 (1992-present). *See Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2009). The absence of a single standard has led to uncertainty among applicants as to what information should be disclosed to the PTO. The single

⁵ To avoid confusion, citations to “Rule 56 ” refer herein to the current regulation, and citations to the “reasonable examiner” standard refer to the former version of the regulation.

proper standard for materiality should be Rule 56. That rule defines information to be “material to patentability when it is not cumulative to information already of record or being made of record in the application” and

- (1) [i]t establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) [i]t refutes, or is inconsistent with, a position the applicant takes in:
 - (i) [o]pposing an argument of unpatentability relied on by the Office, or
 - (ii) [a]sserting an argument of patentability.

37 C.F.R. § 1.56(b) (2009).

First, the PTO knows best what information enables it to fulfill its mission. Rule 56 reflects the agency’s considered judgment and experience regarding what information from applicants the agency believes is necessary to conduct effective examinations. The PTO employs thousands of patent examiners, and the agency has acquired considerable expertise in determining what the agency needs, and does not need, to examine the hundreds of thousands of applications that are filed annually. In order for the agency to manage an effective and efficient examination process and reduce its unwieldy backlog of several hundred thousand applications, it is critical that applicants submit only information that the PTO considers to be material to patentability. As the PTO explained, Rule 56 “strike[s] a balance

between the need of the Office to obtain and consider all known relevant information pertaining to patentability before a patent is granted and the desire to avoid or minimize unnecessary complications in the enforcement of patents.” Duty of Disclosure, 57 Fed. Reg. 2021, 2021 (Jan. 17, 1992). For this reason, the Court should embrace Rule 56 as the standard for materiality, as it has in at least two cases. See *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1353 (Fed. Cir. 2005) (“[W]e give deference to the PTO’s formulation at the time an application is being prosecuted before an examiner of the standard of conduct it expects to be followed in proceedings in the Office.”); *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1129 (Fed. Cir. 2006) (same).

Second, Rule 56 presents clear and straightforward guidance for applicants regarding what information they should submit to the PTO to satisfy their duty of disclosure. See Duty of Disclosure, 57 Fed. Reg. 2021, 2023 (Jan. 17, 1992); see also U.S. Patent & Trademark Off., Manual of Patent Examining Procedure § 2001.04 (8th ed., July 2010) (“MPEP”) (explaining that Rule 56 was “amended to present a clearer and more objective definition of what information the Office considers material to patentability”). With the high stakes of unenforceability as the penalty for inequitable conduct, see *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) (*en banc*), it is critical that applicants have such clear notice to judge whether to submit certain information to the PTO. Indeed, that was not

the case with the former Rule 56, which embodied the “reasonable examiner” standard, and was the reason why the agency promulgated the current rule. *See infra* § III, B (discussing the drawbacks of the “reasonable examiner” standard).

Third, the patent system depends upon applicants acting with candor and good faith when conducting business before the PTO. *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949). Paragraph (b)(2) of Rule 56 prevents applicants from presenting patentability arguments contrary to information known to them. By contrast, the “but for” standard would permit applicants to engage in a level of purposeful gamesmanship on core patentability issues. Accordingly, unlike the “but for” standard, Rule 56—through paragraph (b)(2)—ensures that applicants deal honestly with the agency about all patentability matters.

Fourth, while Rule 56 did not exist at the time of the Supreme Court’s trilogy of cases, the Supreme Court has repeatedly recognized matters related to a patent as “issues of great moment to the public.” *Precision*, 324 U.S. at 815; *see also Hazel-Atlas Glass*, 322 U.S. at 246. Indeed, the Supreme Court has cautioned that the social and economic consequences of a patent “give the public a paramount interest in seeing that patent monopolies” stem from applications “free from fraud or other inequitable conduct.” *Precision*, 324 U.S. at 816. Rule 56 is consistent with the Supreme Court’s guidance in that it prevents applicants from knowingly taking contradictory positions on patentability matters and ensures that examiners have

full access to favorable and unfavorable information, despite the *ex parte* nature of the proceeding.

Lastly, the Court’s “reasonable examiner” standard has its genesis in the PTO’s 1977 version of Rule 56. *See Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984). Given the Court’s willingness to use a materiality standard from a PTO rule, it is reasonable for the Court to now adopt current Rule 56, particularly because that version was promulgated via public notice-and-comment rulemaking after the patent bar criticized the “reasonable examiner” standard as “vague.” *Duty of Disclosure*, 56 Fed. Reg. 37321, 37322 (Aug. 6, 1991); *see also* 57 Fed. Reg. at 2023. To address that criticism, the PTO amended Rule 56 to its current form. In doing so, the agency sought to (i) clarify what information that the agency consider material, and (ii) “ensure that the most pertinent information is considered during examination by the Office.” 56 Fed. Reg. at 37324.

III. There Are Significant Drawbacks With the Other Possible Standards for Materiality

A. The “But For” Standard Is Too Narrow and Is Inconsistent with Supreme Court Precedent

The “but for” standard defines information as material if the patent would not have issued “but for” the omission, misrepresentation, or falsification. *See, e.g., Digital Control*, 437 F.3d at 1315. This standard is too narrow. *See* 57 Fed. Reg.

at 2024 (explaining that the “but for” standard “would not cause the Office to obtain the information it needs to evaluate patentability so that its decisions may be presumed correct by the courts”). It would in essence require the accused infringer to prove invalidity first, leaving little work for the inequitable conduct doctrine to do.

Additionally, if the “but for” standard were to be applied, then applicants would be free to engage in a wide-variety of misconduct, *e.g.*, lying to the agency in an attempt to influence the examiner’s patentability determination, so long as it cannot be proven later that the patent would not have issued “but for” the misconduct. The materiality standard should not be so narrow that it exposes the agency to applicants who lie with impunity on issues of patentability. Such practice would seriously interfere with the agency’s ability to efficiently carry out its mission of granting and issuing patents.

Moreover, the “but for” standard is not supported by Supreme Court precedent. In *Keystone*, for example, although the applicant had learned of a “possible prior use” that “cast doubt upon the validity of the patent,” the Supreme Court did not rule that the patent would not have issued “but for” the failure to disclose the possible prior use. 290 U.S. at 243. Likewise, in *Precision*, the patent owner engaged in various types of misconduct, including knowingly prosecuting a perjury-tainted application before the agency, yet the Supreme Court did not find

that the patent would not have issued “but for” that perjury. 324 U.S. at 819.

Similarly, in *Hazel-Atlas*, the patentee falsified an article in an effort to overcome a rejection, but the Supreme Court did not state that “but for” the misconduct, the patent would not have issued. 322 U.S. at 250. While all of the cases involved applicants who acted deceptively on questions of patentability, neither the Court’s holdings nor its rationale limited the relevant inquiry to a “but for” standard.

The Supreme Court also addressed a situation involving a misrepresentation submitted to the PTO in *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358 (1928), and some may rely on this case in advocating for a “but for” standard.

Corona, however, is unhelpful in understanding the inequitable conduct doctrine. There, the applicant submitted false affidavits, secured a patent, and then sought to enforce the patent. In its defense, the accused infringer raised invalidity only; it did not allege that the patentee had unclean hands or engaged in fraud. The Supreme Court rejected the invalidity defense, reasoning that the affidavits “were not the basis for [the patent] or essentially material to its issue.” *Id.* at 374. While the Supreme Court’s reasoning discusses the materiality of the affidavits, it cannot be used to support a “but for” standard for inequitable conduct because it solely dealt with invalidity. Indeed, the Supreme Court never commented on patent unenforceability until years later in *Keystone*.

Further, 35 U.S.C. § 282, which provides for defenses to infringement, including unenforceability, does not provide any helpful guidance. The legislative history of the 1952 Patent Act reveals that section 282 was “added by amendment in the Senate for greater clarity,” P.J. Federico, *Commentary on the New Patent Act*, 75 J. Pat & Trademark Off. Soc’y 161, 215 (1993), “for the purpose of making sure that the misuse defense was preserved,” Giles S. Rich, *Report on the Patent Act of 1952*, *id.* at 22. This history also notes that section 282 was intended to “include * * * equitable defenses such as laches, estoppel, and unclean hands.” Federico, 75 J. Pat & Trademark Off. Soc’y at 215. The history does not show that Congress sought in listing unenforceability as a defense to codify any particular court decision, such as those addressing fraud with its “but for” reliance element. Nor does it show that Congress intended to codify any particular elements for the various equitable defenses swept into the unenforceability category.

Finally, some may argue that misconduct that does not rise to the level of satisfying the “but for” standard should simply be referred to the Office of Enrollment and Discipline (“OED”) for potential agency disciplinary action. There are at least two reasons why such a scheme is not possible or practical. First, under 28 U.S.C. § 2462, the PTO is required to file charges against an individual within five years of the inequitable conduct. In reality, however, the PTO infrequently learns of the inequitable conduct within this time frame, and consequently, PTO

disciplinary actions arising out of inequitable conduct are often barred by the statute of limitations.

Second, it is unlikely that the PTO would be able to police fraud against the agency during the statute of limitations period. The PTO seldom acquires clear and convincing evidence of the inequitable conduct because the PTO does not have access to the relevant facts, which are typically within the patentee's control. This is different from a typical OED case where an aggrieved client reports to the agency the alleged misconduct and the facts necessary to prove it. Furthermore, the agency is constrained in its ability to investigate "fraud on the PTO" because OED cannot issue subpoenas during their investigations.⁶ *See* 35 U.S.C. § 24 (noting that the PTO's subpoena power only arises in a "contested case").

B. The "Reasonable Examiner" Standard Is Ambiguous

The "reasonable examiner" standard defines material information as that which a reasonable examiner "would 'consider [] important' in deciding whether to

⁶ In the late 1980s, the PTO attempted to prosecute allegations of "fraud on the PTO," but was unsuccessful because it lacked subpoena power as well the necessary resources and thus discontinued this effort. To that end, the PTO explained: "The Office is not the best forum in which to determine whether there was an 'intent to mislead,' such intent is best determined when the trier of facts can observe demeanor of witnesses subjected to cross-examination. * * * A court, with subpoena power, is presently the best forum to consider duty of disclosure issues under the present evidentiary standard for finding an 'intent to mislead.'" *See* Patent and Trademark Office Implementation of 37 C.F.R. 1.56, 1095 Off. Gazette 16 (Oct. 11, 1988).

reject one or more claims.” *Am. Hoist*, 725 F.2d at 1362. This standard is the broadest of the standards, *see Digital Control*, 437 F.3d at 1315, and is ambiguous in that it fails to provide meaningful guidance as to what information a reasonable examiner would consider important in determining patentability. *See Rader*, 59 Am. U. L. Rev. at 783 (explaining that the “reasonable examiner” standard “calls into question almost any undisclosed prior art, not just prior art of consequence to the issuance decision”).

Because applicants are unclear what information to submit to the PTO, they all too often file mounds of information with questionable materiality. *See, e.g.*, U.S. Patent No. 7,651,688 (900 references submitted by the applicant for an “antibody composition” invention in a series of six IDS forms without any indication which ones or parts of the references were most relevant). The agency has seen an increasing trend of applicants “dumping” references on patent examiners in just the past five years. *See* Patently-O, Cutting Back: Average Number of References Cited per Patent (July 13, 2010) (indicating that the mean average number of references cited by an applicant in a patent increased over 50 percent from approximately 15 in 2005 to roughly 25 in 2009). While this practice occurs in only a minority of the several hundreds of thousands of applications filed every year, it nevertheless has resulted in a dramatic increase in the *mean average* of submitted references, akin to raising the ocean’s temperature by a few degrees. This

flood of information strains the agency's examining resources and directly contributes to the backlog. Accordingly, like the "but for" standard, the "reasonable examiner" standard is less than optimal.

IV. The Proper Standard for Intent Should Be a Specific Intent to Deceive

Since the *en banc* Court rejected gross negligence alone as the standard for intent in *Kingsdown*, 863 F.2d at 876, the case law has developed along two different lines regarding the requisite level of intent to prove inequitable conduct. In one line, this Court explained that an inference of intent is appropriate for an omission if:

- (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 did not provide a credible explanation for the withholding.

Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006). In the other line, the Federal Circuit has held that to infer an intent to deceive, "the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008). The proper standard

for intent follows from the *Star Scientific* line and should be an actual intent to deceive.

First, the Supreme Court cases dealing with fraud or unclean hands all involved patentees who lied, cheated, or stole in an effort to procure a patent. In one instance, the Supreme Court described the misconduct as “a deliberately planned and carefully executed scheme to defraud not only the Patent Office but the Circuit Court of Appeals.” *Hazel-Atlas*, 322 U.S. at 245.

Second, this Court, sitting *en banc* in *Kingsdown*, explained that “[t]o be guilty of inequitable conduct, one must have intended to act inequitably,” that is, “with an intent to deceive.” 863 F.2d at 872. Plainly, the *en banc* Court contemplated applying inequitable conduct only in situations where the patentee acted with particularized *mens rea*. Following *Kingsdown*, this Court has repeatedly endorsed the view that inequitable conduct requires not intent to withhold, but rather intent to deceive. *See, e.g., Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1985); *Bruno*, 394 F.3d at 1351; and *Digital Control*, 437 F.3d at 1319.

Third, because inequitable conduct carries the harsh remedy of unenforceability, even where every claim meets the statutory requirements for patentability, *see Kingsdown*, 863 F.2d at 877, the underlying mental state of the intent prong should be correspondingly high. As this Court has recognized, “[j]ust as it is inequitable to permit a patentee who obtained his patent through deliberate

misrepresentations * * * , it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability.”

Star Scientific, 537 F.3d at 1366.

Fourth, patent applicants and their attorneys currently operate under the fear of future inequitable conduct allegations in part because of the unclear intent standard. *See* MPEP § 2001.05 (explaining that applicants typically wish to submit information “even though they may not be required to do so” to avoid the risk of inequitable conduct). As a result, they submit an excessive number of prior art references that may or may not actually be material, as explained earlier. *See* ABA Section of Intellectual Property Law, A Section White Paper: Agenda for 21st Century Patent Reform 2 (2009) (“Applicants disclose too much prior art for the PTO to meaningfully consider, and do not explain its significance, all out of fear that to do otherwise risks a claim of inequitable conduct.”). Tightening the intent standard to a specific intent to deceive can alleviate the unnecessary fear that exists in the patent community. In turn, applicants and their attorneys should discontinue the practice of submitting every document that crosses their desks, and the PTO can focus on those references that really are material during examination and work to reduce the backlog.

V. *Ferring's* Test Should Not be the Standard for Intent Because It Encompasses Negligent Behavior

The *Ferring* test improperly incorporates negligence as the mental state. In particular, it inquires into whether the applicant “should have known” of the materiality of the information. See *Larson Mfg. Co. of So. Dakota, Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1343 (Fed. Cir. 2009) (Linn, J., concurring); see also *Ferring*, 437 F.3d at 1201 (Newman, J., dissenting). Both the Supreme Court and the Federal Circuit sitting *en banc* have, however, rejected “gross negligence” as the standard for intent in the fraud context. See *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 208 (1976) (rejecting a gross negligence theory of liability for securities fraud); *Kingsdown*, 863 F.2d at 876 (*en banc*) (“adopt[ing] the view that a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive”). Given that gross negligence has been rejected as the standard for fraud, *Ferring's* “should have known” inquiry likewise should be rejected. Further, the Supreme Court’s trilogy of cases contemplate affirmative deception and not negligence. See *Precision*, 324 U.S. at 816 (conduct was “steeped in perjury”); *Hazel-Atlas*, 322 U.S. at 250 (“trail of fraud”); and *Keystone*, 290 U.S. at 246-47 (“corruption” in the form of “suppression of [] evidence”).

VI. Intent Should Not Be Inferred From Materiality Alone But Evidence of Materiality May Be Used to Show Intent

Intent must be proven separately from materiality and by clear and convincing evidence. Inferring intent solely from materiality would essentially collapse the intent prong into the materiality prong, transforming inequitable conduct into a strict liability doctrine. Liability would be predicated only on the materiality of the omission, misrepresentation, or falsification. This Court has correctly rejected such a notion in several past cases. *See, e.g., AstraZeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583 F.3d 766, 770 (Fed. Cir. 2009). But evidence of materiality is not irrelevant to the question of intent; it may be used to help show intent circumstantially.⁷

To infer intent from materiality, however, the court must find that the patentee appreciated the materiality of the information contemporaneous to the time of the alleged misconduct. An applicant's duty of disclosure under Rule 56 applies to "contemporaneously or presently known information." 57 Fed. Reg. at 2025; *see also* 37 C.F.R. § 1.56 (2009); 56 Fed. Reg. at 37323; MPEP § 2001.04. As

⁷ One illustration of how intent may be inferred from materiality is when an applicant studiously avoids uncovering material information, despite clear warnings of its existence. *See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1383 (Fed. Cir. 2001) ("one should not be able to cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that information or prior art."). In such circumstances, "deceptive intent may be inferred." *Id.*

the agency explained in promulgating Rule 56, “[t]he fact that information was known years ago does not mean that it was recognized that the information is material to the present application.” 57 Fed. Reg. at 2025.

Additionally, the degree of materiality is relevant to the proof necessary to establish intent. Intuitively, the higher the degree of materiality of the information, the more likely the inference is that the patentee intended to deceive the PTO in omitting, misrepresenting, or falsifying it. *See, e.g., Star Scientific*, 537 F.3d at 1366. Using evidence of materiality to help establish intent does not, however, lower the threshold for intent. While some opinions have characterized the relationship between the materiality and intent prongs as some form of a “sliding scale,” *see, e.g., Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997), that description unfortunately suggests that proof of highly material information significantly reduces the threshold level of proof necessary for intent. That is not correct, as such an approach can render the intent inquiry an afterthought. What a higher level of materiality does is bring the accused infringer relatively closer to meeting the clear and convincing evidentiary burden of intent. *See Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1323-24 (Fed. Cir. May 5, 2010) (Prost, J., concurring). Because the “sliding scale” is often misunderstood in this regard, this Court should clarify that a high degree of materiality does not mean that only a negligible amount of intent is required.

Finally, the absence of a credible explanation for the failure to disclose material information may be considered in inferring intent. “When the absence of a good faith explanation is the only evidence of intent, however, that evidence alone does not constitute clear and convincing evidence warranting an inference of intent.” *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006).

VII. The Intent Standard Should Be Judged by *Star Scientific’s* Single Most Reasonable Inference Test

Apart from embracing a specific intent standard, the Court in *Star Scientific* set forth via the “single most reasonable inference” language an effective prism through which a court should view a patentee’s conduct to assess whether an accused infringer has proven intent by clear and convincing evidence. If the evidence supports two equally plausible inferences—one in favor of and one against deceptive intent—it is impossible to say that there is clear and convincing evidence of intent. *See Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008). This Court should thus adopt the “single most reasonable inference” as the test for judging intent.

VIII. The Materiality-Intent Balancing Should Be Clarified

The final step of the inequitable conduct inquiry is a so-called “materiality-intent balancing” test: “If the requirements of materiality and intent are met, [t]he

court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent,' with a greater showing of one factor allowing a lesser showing of the other.'" *Larson*, 559 F.3d at 1327 (quoting *Digital Control*, 437 F.3d at 1313). The "balancing" inquiry has caused confusion in the inequitable conduct doctrine.

First, by describing the inquiry in terms of balancing the levels of materiality and intent, it is often confused with the "sliding scale" where intent to deceive may be inferred from materiality. *See, e.g., Critikon*, 120 F.3d at 1256. But the "sliding scale" has no relation to the balancing; it applies before any balancing is done.

Second, once the individual threshold levels of materiality and intent are independently met, a court seldom conducts the balancing inquiry. Rather, inequitable conduct is generally found. *See Rader*, 59 Am. L. Rev. at 785 ("[O]nce a court has found both materiality and intent, it is a short, slippery step into the final ruling of unenforceability."). But given the equitable nature of the inequitable conduct doctrine, as emphasized by the Supreme Court, *see, e.g., Precision*, 324 U.S. at 814-16, it is not appropriate to automatically hold a patent unenforceable once the materiality and intent prongs have been proven.

Hence, the "balancing" inquiry should be clarified to establish that it is not a sliding scale or a rigid rule. Rather, it simply requires a court to consider all of the evidence of record in determining whether the equities warrant holding the patent

unenforceable, after the accused infringer establishes the thresholds of materiality and intent by clear and convincing evidence and after the patentee has the opportunity to rebut that evidence. *See Star Scientific*, 537 F.3d at 1368. This review respects the equitable origins of the doctrine. *See supra*, § I. But if an accused infringer proves by clear and convincing evidence that a patentee withheld information that was material under Rule 56 and did so with a specific intent to deceive the PTO, then it should be a fairly rare case in which the patentee could identify other equitable considerations that would tip the balance in favor of enforceability.

IX. The Materiality and Intent Standards Applied by Other Federal Agencies Are Not Helpful

The standards for materiality and intent in other federal agency contexts do not shed light on the appropriate standards to be applied in the patent context. While the Patent Act does not include a specific fraud provision, the Lanham Act does. *See* 15 U.S.C. § 1120. Likewise, some other federal agencies have specific fraud statutes. *See, e.g.*, 17 U.S.C. § 411(b)(1) (Copyright Office); 15 U.S.C. § 78a (Securities and Exchange Commission (“SEC”)); 8 U.S.C. § 1451(a) (Immigration and Naturalization Service (“INS”).

Additionally, courts have construed many of the agencies’ fraud statutes to contain quite diverse standards for materiality and intent. For example, for

materiality, while appellate courts have construed the trademark and copyright fraud statutes to include a standard akin to “but for,” *see, e.g., Morehouse Mfg. Corp. v. J. Strickland & Co.*, 407 F.2d 881, 886 (CCPA 1969) (trademark); *St. Luke’s Cataract & Laser Inst., P.A. v. Sanderson*, 573 F.3d 1186, 1201 (11th Cir. 2009) (copyright), the Supreme Court has read the SEC’s fraud statute to employ a reasonable investor standard, *see TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976), which is similar to the “reasonable examiner” standard, and the INS’s fraud statute to resemble the “but it may have” standard, *see Kungys v. United States*, 485 U.S. 759, 770 (1988).

Because there is no specific patent fraud statute, and because of the lack of uniformity in the various agency fraud statutes for the materiality and intent standards, it is not possible to align the materiality and intent prongs for inequitable conduct with the standards used by other federal agencies. Also, those fraud statutes cannot control the inequitable conduct doctrine, which is judicially-created and in part originates from unclean hands. *See supra* § I.

CONCLUSION

To properly adjust the inequitable conduct doctrine, the PTO respectfully urges the Court to adopt the materiality and intent standards as well as the approach to the materiality-intent balancing advocated herein.

Respectfully submitted,



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August 2, 2010

**CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULES OF APPELLATE PROCEDURE 29(d) AND
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I hereby certify that this amicus brief complies with the type-face and volume limitations set forth in Federal Rules of Appellate Procedure 29(d) and 32(a)(7)(B) because the type face is Garamond, proportionally spaced, fourteen-point font, and the number of words in this brief is 6,999, according to the count of Corel Wordperfect 11.



CERTIFICATE OF SERVICE

I hereby certify that on August 2, 2010, I caused copies of the foregoing **BRIEF FOR THE UNITED STATES AS *AMICUS CURIAE* ON REHEARING *EN BANC* IN SUPPORT OF NEITHER PARTY** to be filed with the Court. In addition, I caused copies to be served upon the following counsel by electronic mail and first-class U.S. mail:

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