

**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.

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

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.

Decided: May 25, 2011

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BRUCE A. LEHMAN, International Intellectual Property Institute, of Washington, DC, for amicus curiae International Intellectual Property Institute, on rehearing en banc.

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JEFFREY D. MILLS, King & Spalding LLP, of Austin, Texas, for amicus curiae Association of Citizens for Patent Protection in the Public Interest on rehearing en banc. With him on the brief was BRIAN C. BANNER.

HENRY C. DINGER, Goodwin Procter LLP, of Boston, Massachusetts, for amici curiae Teva Pharmaceuticals USA, Inc., et al. Cisco Systems, Inc., and Generic Pharmaceutical Association on rehearing en banc. With him on the brief were ELAINE HERRMANN BLAIS, NICHOLAS K. MITROKOSTAS and ANDREW M. BATCHELOR.

DAN L. BAGATELL, Perkins Coie Brown & Bain, P.A., of Phoenix, Arizona, for amicus curiae Intel Corporation

on rehearing en banc. Of counsel on the brief was TINA M. CHAPPELL, Intel Corporation, of Chandler, Arizona.

Before RADER, *Chief Judge*, NEWMAN, LOURIE, BRYSON, GAJARSA, LINN, DYK, PROST, MOORE, O'MALLEY, and REYNA, *Circuit Judges*.

Opinion for the court filed by *Chief Judge* RADER, in which *Circuit Judges* NEWMAN, LOURIE, LINN, MOORE, and REYNA join in full, and in which *Circuit Judge* O'MALLEY joins in part V.

Concurring-in-part and dissenting-in-part opinion filed by *Circuit Judge* O'MALLEY.

Dissenting opinion filed by *Circuit Judge* BRYSON, in which *Circuit Judges* GAJARSA, DYK, and PROST join.

RADER, *Chief Judge*.

The United States District Court for the Northern District of California found U.S. Patent No. 5,820,551 (“the ’551 patent”) unenforceable due to inequitable conduct. *Therasense, Inc. v. Becton, Dickinson & Co.*, 565 F. Supp. 2d 1088 (N.D. Cal. 2008) (“*Trial Opinion*”). Therasense, Inc. (now Abbott Diabetes Care, Inc.) and Abbott Laboratories (collectively, “Abbott”) appeal that judgment. This court vacates and remands for further proceedings consistent with this opinion.

I

The ’551 patent involves disposable blood glucose test strips for diabetes management. These strips employ electrochemical sensors to measure the level of glucose in a sample of blood. When blood contacts a test strip, glucose in the blood reacts with an enzyme on the strip, resulting in the transfer of electrons from the glucose to the enzyme. A mediator transfers these electrons to an

electrode on the strip. Then, the electrons flow from the strip to a glucose meter, which calculates the glucose concentration based on the electrical current.

The '551 patent claims a test strip with an electrochemical sensor for testing whole blood without a membrane over the electrode:

1. A single use disposable electrode strip for attachment to the signal readout circuitry of a sensor to detect a current representative of the concentration of a compound in a drop of a whole blood sample comprising:

a) an elongated support having a substantially flat, planar surface, adapted for releasable attachment to said readout circuitry;

b) a first conductor extending along said surface and comprising a conductive element for connection to said readout circuitry;

c) an active electrode on said strip in electrical contact with said first conductor and positioned to contact said whole blood sample;

d) a second conductor extending along said surface comprising a conductive element for connection to said read out circuitry; and

e) a reference counterelectrode in electrical contact with said second conductor and positioned to contact said whole blood sample,

wherein said active electrode is configured to be exposed to said whole blood sample without an

intervening membrane or other whole blood filtering member

'551 patent col.13 l.29-col.14 l.3 (emphasis added). “Whole blood,” an important term in the claim, means blood that contains all of its components, including red blood cells.

In the prior art, some sensors employed diffusion-limiting membranes to control the flow of glucose to the electrode because the slower mediators of the time could not deal with a rapid influx of glucose. Other prior art sensors used protective membranes to prevent “fouling.” Fouling occurs when red blood cells stick to the active electrode and interfere with electron transfer to the electrode. Protective membranes permit glucose molecules to pass, but not red blood cells.

Abbott filed the original application leading to the '551 patent in 1984. Over thirteen years, that original application saw multiple rejections for anticipation and obviousness, including repeated rejections over U.S. Patent No. 4,545,382 (“the '382 patent”), another patent owned by Abbott. The '382 patent specification discussed protective membranes in the following terms: “Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.” Col.4 ll.63-66. “Live blood” refers to blood within a body.

In 1997, Lawrence Pope, Abbott’s patent attorney, and Dr. Gordon Sanghera, Abbott’s Director of Research and Development, studied the novel features of their application and decided to present a new reason for a patent. Pope presented new claims to the examiner based on a new sensor that did not require a protective membrane for whole blood. Pope asserted that this distinction

would overcome the prior art '382 patent, whose electrodes allegedly required a protective membrane. The examiner requested an affidavit to show that the prior art required a membrane for whole blood at the time of the invention.

To meet this evidentiary request, Dr. Sanghera submitted a declaration to the U.S. Patent and Trademark Office ("PTO") stating:

[O]ne skilled in the art would have felt that an active electrode comprising an enzyme and a mediator would require a protective membrane if it were to be used with a whole blood sample. . . . [O]ne skilled in the art would not read lines 63 to 65 of column 4 of U.S. Patent No. 4,545,382 to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred.

J.A. 7637. Pope, in submitting Sanghera's affidavit, represented:

The art continued to believe [following the '382 patent] that a barrier layer for [a] whole blood sample was necessary

One skilled in the art would *not* have read the disclosure of the ['382 patent] as teaching that the use of a protective membrane with whole blood samples was optional. He would not, especially in view of the working examples, have read the "optionally, but preferably" language at line 63 of column [4] as a technical teaching but rather mere patent phraseology.

. . . .

There is no teaching or suggestion of unprotected active electrodes for use with whole blood specimens in [the '382 patent]

J.A. 7645-46.

Several years earlier, while prosecuting the European counterpart to the '382 patent, European Patent EP 0 078 636 ("EP '636"), Abbott made representations to the European Patent Office ("EPO") regarding the same "optionally, but preferably" language in the European specification. On January 12, 1994, to distinguish a German reference labeled D1, which required a diffusion-limiting membrane, Abbott's European patent counsel argued that their invention did not require a diffusion-limiting membrane:

Contrary to the semipermeable membrane of D1, the protective membrane optionally utilized with the glucose sensor of the patent is [sic] suit is not controlling the permeability of the substrate

Rather, in accordance with column 5, lines 30 to 33 of the patent in suit:

"Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules."

See also claim 10 of the patent in suit as granted according to which the sensor electrode has an outermost protective membrane (11) permeable to water and glucose molecules. . . . Accordingly, *the purpose of the protective membrane of the patent in suit, preferably to be used with in vivo measurements, is a safety measurement to prevent any course [sic] particles coming off during use but not a permeability control for the substrate.*

J.A. 6530-31 (emphases added).

On May 23, 1995, Abbott's European patent counsel submitted another explanation about the D1 reference and EP '636.

“Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.”

It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor. Furthermore it is said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is “permeable” to glucose molecules. This teaches the skilled artisan that, whereas the [D1 membrane] must . . . control the permeability of the glucose . . . the purpose of the protective membrane in the patent in suit is not to control the permeation of the glucose molecules. For this very reason the sensor electrode as claimed does not have (and must not have) a semipermeable membrane in the sense of D1.

J.A. 6585 (first and third emphases added).

II

In March 2004, Becton, Dickinson and Co. (“Becton”) sued Abbott in the District of Massachusetts seeking a declaratory judgment of noninfringement of U.S. Patent Nos. 6,143,164 (“the '164 patent”) and 6,592,745 (“the '745 patent”). Becton's product was a blood glucose test strip, the BD Test Strip. Abbott countersued Becton in the

Northern District of California alleging that Becton's strip infringed the '164, '745, and '551 patents. The District of Massachusetts then transferred its case to the Northern District of California. Abbott then sued Nova Biomedical Corp. ("Nova"), Becton's supplier, alleging infringement of the patents asserted in Abbott's suit against Becton. In August 2005, Abbott also sued Bayer Healthcare LLC ("Bayer"), alleging that its Microfill and Autodisc blood glucose strips infringed the '551 and '745 patents. The Northern District of California consolidated all of the cases.

The district court granted summary judgment of non-infringement of all asserted claims in the '164 and '745 patents. *Therasense, Inc. v. Becton, Dickinson & Co.*, 560 F. Supp. 2d 835, 854, 880 (N.D. Cal. 2008). The district court also found nearly all of the asserted claims of the '745 patent invalid due to anticipation. *Id.* at 880.

Following a bench trial, the district court determined that claims 1-4 of the '551 patent were invalid due to obviousness in light of the '382 patent and U.S. Patent No. 4,225,410 ("the '410 patent"). *Trial Opinion* at 1127. The central issue for obviousness was whether the prior art would have disclosed a glucose sensor without a membrane for whole blood to a person of ordinary skill in the art. The district court found that the '382 patent disclosed sensors in which "a protective membrane was optional in all cases except the case of live blood, in which case the protective membrane was preferred—but not required." *Id.* at 1103. Of primary relevance here, the district court held the '551 patent unenforceable for inequitable conduct because Abbott did not disclose to the PTO its briefs to the EPO filed on January 12, 1994 and May 23, 1995. *Id.* at 1127.

Abbott appealed the judgments of invalidity, unenforceability, and noninfringement. *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289 (Fed. Cir. 2010), *vacated*, 374 Fed. Appx. 35 (Fed. Cir. 2010). A panel of this court unanimously upheld the district court’s judgments of noninfringement and invalidity. *Id.* at 1311. On unenforceability, the panel also affirmed, but with a dissent. *Id.* at 1312-25 (Linn, J., dissenting).

Recognizing the problems created by the expansion and overuse of the inequitable conduct doctrine, this court granted Abbott’s petition for rehearing en banc and vacated the judgment of the panel. *Therasense*, 374 Fed. Appx. at 35. This court now vacates the district court’s inequitable conduct judgment and remands.

III

Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. This judge-made doctrine evolved from a trio of Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct: *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), *overruled on other grounds by Standard Oil Co. v. United States*, 429 U.S. 17 (1976), and *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945).

Keystone involved the manufacture and suppression of evidence. 290 U.S. at 243. The patentee knew of “a possible prior use” by a third party prior to filing a patent application but did not inform the PTO. *Id.* at 243. After the issuance of the patent, the patentee paid the prior user to sign a false affidavit stating that his use was an abandoned experiment and bought his agreement to keep secret the details of the prior use and to suppress evi-

dence. *Id.* With these preparations in place, the patentee then asserted this patent, along with two other patents, against Byers Machine Co. (“Byers”). *Keystone Driller Co. v. Byers Mach. Co.*, 4 F. Supp. 159 (N.D. Ohio 1929). Unaware of the prior use and of the cover-up, the court held the patents valid and infringed and granted an injunction. *Id.* at 160.

The patentee then asserted the same patents against General Excavator Co. and Osgood Co. and sought a temporary injunction based on the decree in the previous Byers case. *Keystone*, 290 U.S. at 242. The district court denied the injunctions but made the defendants post bonds. *Id.* The defendants discovered and introduced evidence of the corrupt transaction between the patentee and the prior user. *Id.* at 243-44. The district court declined to dismiss these cases for unclean hands. *Id.* On appeal, the Sixth Circuit reversed and remanded with instructions to dismiss the complaints. *Id.* The Supreme Court affirmed. *Id.* at 247.

The Supreme Court explained that if the corrupt transaction between the patentee and the prior user had been discovered in the previous Byers case, “the court undoubtedly would have been warranted in holding it sufficient to require dismissal of the cause of action.” *Id.* at 246. Because the patentee used the Byers decree to seek an injunction in the cases against General Excavator Co. and Osgood Co., it did not come to the court with clean hands, and dismissal of these cases was appropriate. *Id.* at 247.

Like *Keystone*, *Hazel-Atlas* involved both the manufacture and suppression of evidence. 322 U.S. at 240. Faced with “apparently insurmountable Patent Office opposition,” the patentee’s attorneys wrote an article describing the invention as a remarkable advance in the

art and had William Clarke, a well-known expert, sign it as his own and publish it in a trade journal. *Id.* After the patentee submitted the Clarke article to the PTO in support of its application, the PTO allowed a patent to issue. *Id.* at 240-41.

The patentee brought suit against Hazel-Atlas Glass Co. (“Hazel-Atlas”), alleging infringement of this patent. *Id.* at 241. The district court found no infringement. *Id.* On appeal, the patentee’s attorneys emphasized the Clarke article, and the Third Circuit reversed the district court’s judgment, holding the patent valid and infringed. *Id.* The patentee then went to great lengths to conceal the false authorship of the Clarke article, contacting Clarke multiple times, including before and after Hazel-Atlas’s investigators spoke to him. *Id.* at 242-43. After Hazel-Atlas settled with the patentee, the patentee paid Clarke a total of \$8,000. *Id.* These facts surfaced in a later suit, *United States v. Hartford-Empire Co.*, 46 F. Supp. 541 (N.D. Ohio 1942). *Hazel-Atlas*, 322 U.S. at 243.

On the basis of these newly-discovered facts, Hazel-Atlas petitioned the Third Circuit to vacate its judgment, but the court refused. *Id.* at 243-44. The Supreme Court reversed. *Id.* at 251. The Supreme Court explained that if the district court had learned of the patentee’s deception before the PTO, it would have been warranted in dismissing the patentee’s case under the doctrine of unclean hands. *Id.* at 250. Likewise, had the Third Circuit learned of the patentee’s suppression of evidence, it also could have dismissed the appeal. *Id.* Accordingly, the Supreme Court vacated the judgment against Hazel-Atlas and reinstated the original judgment dismissing the patentee’s case. *Id.* at 251.

In *Precision*, the patentee suppressed evidence of perjury before the PTO and attempted to enforce the perjury-

tainted patent. 324 U.S. at 816-20. The PTO had declared an interference between two patent applications, one filed by Larson and the other by Zimmerman. *Id.* at 809. Automotive Maintenance Machinery Co. (“Automotive”) owned the Zimmerman application. *Id.* Larson filed his preliminary statement in the PTO proceedings with false dates of conception, disclosure, drawing, description, and reduction to practice. Later, he testified in support of these false dates in an interference proceeding. *Id.* at 809-10.

Automotive discovered this perjury but did not reveal this information to the PTO. *Id.* at 818. Instead, Automotive entered into a private settlement with Larson that gave Automotive the rights to the Larson application and suppressed evidence of Larson’s perjury. *Id.* at 813-14. Automotive eventually received patents on both the Larson and Zimmerman applications. *Id.* at 814. Despite knowing that the Larson patent was tainted with perjury, Automotive sought to enforce it against others. *Id.* at 807.

The district court found that Automotive had unclean hands and dismissed the suit. *Id.* at 808. The Seventh Circuit reversed. *Id.* The Supreme Court reversed the Seventh Circuit’s decision, explaining that dismissal was warranted because not only had the patentee failed to disclose its knowledge of perjury to the PTO, it had actively suppressed evidence of the perjury and magnified its effects. *Id.* at 818-19.

IV

The unclean hands cases of *Keystone*, *Hazel-Atlas*, and *Precision* formed the basis for a new doctrine of inequitable conduct that developed and evolved over time. Each of these unclean hands cases before the Supreme Court dealt with particularly egregious misconduct, including perjury, the manufacture of false evidence, and the sup-

pression of evidence. See *Precision*, 324 U.S. at 816-20; *Hazel-Atlas*, 322 U.S. at 240; *Keystone*, 290 U.S. at 243. Moreover, they all involved “deliberately planned and carefully executed scheme[s] to defraud” not only the PTO but also the courts. *Hazel-Atlas*, 322 U.S. at 245. As the inequitable conduct doctrine evolved from these unclean hands cases, it came to embrace a broader scope of misconduct, including not only egregious affirmative acts of misconduct intended to deceive both the PTO and the courts but also the mere nondisclosure of information to the PTO. Inequitable conduct also diverged from the doctrine of unclean hands by adopting a different and more potent remedy – unenforceability of the entire patent rather than mere dismissal of the instant suit. See *Precision*, 324 U.S. at 819 (dismissing suit); *Hazel-Atlas*, 322 U.S. at 251 (noting that the remedy was limited to dismissal and did not render the patent unenforceable); *Keystone*, 290 U.S. at 247 (affirming dismissal of suit).

In line with this wider scope and stronger remedy, inequitable conduct came to require a finding of both intent to deceive and materiality. *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO. *Id.* The accused infringer must prove both elements—intent and materiality—by clear and convincing evidence. *Id.* If the accused infringer meets its burden, then the district court must weigh the equities to determine whether the applicant’s conduct before the PTO warrants rendering the entire patent unenforceable. *Id.*

This court recognizes that the early unclean hands cases do not present any standard for materiality. Needless to say, this court’s development of a materiality

requirement for inequitable conduct does not (and cannot) supplant Supreme Court precedent. Though inequitable conduct developed from these cases, the unclean hands doctrine remains available to supply a remedy for egregious misconduct like that in the Supreme Court cases.

As inequitable conduct emerged from unclean hands, the standards for intent to deceive and materiality have fluctuated over time. In the past, this court has espoused low standards for meeting the intent requirement, finding it satisfied based on gross negligence or even negligence. *See Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984) (“Where they knew, or should have known, that the withheld reference would be material to the PTO’s consideration, their failure to disclose the reference is sufficient proof of the existence of an intent to mislead the PTO.”); *Orthopedic Equip. Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1383-84 (Fed. Cir. 1983) (requiring only gross negligence to sustain a finding of intent). This court has also previously adopted a broad view of materiality, using a “reasonable examiner” standard based on the PTO’s 1977 amendment to Rule 56. *See Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984); *see also* 37 C.F.R. § 1.56 (1977) (a reference is material if “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”). Further weakening the showing needed to establish inequitable conduct, this court then placed intent and materiality together on a “sliding scale.” *Am. Hoist*, 725 F.2d at 1362. This modification to the inequitable conduct doctrine held patents unenforceable based on a reduced showing of intent if the record contained a strong showing of materiality, and vice versa. In effect, this change conflated, and diluted, the standards for both intent and materiality.

This court embraced these reduced standards for intent and materiality to foster full disclosure to the PTO. *See id.* at 1363. This new focus on encouraging disclosure has had numerous unforeseen and unintended consequences. Most prominently, inequitable conduct has become a significant litigation strategy. A charge of inequitable conduct conveniently expands discovery into corporate practices before patent filing and disqualifies the prosecuting attorney from the patentee's litigation team. *See* Stephen A. Merrill et al., Nat'l Research Council of the Nat'l Academies, *A Patent System for the 21st Century* 122 (2004). Moreover, inequitable conduct charges cast a dark cloud over the patent's validity and paint the patentee as a bad actor. Because the doctrine focuses on the moral turpitude of the patentee with ruinous consequences for the reputation of his patent attorney, it discourages settlement and deflects attention from the merits of validity and infringement issues. Committee Position Paper, *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). Inequitable conduct disputes also "increas[e] the complexity, duration and cost of patent infringement litigation that is already notorious for its complexity and high cost." Brief and Appendix of the American Bar Ass'n as Amicus Curiae at 9.

Perhaps most importantly, the remedy for inequitable conduct is the "atomic bomb" of patent law. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting). Unlike validity defenses, which are claim specific, *see* 35 U.S.C. § 288, inequitable conduct regarding any single claim renders the entire patent unenforceable. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed.

Cir. 1988). Unlike other deficiencies, inequitable conduct cannot be cured by reissue, *Aventis*, 525 F.3d at 1341, n.6, or reexamination, *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995). Moreover, the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family. *See, e.g., Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 808-12 (Fed. Cir. 1990). Thus, a finding of inequitable conduct may endanger a substantial portion of a company's patent portfolio.

A finding of inequitable conduct may also spawn antitrust and unfair competition claims. *See Dow Chemical Co. v. Exxon Corp.*, 139 F.3d 1470, 1471 (Fed. Cir. 1998) (unfair competition claim); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 178 (1965) (antitrust action for treble damages). Further, prevailing on a claim of inequitable conduct often makes a case "exceptional," leading potentially to an award of attorneys' fees under 35 U.S.C. § 285. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001). A finding of inequitable conduct may also prove the crime or fraud exception to the attorney-client privilege. *See In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 807 (Fed. Cir. 2000).

With these far-reaching consequences, it is no wonder that charging inequitable conduct has become a common litigation tactic. One study estimated that eighty percent of patent infringement cases included allegations of inequitable conduct. Committee Position Paper at 75; *see also* Christian Mammen, *Controlling the "Plague": Reforming the Doctrine of Inequitable Conduct*, 24 Berkeley Tech. L.J. 1329, 1358 (2009). Inequitable conduct "has been overplayed, is appearing in nearly every patent suit, and is cluttering up the patent system." *Kimberly-Clark*

Corp. v. Johnson & Johnson, 745 F.2d 1437, 1454 (Fed. Cir. 1984). “[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client’s interests adequately, perhaps.” *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988); *see also* *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1358 (Fed. Cir. 2008); *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1482 (Fed. Cir. 1998); *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997); *Allied Colloids Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1578 (Fed. Cir. 1995); *Molins*, 48 F.3d at 1182.

Left unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system. Because allegations of inequitable conduct are routinely brought on “the slenderest grounds,” *Burlington Indus.*, 849 F.2d at 1422, patent prosecutors constantly confront the specter of inequitable conduct charges. With inequitable conduct casting the shadow of a hangman’s noose, it is unsurprising that patent prosecutors regularly bury PTO examiners with a deluge of prior art references, most of which have marginal value. *See* Brief for the United States as Amicus Curiae at 17 (submission of nine hundred references without any indication which ones were most relevant); Brief of the Biotechnology Industry Organization as Amicus Curiae at 7 (submission of eighteen pages of cited references, including five pages listing references to claims, office actions, declarations, amendments, interview summaries, and other communications in related applications). “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.” ABA Section of

Intellectual Property Law, *A Section White Paper: Agenda for 21st Century Patent Reform 2* (2009). This tidal wave of disclosure makes identifying the most relevant prior art more difficult. See Brief for the United States as Amicus Curiae at 1 (submission of “large numbers of prior art references of questionable materiality . . . harms the effectiveness of the examination process”). “This flood of information strains the agency’s examining resources and directly contributes to the backlog.” *Id.* at 17-18.

While honesty at the PTO is essential, low standards for intent and materiality have inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality. This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.

V

To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO. *Star*, 537 F.3d at 1366 (citing *Kingsdown*, 863 F.2d at 876). A finding that the misrepresentation or omission amounts to gross negligence or negligence under a “should have known” standard does not satisfy this intent requirement. *Kingsdown*, 863 F.2d at 876. “In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference.” *Molins*, 48 F.3d at 1181 (emphases added). In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.

This requirement of knowledge and deliberate action has origins in the trio of Supreme Court cases that set in motion the development of the inequitable conduct doctrine. In each of those cases, the patentee acted knowingly and deliberately with the purpose of defrauding the PTO and the courts. See *Precision*, 325 U.S. at 815-16 (assertion of patent known to be tainted by perjury); *Hazel-Atlas*, 322 U.S. at 245 (a “deliberately planned and carefully executed scheme to defraud” the PTO involving both bribery and perjury); *Keystone*, 290 U.S. at 246-47 (bribery and suppression of evidence).

Intent and materiality are separate requirements. *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed. Cir. 2003). A district court should not use a “sliding scale,” where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa. Moreover, a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality. Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive. See *Star*, 537 F.3d at 1366 (“the fact that information later found material was not disclosed cannot, by itself, satisfy the deceptive intent element of inequitable conduct”).

Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence. *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009). However, to meet the clear and convincing evidence standard, the specific intent to deceive must be “the single most reasonable inference able to be drawn from the evidence.” *Star*, 537 F.3d at 1366. Indeed, the evidence “must be sufficient to *require* a finding of deceitful intent

in the light of all the circumstances.” *Kingsdown*, 863 F.2d at 873 (emphasis added). Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found. See *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (“Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”). This court reviews the district court’s factual findings regarding what reasonable inferences may be drawn from the evidence for clear error. See *Star*, 537 F.3d at 1365.

Because the party alleging inequitable conduct bears the burden of proof, the “patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence.” *Star*, 537 F.3d at 1368. The absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.

VI

In the past, this court has tried to address the proliferation of inequitable conduct charges by raising the intent standard alone. In *Kingsdown*, this court made clear that gross negligence alone was not enough to justify an inference of intent to deceive. 863 F.2d at 876. *Kingsdown* established that “the involved conduct . . . must indicate sufficient culpability to *require* a finding of intent to deceive.” *Id.* (emphasis added). This higher intent standard, standing alone, did not reduce the number of inequitable conduct cases before the courts and did not cure the problem of overdisclosure of marginally relevant prior art to the PTO. To address these concerns, this court adjusts as well the standard for materiality.

In *Corona Cord Tire Co. v. Doan Chemical Corp.*, the Supreme Court considered the materiality of a patentee's misrepresentation to the PTO. 276 U.S. 358, 373-74 (1928). The patentee had submitted two affidavits, falsely claiming that the invention had been used in the production of rubber goods when in fact only test slabs of rubber had been produced. *Id.* Because the misrepresentation was not the but-for cause of the patent's issuance, the Court held that it was immaterial and refused to extinguish the patent's presumption of validity:

Production of rubber goods for use or sale was not indispensable to the granting of the patent. Hence the affidavits, though perhaps reckless, were not the basis for it or essentially material to its issue. The reasonable presumption of validity furnished by the grant of the patent, therefore, would not seem to be destroyed.

Id. at 374. Although *Corona Cord* does not address unclean hands, the precursor to inequitable conduct, it demonstrates the Court's unwillingness to extinguish the statutory presumption of validity where the patentee made a misrepresentation to the PTO that did not affect the issuance of the patent. *Corona Cord* thus supports a but-for materiality standard for inequitable conduct, particularly given that the severe remedy of unenforceability for inequitable conduct far exceeds the mere removal of a presumption of validity.

This court holds that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine

whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction. See Manual of Patent Examining Procedure (“MPEP”) §§ 706, 2111 (8th ed. Rev. 8, July 2010). Often the patentability of a claim will be congruent with the validity determination—if a claim is properly invalidated in district court based on the deliberately withheld reference, then that reference is necessarily material because a finding of invalidity in a district court requires clear and convincing evidence, a higher evidentiary burden than that used in prosecution at the PTO. However, even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO’s different evidentiary standards. See MPEP §§ 706 (preponderance of the evidence), 2111 (broadest reasonable construction).

As an equitable doctrine, inequitable conduct hinges on basic fairness. “[T]he remedy imposed by a court of equity should be commensurate with the violation.” *Columbus Bd. of Educ. v. Penick*, 443 U.S. 449, 465 (1979). Because inequitable conduct renders an entire patent (or even a patent family) unenforceable, as a general rule, this doctrine should only be applied in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim. See *Star*, 537 F.3d at 1366 (“[j]ust as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee committed only minor missteps or acted with minimal culpability”). After all, the patentee obtains no

advantage from misconduct if the patent would have issued anyway. See *Keystone*, 290 U.S. at 245 (“The equitable powers of the court can never be exerted in behalf of one . . . who by deceit or any unfair means has *gained an advantage.*”) (emphasis added) (internal citations omitted). Moreover, enforcement of an otherwise valid patent does not injure the public merely because of misconduct, lurking somewhere in patent prosecution, that was immaterial to the patent’s issuance.

Although but-for materiality generally must be proved to satisfy the materiality prong of inequitable conduct, this court recognizes an exception in cases of affirmative egregious misconduct. This exception to the general rule requiring but-for proof incorporates elements of the early unclean hands cases before the Supreme Court, which dealt with “deliberately planned and carefully executed scheme[s]” to defraud the PTO and the courts. *Hazel-Atlas*, 322 U.S. at 245. When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material. See *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983) (“there is no room to argue that submission of false affidavits is not material”); see also *Refac Int’l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1583 (Fed. Cir. 1996) (finding the intentional omission of declarant’s employment with inventor’s company rendered the affidavit false and that “[a]ffidavits are inherently material”). After all, a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent. See *id.* at 247 (pointing out that patentee’s lawyers “went to considerable trouble and expense” to manufacture false evidence because they believed it was needed to obtain issuance of the patent). Because neither mere nondisclosure of prior art references to the PTO nor

failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct, claims of inequitable conduct that are based on such omissions require proof of but-for materiality. By creating an exception to punish affirmative egregious acts without penalizing the failure to disclose information that would not have changed the issuance decision, this court strikes a necessary balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct.

The concurrence mischaracterizes this exception for affirmative egregious acts by limiting it to the example provided – the filing of an unmistakably false affidavit. Based on this misunderstanding, the concurrence asserts that this court’s test for materiality is unduly rigid and contrary to Supreme Court precedent. In actuality, however, the materiality standard set forth in this opinion includes an exception for affirmative acts of egregious misconduct, not just the filing of false affidavits. Accordingly, the general rule requiring but-for materiality provides clear guidance to patent practitioners and courts, while the egregious misconduct exception gives the test sufficient flexibility to capture extraordinary circumstances. Thus, not only is this court’s approach sensitive to varied facts and equitable considerations, it is also consistent with the early unclean hands cases – all of which dealt with egregious misconduct. *See Precision*, 324 U.S. at 816-20 (perjury and suppression of evidence); *Hazel-Atlas*, 322 U.S. at 240 (manufacture and suppression of evidence); *Keystone*, 290 U.S. at 243 (bribery and suppression of evidence).

The concurrence appears to eschew the use of *any* test because, by definition, under any test for materiality, a district court could not find inequitable conduct in cases “where the conduct in question would not be defined as

such [under the test].” Although equitable doctrines require some measure of flexibility, abandoning the use of tests entirely is contrary to both longstanding practice and Supreme Court precedent. Courts have long applied rules and tests in determining whether a particular factual situation falls within the scope of an equitable doctrine. *See, e.g., Winter v. Natural Res. Def. Council, Inc.*, 129 S.Ct. 365, 374 (2008) (four-factor test for preliminary injunctions); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (four-factor test for permanent injunctions); *Gutierrez v. Waterman S.S. Corp.*, 373 U.S. 206, 215 (1963) (“the test of laches” requires both unreasonable delay and consequent prejudice). Moreover, the Supreme Court has made clear that such tests serve an important purpose in limiting the discretion of district courts.

[C]ourts of equity must be governed by rules and precedents no less than the courts of law . . . [because] the alternative is to use each equity chancellor’s conscience as a measure of equity, which alternative would be as arbitrary and uncertain as measuring distance by the length of each chancellor’s foot. . . .

After all, equitable rules that guide lower courts reduce uncertainty, avoid unfair surprise, minimize disparate treatment of similar cases, and thereby help all litigants. . . .

Lonchar v. Thomas, 517 U.S. 314, 323 (1996) (internal quotations omitted). This court therefore rejects the view that its test – albeit flexible enough to capture varying manifestations of egregious and abusive conduct – is inappropriate in the context of the way inequitable conduct has metastasized.

This court does not adopt the definition of materiality in PTO Rule 56. As an initial matter, this court is not bound by the definition of materiality in PTO rules. See *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (“[T]he broadest of the PTO’s rulemaking powers . . . does NOT grant the Commissioner the authority to issue substantive rules.”); see also 57 Fed. Reg. 2021 (Jan. 17, 1992) (The PTO stated that Rule 56 “do[es] not define fraud or inequitable conduct.”). While this court respects the PTO’s knowledge in its area of expertise, the routine invocation of inequitable conduct in patent litigation has had adverse ramifications beyond its effect on the PTO. As discussed above, patent prosecutors, inventors, courts, and the public at large have an interest in reining in inequitable conduct. Notably, both the American Bar Association and the American Intellectual Property Law Association, which represent a wide spectrum of interests, support requiring but-for materiality (which is absent from Rule 56).

This court has looked to the PTO’s Rule 56 in the past as a starting point for determining materiality. See *Am. Hoist*, 725 F.2d at 1363. Rule 56 has gone through several revisions, from the “fraud” standard in its original promulgation in 1949 to the “reasonable examiner” standard in 1977 to the current version, which includes any information that “refutes or is inconsistent with” any position the applicant took regarding patentability. See 37 C.F.R. § 1.56 (1950); 37 C.F.R. § 1.56 (1977); 37 C.F.R. § 1.56 (1992). Tying the materiality standard for inequitable conduct to PTO rules, which understandably change from time to time, has led to uncertainty and inconsistency in the development of the inequitable conduct doctrine. See, e.g., *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006) (applying 1977 version of Rule 56); *Bruno Independent Living Aids*,

Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1352-53 (Fed. Cir. 2005) (applying 1992 version of Rule 56). Experience thus counsels against this court abdicating its responsibility to determine the boundaries for inequitable conduct.

This court declines to adopt the current version of Rule 56 in defining inequitable conduct because reliance on this standard has resulted in the very problems this court sought to address by taking this case en banc. Rule 56 provides that information is material if it is not cumulative and:

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

37 C.F.R. § 1.56. Rule 56 further provides that a “prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable . . . *before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.*” *Id.* (emphasis added). The first prong of Rule 56 is overly broad because information is considered material even if the information would be rendered irrelevant in light of subsequent argument or explanation by the patentee. Under this standard, inequitable conduct could be found based on an applicant’s failure to disclose information that a patent examiner would readily agree was not relevant to the prosecution after considering the patentee’s argument. Likewise, the second prong of Rule 56 broadly encom-

passes anything that could be considered marginally relevant to patentability. If an applicant were to assert that his invention would have been non-obvious, for example, anything bearing any relation to obviousness could be found material under the second prong of Rule 56. Because Rule 56 sets such a low bar for materiality, adopting this standard would inevitably result in patent prosecutors continuing the existing practice of disclosing too much prior art of marginal relevance and patent litigators continuing to charge inequitable conduct in nearly every case as a litigation strategy.

The dissent's critique of but-for materiality relies heavily on definitions of materiality in other contexts. Contrary to the implication made in the dissent, however, but-for proof *is* required to establish common law fraud. Common law fraud requires proof of reliance, which is equivalent to the but-for test for materiality set forth in this opinion. *See* 37 C.J.S. *Fraud* § 51 (“the reliance element of a fraud claim requires that the misrepresentation actually induced the injured party to change its course of action”); *Restatement (Second) of Torts* § 525 (1977) (fraud requires that the party “relies on the misrepresentation in acting or refraining from action”); *see, e.g., Exxon Mobil Corp. v. Ala. Dept. of Conservation & Natural Res.*, 986 So. 2d 1093, 1116 (Ala. 2007) (reliance element of fraud “can be met only if the plaintiff does, or does not do, something that the plaintiff would or would not have done but for the misrepresentation of a material fact”); *Alliance Mortgage Co. v. Rothwell*, 10 Cal. 4th 1226, 1239 (Cal. 1995) (same); *Luscher v. Empkey*, 206 Neb. 572, 576 (Neb. 1980) (same); *Spencer v. Ellis*, 216 Or. 554, 561 (Or. 1959) (same). The remaining examples in the dissent, where but-for materiality is not required, have limited relevance to inequitable conduct. While but-for materiality may not be required in every context, it is

appropriate for inequitable conduct in light of the numerous adverse consequences of a looser standard.

Moreover, if this court were to consider standards of materiality in other contexts, the most analogous area of law is copyright. *See Sony Corp. of Am. v. Univ. City Studios, Inc.*, 464 U.S. 417, 439 (1984) (finding it appropriate to draw an analogy between copyrights and patents “because of the historic kinship between patent law and copyright law”). But-for proof is required to invalidate both copyrights and trademarks based on applicant misconduct. *See* 17 U.S.C. § 411(b)(1) (copyright); *Citibank, N.A. v. Citibanc Group, Inc.*, 724 F.2d 1540, 1544 (11th Cir. 1984) (trademarks). The dissent concedes that “but for” materiality is required to cancel a trademark but contends that it is not required to invalidate federal registration of a copyright. Various courts have held otherwise. *See* 2 Melville B. Nimmer & David Nimmer, *Nimmer on Copyright* § 7.20[B][1] (rev. ed. 2010) (“plaintiff’s failure to inform the Copyright Office of given facts is without substance, to the extent that the Office would have registered the subject work even had it known those facts”). Moreover, the Copyright Act has codified this “but for” requirement, making clear that copyright registration is sufficient to permit an infringement suit, even if the certificate of registration contains inaccurate information, unless “the inaccuracy of the information, if known, would have caused the Register of Copyrights to refuse registration.” 17 U.S.C. § 411(b)(1); *see also* 2 *Nimmer on Copyright* § 7.20[B][2] (explaining that the materiality “standard [set forth in the 2008 amendment to the Copyright Act] is well in line with the construction of the Act prior to this amendment”).

VII

In this case, the district court held the '551 patent unenforceable for inequitable conduct because Abbott did not disclose briefs it submitted to the EPO regarding the European counterpart of the '382 patent. *Trial Opinion* at 1127. Because the district court found statements made in the EPO briefs material under the PTO's Rule 56 materiality standard, not under the but-for materiality standard set forth in this opinion, this court vacates the district court's findings of materiality. *Id.* at 1113, 1115. On remand, the district court should determine whether the PTO would not have granted the patent but for Abbott's failure to disclose the EPO briefs. In particular, the district court must determine whether the PTO would have found Sanghera's declaration and Pope's accompanying submission unpersuasive in overcoming the obviousness rejection over the '382 patent if Abbott had disclosed the EPO briefs.

The district court found intent to deceive based on the absence of a good faith explanation for failing to disclose the EPO briefs. *Id.* at 1113-16. However, a "patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence." *Star*, 537 F.3d at 1368. The district court also relied upon the "should have known" negligence standard in reaching its finding of intent. *See Trial Opinion* at 1113 ("Attorney Pope knew or should have known that the withheld information would have been highly material to the examiner"). Because the district court did not find intent to deceive under the knowing and deliberate standard set forth in this opinion, this court vacates the district court's findings of intent. *Id.* at 1113-16. On remand, the district court should determine whether there is clear and convincing evidence demonstrating that Sanghera or Pope

knew of the EPO briefs, knew of their materiality, and made the conscious decision not to disclose them in order to deceive the PTO.

For the foregoing reasons, this court vacates the district court's finding of inequitable conduct and remands for further proceedings consistent with this opinion. This court also reinstates Parts I, III, and IV of the panel decision reported at 593 F.3d 1289, affirming the district court's judgment of obviousness, noninfringement, and anticipation, respectively. The judgment below is

**AFFIRMED-IN-PART, VACATED-IN-PART, and
REMANDED-IN-PART.**

COSTS

Each party shall bear its own costs.

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.

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

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.

O'MALLEY, *Circuit Judge*, concurring in part and dissenting in part.

Patent practitioners regularly call on this court to provide clear guidelines. They seek to know under precisely what circumstances governing principles will be applied, and precisely how they will be applied. While

precision may be in the nature of what patent practitioners do, and the desire for defining rules in the scientific world understandable, the law does not always lend itself to such precision. Indeed, when dealing with the application of equitable principles and remedies, the law is imprecise by design.

I understand and admire the majority's desire to respond to practitioners' calls for precision and clarity. I also understand its concern with perceived litigation abuses surrounding assertions of inequitable conduct. I believe, however, that the majority responds to that call and addresses those concerns in ways that fail to acknowledge and remain true to the equitable nature of the doctrine it seeks to cabin.

I respectfully dissent from those portions of the majority opinion which describe the test it directs lower courts to apply in assessing materiality and which vacates and remands for further inquiry the materiality determinations made by the district court in this case. As explained below, I concur in the remainder of the majority's decision and judgment.

I.

I concur in the majority's decision to vacate and remand the judgment of the district court with instructions to reconsider its finding of inequitable conduct. Specifically, because the district court understandably referred to standards governing its intent determination drawn from our prior case law, the district court should be given the opportunity to assess, in the first instance, whether the evidence, and its credibility determinations, support a finding of a specific intent to deceive. In this regard, like the other dissenters, I agree with the majority's holding that, as a prerequisite to a finding of inequitable conduct, a district court must find that the conduct at issue is of

“sufficient culpability to require a finding of intent to deceive.” *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988). In making this determination, intent to deceive and materiality must be found separately. District courts may not employ a “sliding scale,” nor may they infer intent from materiality alone.¹ Finally, I agree that a district court may infer intent from indirect and circumstantial evidence, but only where it is “the single most reasonable inference able to be drawn from the evidence.” Maj. Op. at 25 (quoting *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

II.

It is at this point that my views, respectfully, diverge from those of both the majority and the other dissenters. This is so because, when addressing the types of conduct that should be deemed of sufficient concern to allow for a finding of inequitable conduct, both the majority and dissent strain too hard to impose hard and fast rules.

“The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case.” *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982) (quoting *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944)). While courts of

¹ While I join this portion of the majority opinion (Part V), I do so with the understanding that the majority does not hold that it is impermissible for a court to consider the level of materiality as circumstantial evidence in its intent analysis. As in all other legal inquiries involving multiple elements, the district court may rely on the same items of evidence in both its materiality and intent inquiries. A district court must, however, reach separate conclusions of intent and materiality and may not base a finding of specific intent to deceive on materiality alone, regardless of the level of materiality.

equity “must be governed by rules and precedents no less than the courts of law,” *Lonchar v. Thomas*, 517 U.S. 314, 323 (1996), “[f]lexibility rather than rigidity has distinguished” equitable jurisdiction, *Weinberger*, 456 U.S. at 312. “Equity eschews mechanical rules; it depends on flexibility.” *Holmberg v. Armbrecht*, 327 U.S. 392, 396 (1946).

Traditional notions of equitable relief apply with equal force in the context of patents. *eBay Inc. v. Mercexchange, LLC*, 547 U.S. 388, 393-94 (2006) (holding that a categorical rule of granting an injunction to a prevailing patent holder abrogates a district court’s discretion in granting equitable relief and runs afoul of traditional principles of equity). We have long recognized that the doctrine of inequitable conduct is based in equity. *Kingsdown*, 863 F.2d at 876 (“[T]he ultimate question of whether inequitable conduct occurred is equitable in nature.”). Despite this longstanding principle, both the majority and dissenting opinions eschew flexibility in favor of rigidity. Both opinions suggest tests for materiality to apply in all cases. Their respective materiality inquiries are black or white, while equity requires judicial consideration of shades of gray.

The majority defines materiality under a but-for test, with an exception for intentionally false affidavits filed with the PTO.² Maj. Op. at 27-30. The dissent, on the

² The majority responds to this characterization, and to the general criticism in this opinion, by defining its test more broadly and acknowledging a degree of flexibility within its four corners. For that, I applaud the majority. I do not think, however, that this additional explanation is sufficient to address all of the concerns expressed in this opinion. I remain of the view that the test I propose here is the most consistent with the doctrine’s origins.

other hand, defines materiality according to Rule 56. Both tests fail to provide district courts with flexibility to find inequitable conduct in an extraordinary case where the conduct in question would not be defined as such under either test. This result is contrary to the very nature of equity and centuries of Supreme Court precedent. I cannot, accordingly, lend support to either of the immutable tests proposed by my colleagues.

While the majority states that, despite the strictures of the test it adopts, “the unclean hands doctrine remains available to supply a remedy for egregious misconduct like that in the Supreme Court cases,” that statement does not address the concerns I express here.³ Maj. Op. at 20. Since, as the majority painstakingly explains, the doctrine of inequitable conduct we are defining grew out of those “unclean hands” cases, the asserted dichotomy is a false one. *See Consol. Aluminum Corp. v. Foseco Int’l, Ltd.*, 910 F.2d 804, 812 (Fed. Cir. 1990) (“Indeed, what we have termed ‘inequitable conduct’ is no more than the unclean hands doctrine applied to particular conduct before the PTO.”) (citations omitted). There is no support – and the majority cites none – for the proposition that inequitable conduct is somehow independent of the unclean hands principles the Supreme Court described and explained in its trilogy of cases. The remainder of the majority opinion makes clear, moreover, that the majority’s purpose, and that of the test it adopts, is to delimit and narrow the contours of the unclean hands doctrine

³ Indeed, this language raises some additional concerns. If “unclean hands” remains available in cases of PTO misconduct, charges of unclean hands could simply supplant the very allegations of inequitable conduct the majority seeks to curb.

when applied to the application process before the PTO, not to acknowledge flexibility in it.⁴

We should adopt a test that provides as much guidance to district courts and patent applicants as possible, but, in doing so, we may not disregard the equitable nature of the inquiry at hand. Thus, we must make clear that, while we believe the test we offer encompasses virtually all forms of conduct sufficient to warrant a finding of inequitable conduct, we leave open the possibility that some form of intentional misconduct which we do not currently envision could warrant equitable relief. This approach respects the Supreme Court's recognition that courts of equity "exercise judgment in light of prior precedent, but with awareness of the fact that specific circumstances, often hard to predict in advance, could warrant special treatment in an appropriate case." *Holland v. Florida*, 130 S. Ct. 2549, 2563 (2010).

Consistent with the flexible nature of equity jurisdiction, moreover, we should recognize that determining the proper remedy for a given instance of inequitable conduct is within the discretion of district courts, subject, of course, to statutory constraints. *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245-46 (1933) ("[Courts of equity] are not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion."); *Mills v. Elec. Auto-Lite Co.*, 396 U.S. 375, 386 (1970) ("In selecting a remedy the lower courts should

⁴ At the other end of the spectrum, the dissent's acknowledgement that a district court retains discretion *to decline* to find inequitable conduct even in the face of evidence of materiality and intent is similarly insufficient to undercut the unyielding nature of the test for inequitable conduct it adopts. It clearly does not allow, for instance, for a finding of inequitable conduct for conduct not encompassed by Rule 56.

exercise the sound discretion which guides the determinations of courts of equity, keeping in mind the role of equity as the instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims.”) (internal quotations and citations omitted). While we have held previously that a finding of inequitable conduct renders unenforceable all claims of the wrongly procured patent and, in certain circumstances, related patents, this singular remedy is neither compelled by statute, nor consistent with the equitable nature of the doctrine.⁵ Accordingly, I would overrule those cases and hold that, in the exercise of its discretion, a district court may choose to render fewer than all claims unenforceable, may simply dismiss the action before it, or may fashion some other reasonable remedy, so long as the remedy imposed by the court is “commensurate with the violation.” *Columbus Bd. of Educ. v. Penick*, 443 U.S. 449, 465 (1979); see also *Hecht*, 321 U.S. at 329 (“The essence of equity jurisdiction has

⁵ While the 1952 Act codified the defense of unclean hands in paragraph (1) of 35 U.S.C. § 282, it did not specify a remedy. See 35 U.S.C. § 282 (providing that “unenforceability” is a defense to an infringement action); P. J. Federico, “Commentary on the New Patent Act,” 75 J. PAT. & TRADEMARK OFF. SOC’Y 161, 215 (1993) (explaining that paragraph (1) includes “equitable defenses such as laches, estoppel and unclean hands”). The statute, thus, provides no guidance as to whether, in its equitable discretion, a court may render some, but not all, claims unenforceable. In *J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553 (Fed. Cir. 1984), we cited cases collected from a treatise for the proposition that inequitable conduct renders all of a patent’s claims unenforceable. *Id.* at 1561. None of those cases, however, are binding on this court and, for the reasons stated above, I find this proposition inconsistent with the power of the Chancellor to “mould” each decree to the necessities of the particular case.

been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case.”); *Miller v. French*, 530 U.S. 327, 360 (2000) (“These cases recognize the importance of permitting courts in equity cases to tailor relief . . . to the exigencies of particular cases and individual circumstances. In doing so, they recognize the fact that *in certain circumstances justice requires the flexibility necessary to treat different cases differently – the rationale that underlies equity itself.*”) (Breyer, J., dissenting) (emphasis added). Allowing for flexibility in the remedy would reduce the incentive to use inequitable conduct as a litigation tactic and address many of the concerns that trouble my colleagues and were expressed by Abbott and certain amici in these *en banc* proceedings.⁶

III.

To provide guidance to district courts to aid in the exercise of their discretion in inequitable conduct inquiries – beyond the Supreme Court’s direction that “any 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 by the chancellor,” *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814-16 (1945) – I believe such guidance should reflect the concerns expressed by the Supreme Court in the case trilogy from which the doctrine emerged. As the Court said in *Precision*, at minimum,

⁶ One of the evils described by Abbott and amici is the possibility of an order barring enforcement of a patent based on misrepresentation of an applicant’s “small entity status.” To the extent unenforceability may be too harsh in such circumstances – a point on which I do not opine – district courts would have discretion to fashion some lesser remedy to address that form of intentional deception.

equity requires that, when seeking the public benefit of a government sponsored monopoly, applicants must act “fairly and without fraud or deceit.” *Id.* Similarly, in *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), the Court found that, regardless of the impact of such conduct on patentability, the doors of equity should be closed to a patentee who presented to the patent office, as impartial, an article it authored. *Id.* at 247.

With this general guidance in mind, I believe conduct should be deemed material where: (1) but for the conduct (whether it be in the form of an affirmative act or intentional non-disclosure), the patent would not have issued (as Chief Judge Rader explains that concept in the majority opinion); (2) the conduct constitutes a false or misleading representation of fact (rendered so either because the statement made is false on its face or information is omitted which, if known, would render the representation false or misleading); or (3) the district court finds that the behavior is so offensive that the court is left with a firm conviction that the integrity of the PTO process as to the application at issue was wholly undermined. In adopting such a test, I also believe we should confirm, as explained above, that the equitable nature of the doctrine demands that this test provide guidance only – albeit firm guidance – to district courts with respect to the exercise of their discretion in the face of inequitable conduct claims.

For the reasons ably articulated by the majority, I do not believe we should direct district courts to use Rule 56 as the measure of materiality in this context. As the majority points out, among other things, it is both too vague and too broad – leaving room for findings of inequitable conduct in circumstances not sufficiently egregious to fall within the bounds of the Supreme Court trilogy from which the doctrine emerged. I also cannot agree

completely with the test proposed by the majority. Given the scope and complexity of PTO proceedings, misconduct can and does occur outside the context of written affidavits. In certain circumstances, regardless of the impact on patent issuance, such misconduct is sufficiently egregious that, when accompanied by the requisite intent to deceive, it could support a finding of inequitable conduct. Indeed, in *Hazel-Atlas*, the article in question was not presented to the PTO through an affidavit. 322 U.S. at 240-41. Both tests, moreover, fail to allow room to address conduct beyond their contours which equity should not ignore.

IV.

Applying the test I propose, or any reasonable test for materiality that comports with Supreme Court precedent, I would affirm the district court's finding that the nondisclosure of information in this case was material. Indeed, I believe the omissions here qualify as material under the majority's "but-for plus" standard and that, even accepting that test as the governing standard, a remand on the issue of materiality is neither necessary nor appropriate.

As the other dissenters note, whether the prior art taught that glucose sensors could be used to test whole blood without a protective membrane was a key focus of the PTO examiner's patentability inquiry. After requesting permission to submit extrinsic evidence in response to a rejection from the PTO, Abbott submitted a sworn declaration from its expert Dr. Gordon Sanghera accompanied by statements from its counsel Lawrence Pope. Both contained representations to the examiner regarding what they alleged to be the appropriate understanding of the critical prior art reference with which the examiner was concerned. Among other things, they asserted unequivocally that one skilled in the art would not have read

the prior art to say that use of a protective membrane with whole blood samples was optional. Omitted from these declarations was the fact that Abbott had made contrary representations on this same matter to the European Patent Office (“EPO”) in connection with the earlier prosecution of a European patent application. There, Abbott represented that it was “unequivocally clear” that the same prior art language meant that the protective membrane was, in fact, optional.

The district court concluded that these non-disclosures were “highly material” because “they centered on the precise sentence in question [in the prior art reference], its meaning and what it taught.” *Therasense, Inc. v. Becton, Dickson & Co.*, 565 F. Supp. 2d 1088, 1112 (N.D. Cal. 2008). More specifically, the district court found:

This is unlike the situation where a reference is already before an examiner who can draw his or her own conclusions as to what it teaches and is able to discount spin offered by counsel. *See Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008). Although the key sentence itself was indeed before Examiner Shay, the inquiry had shifted to a point of extrinsic evidence. That is, Examiner Shay had acquiesced to Attorney Pope’s request to resort to extrinsic evidence to show that the sentence would have been understood by skilled artisans differently than its words suggested. Having received permission to supply extrinsic evidence, Attorney Pope was duty-bound to present any inconsistent extrinsic information known to him. In the arena of extrinsic evidence, the examiner was unable to fend for himself. He had no way of knowing what, if any, contrary extrinsic information had been left out of the Sang-

hera declaration. He was completely dependent on Attorney Pope and Dr. Sanghera to fully disclose any extrinsic information, pro and con, known to them on the factual point covered by the submission.

Id. The district court's materiality conclusions were thorough and correct. They should be affirmed.

V.

I do not weigh in on the policy debate between the majority and the dissenters. There are merits to the concerns expressed by each, and they may be relevant, in varying degrees, to the exercise of a court's discretion in a particular case. Policy concerns cannot, however, justify adopting broad legal standards that diverge from doctrines explicated by the Supreme Court. A desire to provide immutable guidance to lower courts and parties similarly is not sufficient to justify the court's attempt to corral an equitable doctrine with neat tests.

To the extent there are concerns with litigation abuses surrounding the improper use of this otherwise important doctrine, there are vehicles available to the district court to address those concerns. Careful application of the pleading requirements set forth in *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009), early case management techniques designed to ferret out and test unsupported inequitable conduct claims, orders to stay discovery or consideration of such claims pending all other determinations in the case, or even sanctions, are all tools district courts can employ where appropriate.

For these reasons, I concur in part in and dissent in part from the decision the majority announces today. I would leave to district courts the discretion to apply this

equitable doctrine to the unique circumstances with which they are presented, while encouraging them to keep in sight their obligation to guard against abuses of it.

**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.

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

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.

BRYSON, *Circuit Judge*, with whom GAJARSA, DYK, and PROST, *Circuit Judges*, join, dissenting.

There is broad consensus that the law of inequitable conduct is in an unsatisfactory state and needs adjust-

ment. In recent years, differing standards have been applied in determining whether particular conduct rises to the level of inequitable conduct sufficient to render a patent unenforceable. That doctrinal uncertainty has had adverse consequences both for patent litigation and for the PTO. In litigation, counterclaims of inequitable conduct have been raised in too many cases and have proved difficult to resolve. In the PTO, the lack of a clear and uniform standard for inequitable conduct has led some patent prosecutors to err on the side of “over-disclosure” in order to avoid the risk of rendering all claims of an otherwise valid patent unenforceable because of the omission of some marginally relevant reference. As a result, examiners have frequently been swamped with an excess of prior art references having little relevance to the applications before them.

These problems can be traced, at least in part, to doctrinal uncertainty on three points: First, what standard of intent should be applied in assessing an allegation that an applicant has made false representations or failed to disclose material facts to the PTO. Second, what standard of materiality should be applied to such misrepresentations or nondisclosures. Third, whether there should be a “sliding scale” under which a strong showing of either materiality or intent should be able to make up for a weaker showing on the other element.

There is substantial agreement as to the proper resolution of two of those three issues. First, the parties to this case and most of the amici agree that proof of inequitable conduct should require a showing of specific intent to deceive the PTO; negligence, or even gross negligence, should not be enough. Second, the parties and most of the amici agree that a party invoking the defense of inequitable conduct should be required to prove both specific

intent and materiality by clear and convincing evidence; there should be no “sliding scale” whereby a strong showing as to one element can make up for weaker proof as to the other.

However, on the remaining issue—the proper standard to apply in determining whether the conduct at issue is sufficiently material to render the patent in suit unenforceable—there is sharp disagreement. That disagreement is what divides the court in this case. The majority takes the position that nondisclosures should be deemed sufficiently material to trigger the defense of inequitable conduct only if, had the matter in question been disclosed, the applicant would not have obtained a patent. That position, however, marks a significant and, I believe, unwise departure from this court’s precedents. Since its first days, this court has looked to the PTO’s disclosure rule, Rule 56, 37 C.F.R. § 1.56, as the standard for defining materiality in inequitable conduct cases involving the failure to disclose material information. In its current form, that rule provides that information is material not only if it establishes a *prima facie* case of unpatentability, but also if it refutes or is inconsistent with a position the applicant takes before the PTO with respect to patentability. I would adhere to the materiality standard set forth in the PTO’s disclosure rule for two basic reasons: First, the PTO is in the best position to know what information examiners need to conduct effective and efficient examinations, i.e., what information is material to the examination process. Second, the higher standard of materiality adopted by the majority will not provide appropriate incentives for patent applicants to comply with the disclosure obligations the PTO places upon them.

Twenty-three years ago, in *Kingsdown Medical Consultants v. Hollister, Inc.*, this court was faced with con-

flicting precedents regarding the “intent” requirement of the doctrine of inequitable conduct. The court resolved those conflicts in an en banc decision that all members of the court joined. 863 F.2d 867 (Fed. Cir. 1988) (en banc). The court held that even proof of “gross negligence” is not sufficient to satisfy the intent to deceive requirement. Instead, the court concluded that in order for particular conduct to justify holding a patent unenforceable, the conduct in question, “viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.” *Id.* at 876.

The *Kingsdown* court did not find it necessary to address the proper standard for determining materiality, because that issue had been addressed in earlier cases. Four years before *Kingsdown*, a five-judge panel opinion in *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553 (Fed. Cir. 1984), had addressed the materiality requirement and made the following observations, which have remained the law until today: First, the court endorsed the principle, previously adopted by our predecessor court, that inequitable conduct is broader than common law fraud. *Id.* at 1559 (citing *Norton v. Curtiss*, 433 F.3d 779, 793 (CCPA 1970)). Second, the court explained that inequitable conduct could be based on the failure to disclose material information as well as the submission of false material information. *Id.* Third, the court stated that the disclosure requirement set forth in PTO Rule 56, 37 C.F.R. § 1.56 (1984), established “the appropriate starting point” because that standard “most closely aligns with how one ought to conduct business with the PTO.” *J.P. Stevens*, 747 F.2d at 1559. In so doing, the court referred to its earlier opinion in *Driscoll v. Cebalo*, 731 F.2d 878, 884 (Fed. Cir. 1984), where the court had stated that PTO Rule 56 “essentially represents a codification of

the ‘clean hands’ maxim as applied to patent applicants.” Moreover, just a year before the decision in *Kingsdown*, the court in *Gardco Manufacturing, Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1214 (Fed. Cir. 1987), had reiterated that Rule 56 set forth the appropriate standard for determining the materiality of undisclosed information in an inequitable conduct case.

Since that time there have been occasional departures from the holding in *Kingsdown* as to the requisite level of intent to establish inequitable conduct. As to materiality, however, the court has consistently held that the PTO’s Rule 56 sets the proper baseline for determining materiality, although there has been some variation in our decisions with regard to which version of the PTO’s rule applies in particular cases.

The appropriate cure for departures from the principles of inequitable conduct that were put in place at the time of *Kingsdown* would be to reaffirm those principles, as summarized above. The majority, however, has taken a far more radical approach. With respect to the issue of materiality, the majority has adopted a test that has no support in this court’s cases and is inconsistent with a long line of precedents dating back to the early years of this court. The effect of the majority’s new test, moreover, does not merely reform the doctrine of inequitable conduct, but comes close to abolishing it altogether. I respectfully dissent from that aspect of the court’s decision. In my view, what is needed is not to jettison the doctrine of inequitable conduct, but simply to reaffirm the principles set down in the early years of this court in light of the provisions of the current PTO disclosure rule, and require adherence to those principles. As applied to the duty of an applicant or attorney to disclose material

information in the course of prosecuting a patent application, those principles can be summarized as follows:

1. Inequitable conduct requires proof, by clear and convincing evidence, that the applicant or attorney intended to mislead the PTO with respect to a material matter.

2. Materiality is measured by what the PTO demands of those who apply for and prosecute patent applications. The disclosure standard that the PTO expects those parties to comply with is set forth in the current version of the PTO's Rule 56. Under that standard, inequitable conduct requires proof that the information at issue either established, by itself or in combination with other information, a prima facie case of unpatentability, or was inconsistent with a position taken by the applicant before the PTO with respect to patentability.

3. Intent to mislead and materiality must be separately proved. There is no "sliding scale" under which the degree of intent that must be proved depends on the strength of the showing as to the materiality of the information at issue.¹

¹ It is important to distinguish between relaxing the required proof of intent if the proof of materiality is strong, which is impermissible, as opposed to considering the degree of materiality as relevant to the issue of intent, which is appropriate, particularly given that direct evidence of intent, such as an admission of deceptive purpose, is seldom available. See *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1366 (Fed. Cir. 2007); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1190-91 (Fed. Cir. 2006); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001); *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1189 (Fed. Cir. 1993); *Merck &*

These principles not only are consistent with our law on inequitable conduct but, if implemented consistently, should be sufficient to address the practical problems that have arisen under the current regime. While the majority is correct that inequitable conduct claims have been raised too often in the past, there are less Draconian means of addressing that problem than those proposed by the majority. First, the refinements to the doctrine suggested here would be likely to significantly reduce the frequency with which the defense is raised. Second, this court has recently held that the strict pleading requirements of Fed. R. Civ. P. 9(b) apply to counterclaims of inequitable conduct, requiring detailed factual averments and not merely notice pleading with respect to such claims. Such pleading requirements are likely to discourage baseless counterclaims. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-29 (Fed. Cir. 2009). Third, assertions of inequitable conduct that lack factual and legal support can be controlled by trial courts through application of the sanctions provided by Fed. R. Civ. P. 11. Finally, as this court has repeatedly held, the doctrine of inequitable conduct is an equitable doctrine, and even when the elements of intent and materiality are satisfied, it remains for the district court to determine, in the exercise of its equitable judgment, whether, “in light of all the particular circumstances, the conduct of the patentee is so culpable that its patent should not be enforced.” *LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066, 1070 (Fed. Cir. 1992).

With regard to the problem of “over-disclosure” of large numbers of marginally relevant references in the course of patent prosecution, the PTO in its amicus brief

Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1422 (Fed. Cir. 1989).

expresses confidence that strict judicial adherence to the “clear and convincing” standard by which accused infringers must prove specific intent to deceive the PTO will largely solve that problem. Since the problem of over-disclosure directly affects the PTO, there is no reason not to credit the PTO’s assertion that a tightening of the intent element of the inequitable conduct doctrine should be sufficient to address the problem and that a drastic modification of the materiality element not only is not required, but would be contrary to the PTO’s interest in efficient examinations.

II

The majority holds that a failure to disclose information is “material” for purposes of inequitable conduct only if it satisfies the “but for” test; i.e., the conduct must be such that, but for the conduct, the claims would have been found unpatentable. This is not a tweak to the doctrine of inequitable conduct; it is fundamental change that would have the effect of eliminating the independent role of the doctrine of inequitable conduct as to disclosure obligations except in limited circumstances. This court has repeatedly rejected the “but for” test as too restrictive in light of the policies served by the inequitable conduct doctrine. *See Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1421 (Fed. Cir. 1989); *see also Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1132 (Fed. Cir. 2006); *Hoffmann-LaRoche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 (Fed. Cir. 2003); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1179-80 (Fed. Cir. 1995); *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1396 (Fed. Cir. 1986). Those policies dictate that it should continue to do so.

As the PTO persuasively argues in its amicus brief, the “but for” standard for materiality is too restrictive to

serve the purposes that the doctrine of inequitable conduct was designed to promote. If a failure to disclose constitutes inequitable conduct only when a proper disclosure would result in rejection of a claim, there will be little incentive for applicants to be candid with the PTO, because in most instances the sanction of inequitable conduct will apply only if the claims that issue are invalid anyway. For example, under the “but for” test of materiality, an applicant considering whether to disclose facts about a possible prior use of the invention would have little reason to disclose those facts to the PTO. If the applicant remained silent about the prior use, the patent issued, and the prior use was never discovered, the applicant would benefit from the nondisclosure. But even if the prior use was discovered during litigation, the failure to disclose would be held to constitute inequitable conduct only if the prior use otherwise rendered the relevant claims invalid. The applicant would thus lose nothing by concealing the prior use from the PTO, because he would not be at risk of losing the right to enforce an otherwise valid patent.

In that situation, particularly if the opportunity to obtain a valuable patent is at stake, there will be no inducement for the applicant to be forthcoming. If the applicant withholds prior art or misleadingly discloses particular matters and succeeds, he obtains a patent that would not have issued otherwise. Even if the nondisclosure or misleading disclosure is later discovered, under the majority’s rule the applicant is no worse off, as the patent will be lost only if the claims would otherwise be held invalid. So there is little to lose by following a course of deceit. It is no indictment of the uprightness and professionalism of patent applicants and prosecutors as a group to say that they should not be subjected to an incentive system such as that. After all, it has long been

recognized that “an open door may tempt a saint.” Given the large stakes sometimes at issue in patent prosecutions, a regime that ensures that a dishonest but potentially profitable course of action can be pursued with essentially no marginal added risk is an unwise regime no matter how virtuous its subjects.

It is unrealistic to expect that other means will provide an effective deterrent to ensure that material information will not be withheld during patent prosecutions. The PTO advises us that the prospect of enforcing the duty of disclosure other than through the threat of inequitable conduct claims is not possible or practical. The prospect of agency disciplinary action for disclosure violations is unrealistic, the PTO explains, because the Office is required by statute to file any charges within five years, *see* 28 U.S.C. § 2462, and it seldom learns of inequitable conduct within that period of time. In addition, the PTO explains that it rarely has access to relevant facts regarding inequitable conduct, because it lacks investigative resources. As a result, the PTO has concluded that a court is the best forum in which to consider alleged breaches of the disclosure duty in the context of an inequitable conduct defense. *See* Patent and Trademark Office Implementation of 37 C.F.R. § 1.56, 1095 Off. Gaz. Pat. & Trademark Office 16 (Oct. 11, 1988).

III

Aside from its practical infirmities, the “but for” standard adopted by the majority is inconsistent with the duty that the Supreme Court and the PTO have both described as applying to those who seek patents in the *ex parte* application process.

A

The doctrine of inequitable conduct has its origins in a trilogy of Supreme Court decisions dating back to the 1930s. The first of the three cases, *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), applied the equitable principle of “unclean hands” in a case in which a patentee’s representative had obtained a false affidavit and taken other steps to avoid the disclosure of a possibly invalidating prior use of the patented invention. The patentee obtained a favorable decree in an infringement action against a different defendant and then relied on that decree in obtaining preliminary injunctions against the defendants in the cases before the Court.

The Supreme Court found the connection between earlier and later cases to be sufficient “to show that plaintiff did not come with clean hands” in the later cases. Based on that finding, the Court concluded that the previous misconduct justified the dismissal of the complaints in those cases. In reaching that determination, the Court did not find it necessary to decide whether the evidence of prior use that the plaintiff had suppressed would have had the effect of invalidating the patent. It was enough that the improper conduct had “immediate and necessary relation to the equity [that the patentee sought] in respect of the matter in litigation.” 290 U.S. at 245.

A decade later, in *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), the Supreme Court again held a patent unenforceable, this time in part because of misconduct by the patentee before the Patent Office in obtaining the patent. The patentee, encountering resistance to issuance of the patent by the Patent Office, arranged for the publication of an article in a trade

publication that described the invention as a remarkable advance in the field. The article purported to be the product of a disinterested party, even though it was actually written by one of the patentee's lawyers. The patent ultimately issued. The article was also used in court, where it assisted the patentee in obtaining a favorable judgment from an appellate court. The patentee subsequently went to considerable lengths to ensure that the truth regarding the authorship of the article would not emerge. The efforts at concealment failed, however, and the accused infringer sought relief in the lower court based on the misconduct.

Because the misconduct was discovered after the expiration of the term of court during which the judgment in question was entered, the Supreme Court invoked the doctrine of after-discovered fraud, which permitted a court to revisit a judgment even after the end of the term in which it was entered, if the circumstances "are deemed sufficiently gross to demand a departure from rigid adherence to the term rule." 322 U.S. at 244. The Court found that standard to be satisfied on the facts before it.

In response to the argument that the article in question was not "basic" to the issues in litigation, the Supreme Court stated that the circumstances did not "call for such an attempted appraisal." 322 U.S. at 247. The Court explained: "Hartford's officials and lawyers thought the article material. They conceived it in an effort to persuade a hostile Patent Office to grant their patent application, and went to considerable trouble and expense to get it published." *Id.* The Court added that Hartford's fraud "had its genesis in the plan to publish an article for the deliberate purpose of deceiving the Patent Office Had the District Court learned of the fraud on the Patent Office at the original infringement trial, it

would have been warranted in dismissing Hartford’s case.” *Id.* at 250. Significantly, the Court did not regard the issue of Hartford’s conduct as turning on whether the fraudulent conduct was the “but for” cause of the issuance of the patent. The Court stated that it would have come to the same conclusion even if the statements from the fraudulently procured article were actually true. *Id.* at 247. “But for” causation was not necessary to finding materiality. Instead, the Court focused on the patentee’s “deliberate purpose of deceiving the Patent Office” as the core reason for refusing to enforce the patentee’s rights in the patent.

A year later, the Supreme Court again addressed the issue of the effect of misconduct during proceedings before the Patent Office on subsequent patent enforcement actions in court. That case, *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), arose following an involved sequence of events, the upshot of which was that Automotive obtained rights to a patent knowing that the original applicant had made false statements pertaining to the dates of conception and reduction to practice of the claimed invention. The Supreme Court held the patent unenforceable, applying the doctrine of unclean hands against the patent owner based on its knowledge of the misconduct that occurred during the prosecution of the patent.

The Court explained that the sort of misconduct necessary to trigger a court’s refusal to aid “the unclean litigant” need not be “of such a nature as to be punishable as a crime or as to justify legal proceedings of any character. Any 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 by the chancellor.” 324 U.S. at 815. The Court added

that “where a suit in equity concerns the public interest as well as the private interests of the litigants this doctrine assumes even wider and more significant proportions.” *Id.* The enforcement of a patent, the Court stated, is a matter “concerning far more than the interests of the adverse parties. The possession and assertion of patent rights are ‘issues of great moment to the public.’” *Id.* In a statement that has served as the basis for the subsequent development of the doctrine of inequitable conduct, the Court added 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.

The Court refused to enforce Automotive’s patent because it concluded that Automotive “knew and suppressed facts that, at the very least, should have been brought in some way to the attention of the Patent Office.” 324 U.S. at 818. The Court explained, “Those 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 inequitable conduct underlying the applications in issue. . . . Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies.” Because Automotive had prosecuted the patent application and obtained the patent “without ever attempting to reveal to the Patent Office or to anyone else the facts it possessed concerning the application’s fraudulent ancestry,” the Court concluded that Automotive “has not displayed that standard of conduct requisite to the maintenance of this suit in equity.” *Id.* at 819.

As in the *Keystone* and *Hazel-Atlas* cases, the Supreme Court in the *Precision Instrument* case did not look to whether the conduct in question would have rendered the plaintiff's application unpatentable. In holding all of Automotive's patents to be unenforceable, the Court found it was enough that the plaintiff had intentionally withheld information from the Patent Office that should have been submitted so that the Patent Office could consider it. There was no suggestion in the Court's opinion that the dismissal of the action would be appropriate only if, but for the conduct, the patent would not have issued.

The principles set down by the Court in *Keystone*, *Hazel Atlas*, and *Precision Instrument* can be summarized as follows: (1) the public has a special interest in seeing that patent monopolies "spring from backgrounds free from fraud or other inequitable conduct"; (2) as a corollary to that public interest, patent applicants "have an uncompromising duty to report to [the Patent Office] all facts concerning possible fraud or inequitable conduct underlying the applications"; (3) all facts relevant to such matters must be submitted to the Patent Office, "which can then pass upon the sufficiency of the evidence"; (4) the intentional failure to disclose to the Patent Office that a patent application is tainted by fraud is sufficient cause to justify not enforcing the patent; and (5) the misconduct in question need not constitute actionable fraud; it is sufficient if the conduct constitutes a willful act that violates standards of equitable conduct in dealing with the Patent Office.²

² Two decades before the *Keystone-Hazel-Precision* trilogy, the Supreme Court considered the effect of misstatements made during prosecution on the validity of a patent on a method for vulcanizing rubber. *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358 (1928).

Before the Patent Office, the inventor attempted to swear behind a reference by submitting affidavits averring an earlier date of conception and reduction to practice for his invention. The inventor asserted that he had successfully used the claimed method “in the vulcanization of rubber goods,” and one of his fellow chemists stated that the method had been used “in the actual vulcanization of rubber goods, such as hose, tires, belts, valves and other mechanical goods.” *Id.* at 373. In fact, at the time referred to in the affidavits the inventor had used his method only on test slabs of rubber. The Court noted that whether the claimed method was used in the production of useful articles was not relevant to the asserted claims, and it therefore held that the false affidavit, while reckless, was not “the basis for” or “essentially material to” the issuance of the patent. The Court therefore declined to invalidate the asserted claims on that ground. *Id.* at 374.

Although the majority cites *Corona* as support for its narrow interpretation of the materiality requirement for inequitable conduct, *Corona* is of little relevance to that issue. *Corona* predates the creation of the inequitable conduct doctrine and has never been cited by the Supreme Court in any case addressing unclean hands or inequitable conduct. Apart from the fact that the decision addressed the issue of validity, rather than enforceability, the Court’s decision was based on its conclusion that the affidavit in question was not material because what mattered was that the method had been used to vulcanize rubber, not that it had been used to vulcanize rubber that was in turn used to make particular goods. Given that the nature of the rubber objects that the inventor vulcanized was not relevant to the issues before the Patent Office, it is not surprising that the Court found the error not to be material. In any event, the Court’s choice of language—stating that the affidavits “were not the basis for [the issuance of the patent] or essentially material to its issue,” is not restricted to a “but for” test, but suggests a broader standard for materiality.

Shortly after the decisions in the *Keystone*, *Hazel Atlas*, and *Precision Instrument* cases, the Supreme Court made a further observation that bears directly on the responsibilities of attorneys and applicants who appear before the PTO. The Court endorsed the statement that, “By reason of the nature of an application for patent, the relationship of attorneys to the Patent Office requires the highest degree of candor and good faith. In its relation to applicants, the Office . . . must rely upon their integrity and deal with them in a spirit of trust and confidence” *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949). Because the PTO lacks the investigative and research resources to look behind representations by applicants and their counsel, it necessarily relies on those representations as to many facts that arise during the prosecution of patent applications, including experimental results obtained by the applicants, the state of the prior art, and the knowledge of persons of skill in the art in the field in question. Some of these facts will be uniquely in the hands of the applicant and, as a practical matter, undiscoverable by an examiner at the PTO. For those reasons, the PTO has imposed a duty on applicants to provide examiners with information that is material to patentability.

B

The PTO has defined the disclosure obligation for those involved in patent prosecutions in its Rule 56, which the PTO has promulgated under its statutory authority to establish regulations that “govern the conduct of proceedings in the Office.” 35 U.S.C. § 2(b). When Rule 56 was first promulgated in 1949, the portion of the rule that addressed inequitable conduct provided that “any application fraudulently filed or in connection with which any fraud is practiced or attempted on the Patent Office, may be stricken.” 37 C.F.R. § 1.56 (1950).

The Court of Customs and Patent Appeals construed the PTO's disclosure rule in its 1970 decision in *Norton v. Curtiss*, 433 F.2d at 779. The court in that case upheld the Commissioner's authority to strike a patent application for fraud on the PTO in violation of the PTO's Rule 56. Interpreting the term "fraud" in Rule 56, the court began by noting that the term should not be limited to the kind of fraud that would be independently actionable as a tort or crime (which the court referred to as "technical fraud"). Instead, the court explained that "fraud" as used in the Rule included "a wider range of 'inequitable' conduct" that would justify holding a patent unenforceable. *Id.* at 793. Defining fraud more broadly for the purpose of Rule 56 was justified, the court ruled, because "applicants before the Patent Office are being held to a relationship of confidence and trust to that agency. The indicated expansion of the concept of 'fraud' manifests an attempt by the courts to make this relationship meaningful." *Id.*

In language paralleling the Supreme Court's discussion in *Kingsland v. Dorsey*, the *Norton* court recognized "a relationship of trust between the Patent Office and those wishing to avail themselves of the governmental grants which that agency has been given authority to issue." 433 F.2d at 793. In light of the ex parte nature of patent prosecution, the number of applications filed, and the limited capacity of the PTO "to ascertain the facts necessary to adjudge the patentable merits of each application," the court stated that the "highest standards of honesty and candor on the part of applicants presenting such facts to the office are . . . necessary elements in a working patent system." *Id.* at 794. For that reason, the court approved of "the expansion of the types of misconduct for which applicants will be penalized." *Id.*

In light of those policies, the court explained that the test for materiality “cannot be applied too narrowly if the relationship of confidence and trust between applicants and the Patent Office is to have any real meaning,” and that findings of materiality should not be limited to those cases in which the true facts, if they had been known, “would most likely have prevented the allowance of the particular claims at issue.” 433 F.2d at 795. In such cases, the claims at issue “would probably be invalid, in any event,” and the question whether the patent was unenforceable “would really be of secondary importance.” *Id.* Accordingly, the court concluded that a proper interpretation of the materiality element must include factors other than the patentability of the claims at issue, including “the subjective considerations of the examiner and the applicant.” *Id.*

In 1977, the PTO substantially revised Rule 56 to make more explicit the disclosure obligations imposed on patent applicants. Patent Examining and Appeal Procedures, 41 Fed. Reg. 43,729, 43,730 (proposed Oct. 4, 1976). The 1977 version of the rule imposed a “duty of candor and good faith” on those involved in the preparation or prosecution of patent applications and required them “to disclose to the Office information they are aware of which is material to the examination of the application.” The rule defined information as “material” if there was “a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”

Shortly after this court’s creation, the court began addressing inequitable conduct claims raised in the course of patent infringement litigation. From the outset, the court looked to the PTO’s Rule 56 as setting an appropriate standard for the materiality prong of the doctrine of

inequitable conduct. See *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir. 1984) (“The PTO ‘standard’ is an appropriate starting point for any discussion of materiality”; failure to satisfy that disclosure obligation, combined with an intent to deceive the PTO, can render a patent unenforceable); *J.P. Stevens*, 747 F.2d at 1559 (adopting the materiality requirement from Rule 56); *Gardco*, 820 F.2d at 1214 (Rule 56 is “appropriate starting point for determining materiality”) (quotation omitted); *Fox Indus., Inc. v. Structural Pres. Sys.*, 922 F.2d 801, 803 (Fed. Cir. 1990) (adopting Rule 56 standard for materiality). In particular, the court endorsed the use of that standard as the proper test for materiality when an appropriate level of intent was shown. See *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 992 (Fed. Cir. 1988) (“Nondisclosed or false information is material if there is a substantial likelihood that a reasonable examiner would have considered the omitted reference or false information important in deciding whether to allow the application to issue as a patent.”); *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1440 (Fed. Cir. 1991) (“Information is material if there is ‘substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.’”) (citing the 1977 version of PTO Rule 56).

In the ensuing years, this court has regularly referred to the “reasonable examiner” test as the standard for measuring materiality in cases raising claims of inequitable conduct. See, e.g., *Golden Hour Data Sys., Inc. v. Emscharts, Inc.*, 614 F.3d 1367, 1373-74 (Fed. Cir. 2010); *Leviton Mfg. Co. v. Universal Sec. Instruments, Inc.*, 606 F.3d 1353, 1358-59 (Fed. Cir. 2010); *Astrazeneca Pharms. LP v. Teva Pharm. USA, Inc.*, 583 F.3d 766, 773 (Fed. Cir. 2009); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329

F.3d 1358, 1363 (Fed. Cir. 2003) (citing cases). Under that test, the court has consistently ruled that a false statement or nondisclosure may be material for purposes of an inequitable conduct determination even if the invention in question would otherwise be patentable. *See, e.g., Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314 (Fed. Cir. 2006); *Li Second Family Ltd. P'ship v. Toshiba Corp.*, 231 F.3d 1373, 1380-81 (Fed. Cir. 2000); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322 (Fed. Cir. 2000); *A.B. Dick*, 798 F.2d at 1397.

In 1992, the PTO revised Rule 56, adopting what it called a “clearer and more objective definition of what information the Office considers material to patentability.” Duty of Disclosure, 57 Fed. Reg. 2021, 2023 (Jan. 17, 1992). As revised in 1992, the current version of Rule 56 imposes a duty on individuals associated with the filing and prosecution of an application to disclose to the Office all information known to be material to patentability as defined in the rule. Rule 56(a). The rule then states that information is “material” if it is “not cumulative to information already of record or being made of record in the application” and

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

The first part of Rule 56(b) requires the applicant to provide information that, at least absent explanation or further supplementation, would compel the conclusion

that the invention is unpatentable. The rule explains that a “prima facie case of unpatentability” is established “when the information compels a conclusion that a claim is unpatentable under the preponderance of the evidence, burden-of-proof standard, giving each term its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.” In adopting the rule, the PTO explained that it intended for applicants to submit references, of which they were aware, that would render the pending claims unpatentable over the references. Proposed Rules, 56 Fed. Reg. 37,321, 37,324 (Aug. 6, 1991). The PTO added that it is the role of the examiner, not the applicant, to analyze the sufficiency and weight of a rebuttal argument. See *id.* The intent standard imposed by Rule 56 and adopted by this court answers the majority’s concerns regarding the breadth of the first part of Rule 56(b). That provision applies only to applicants who act with the specific intent to deceive the PTO by withholding prior art that is so powerful as to render the pending claims invalid in the absence of further explanation.

It is the second part of the rule, Rule 56(b)(2), to which the appellants object. That part of the rule requires the applicant to provide information that is inconsistent with or refutes a position taken by the applicant before the office. Rule 56(b)(2) clearly goes beyond a “but for” test and is therefore the focus of the dispute in this case.

At the time it adopted the 1992 revision to Rule 56, the PTO considered the possibility of adopting a “but for” test of materiality of the sort that the majority has adopted today. The Office rejected that test, concluding

that adopting such a narrow 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.” The PTO added that if it did not have the needed information, “meaningful examination of patent applications will take place for the first time in an infringement case before a district court.” Duty of Disclosure, 57 Fed. Reg. at 2023.

In the aftermath of that change, this court has frequently treated the PTO’s new version of the rule as setting forth the proper standard for materiality, in cases involving claims of failure to disclose material information, at least for applications processed after 1992. In *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*, 394 F.3d 1348 (Fed. Cir. 2005), the court quoted the 1992 version of Rule 56 and held that for patents prosecuted while that version of the rule was in effect, “we evaluate the materiality of the [undisclosed matter] under the standard set forth in the applicable amended rule.” *Id.* at 1352-53; *see also Hoffmann-LaRoche*, 323 F.3d at 1368 n.2. The court added that “we 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.” *Bruno*, 394 F.3d at 1353; *see also Bd. of Educ. v. Am. Bioscience, Inc.*, 333 F.3d 1330, 1343 (Fed. Cir. 2003); *Purdue Pharma L.P.*, 438 F.3d at 1129; *Mon-santo Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1237 (Fed. Cir. 2008); *Taltech Ltd. v. Esquel Enters. Ltd.*, 604 F.3d 1324, 1333 (Fed. Cir. 2010). As it did before 1992, the court has continued to make clear that it does not apply a “but for” test for materiality. *See Golden Hour Data Sys.*, 614 F.3d at 1374; *Hoffmann-LaRoche*, 323 F.3d at 1368; *Molins PLC*, 48 F.3d at 1179-80.

On occasion, when addressing the issue of materiality, this court has referred to both the 1977 standard and the 1992 standard that supplanted it as pertinent to the definition of materiality. *See, e.g., Digital Control*, 437 F.3d at 1316. The court has done so in light of the fact that, as the PTO has explained, the 1992 standard was not meant to signal a sharp departure from the 1977 standard. Yet while the two standards were not meant to be dramatically different, the court has recognized that the PTO regards the 1992 standard as setting forth a clearer and more precise statement of the disclosure necessary to conducting efficient examinations. *See Rothman v. Target Corp.*, 556 F.3d 1310, 1323 (Fed. Cir. 2009); *Purdue Pharma L.P.*, 438 F.3d at 1129; *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005).

The PTO has explained that the 1992 amendment was proposed “to address criticism concerning a perceived lack of certainty in the materiality standard.” M.P.E.P. § 2001.04. The revised rule was intended “to provide greater clarity and hopefully minimize the burden of litigation on the question of inequitable conduct before the Office, while providing the Office with the information necessary for effective and efficient examination of patent applications.” *Id.* Moreover, in its brief in this case the PTO has urged this court to adopt the standard set forth in the current PTO Rule 56 as the standard for material nondisclosures rather than referring to both the 1992 standard and the “reasonable examiner” standard from the 1977 version of the Rule.

Because the PTO is the best judge of what information its examiners need to conduct effective examinations, the PTO’s definition of materiality is entitled to deference in determining whether the failure to disclose particular

information during patent prosecution constitutes inequitable conduct. Moreover, because the PTO has refined the materiality standard in setting forth what it expects of applicants and their representatives, there is no need for courts to apply a broader test of materiality in adjudicating inequitable conduct claims, as doing so could at least theoretically result in the imposition of sanctions for a failure to disclose matters that the PTO does not require to be disclosed.³ This is not to suggest that any disclosure

³ The PTO's Rule 56 deals with the "duty to disclose information material to patentability" and does not explicitly address affirmative false statements to the PTO made by parties prosecuting a patent application. In some instances, as in this case, a false or misleading affirmative statement also violates the disclosure requirement, because when a party makes a statement that is inconsistent with the party's own prior statement, the failure to disclose the prior statement constitutes a failure to disclose information that "refutes, or is inconsistent with, a position the applicant takes" in asserting patentability or opposing an argument of unpatentability relied on by the PTO. Rule 56(b)(2). An affirmative false statement that does not separately violate the disclosure rules may nonetheless be contrary to the broader "duty of candor and good faith" referred to in paragraph (a) of Rule 56, which is imposed on "each individual associated with the filing and prosecution of a patent application." See *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1231-32 (Fed. Cir. 2007); *Dayco Prods.*, 329 F.3d at 1363-64.

The majority holds that the "but for" test does not apply to "affirmative acts of egregious misconduct." It then adds that neither "nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct" under any circumstances. As this case illustrates, it is often difficult to draw a line between nondisclosure and affirmative misrepresentation. For example, is a submission to the PTO that purports to describe the state of the prior art but knowingly omits the closest prior art an "affirmative act" of misconduct or merely a "non-

requirement that the PTO might have devised would serve as a predicate for an inequitable conduct charge. Because inequitable conduct is an equitable doctrine applied by courts, and not simply a mechanism for judicial enforcement of PTO rules, the scope of the court-made doctrine is not inseparably tied to the breadth of the PTO's disclosure rules. However, the basic purposes of both the inequitable conduct doctrine and Rule 56 are the same, and the disclosure duties that the PTO imposes on applicants, which are defined by Rule 56, are reasonably calculated to produce the disclosure necessary to promote efficient conduct of examinations and to discourage the types of omissions and misrepresentations that (if made intentionally) raise equitable concerns. In these circumstances, considerations of efficiency and economy encourage us to embrace the PTO's approach. So long as it

disclosure of information"? Even the *Hazel-Atlas* case, which the majority describes as an example of egregious misconduct, could be regarded as an instance of nondisclosure, as the problem identified by the Supreme Court was the failure to disclose that the article in question was actually written by an attorney for the patentee. The distinction between "affirmative acts" and "nondisclosure" is thus apt to become fertile ground for litigation in the future, not to mention the distinction between "egregious" misconduct and misconduct that is assertedly less than "egregious."

Contrary to the statement in Judge O'Malley's separate opinion, nothing in this opinion rejects the application of the doctrine of inequitable conduct (or "unclean hands") as applied to other forms of misconduct, in litigation or otherwise. This case deals with the consequences of nondisclosure in violation of the duty of disclosure imposed by the PTO's Rule 56, and this opinion is directed solely to the role of the doctrine of inequitable conduct in that context.

reasonably aligns with our own equitable calculus, we should defer to the PTO's assessment of its needs and treat intentional breaches of the PTO's disclosure rules as providing a basis for a finding of inequitable conduct. See *Bruno Indep. Living*, 394 F.3d at 1353.

C

The materiality standard set forth in Rule 56, as adopted in 1977 and refined in 1992, is not an idiosyncratic contrivance of the PTO; quite the contrary, it is consistent with the materiality standard that is applied in a wide variety of other analogous contexts. Although the relationship between the PTO and patent applicants is unusual in our law, it is nonetheless appropriate to look to the way the concept of materiality is applied in other areas, as disclosure obligations and requirements of candor are imposed on parties in a wide variety of settings.

Securities law provides a particularly instructive analogy, as proxy issuers and corporate insiders often have access to information relevant to a stockholder's decision that even the most diligent investor could not discover. Similarly, a patent applicant is often in a better position than the examiner to know of relevant art or potentially invalidating circumstances, such as prior use. Notably, in the securities law context, a nondisclosure is typically regarded as material without the need to prove reliance. Thus, for example, in the case of those who have an affirmative duty of disclosure to investors under the securities laws and who fail to comply with that duty, the Supreme Court has held that "positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them impor-

tant in the making of [the investment] decision.” *Affiliated Ute Citizens v. United States*, 406 U.S. 128, 153-54 (1972). The Supreme Court recently reaffirmed that standard in *Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156 (U.S. Mar. 22, 2011). In a passage that addressed concerns similar to those raised in this case, the Court explained that it had adopted the “reasonable investor” standard to ensure that investors would have access to information important to their investment decisions, while being “careful not to set too low a standard of materiality, for fear that management would bury the shareholders in an avalanche of trivial information.” *Id.*, slip op. 10 (quotations and citations omitted).

The Supreme Court has adopted a similar materiality standard—and rejected a “but for” test for materiality—in the context of section 14(a) of the Securities Exchange Act of 1934, regarding proxy solicitations. *See TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438 (1976). There, the Court stated that an 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 449. Significantly, for our purposes, the Court added that the proper standard

does not require proof of a substantial likelihood that disclosure of the omitted fact would have caused the reasonable investor to change his vote. What the standard does contemplate is a showing of a substantial likelihood that, under all the circumstances, the omitted fact would have assumed actual significance in the deliberations of the reasonable shareholder.

Id.

Even in criminal proceedings that require proof of materiality, such as prosecutions under the federal mail and wire fraud statutes, 18 U.S.C. §§ 1341, 1343, a “but for” test of materiality is not applied. Those laws penalize not only affirmative misrepresentations, but also the concealment of material facts. *United States v. Olatunji*, 872 F.2d 1161, 1167 (3d Cir. 1989); *United States v. O’Malley*, 707 F.2d 1240, 1247 (11th Cir. 1983). When a charge of mail or wire fraud is based on the nondisclosure of material information in violation of a duty to disclose, proof of materiality does not require a showing of actual reliance on the part of the victim; all that is required is proof that the nondisclosure or concealment be capable of influencing the intended victim. *See Neder v. United States*, 527 U.S. 1, 16, 24-25 (1999). *See also United States v. Riley*, 621 F.3d 312, 332-33 (3d Cir. 2010) (nondisclosed relationship between mayor and purchaser of city property was material “even if the relationship would not have per se barred [the purchase.]”); *United States v. Szur*, 289 F.3d 200, 211-12 (2d Cir. 2002) (securities broker owed duty to customers to disclose that broker would earn “exorbitant” commission on trades; such information was material for the purpose of the wire fraud statute because it would have been “relevant to a customer’s decision to purchase the stock”); *United States v. Bronston*, 658 F.2d 920, 926 (2d Cir. 1981) (concealment of information that defendant is under a duty to disclose is material if the nondisclosure “could or does result in harm” to the victim).

The same principles have been applied to nondisclosures of material information in civil matters, even civil matters that have been regarded as having grave personal consequences. In a denaturalization proceeding, for example, a “concealment or misrepresentation” made in the course of the naturalization process is considered

“material” under 8 U.S.C. § 1427(a) if it has “a natural tendency to influence the decisions of the Immigration and Naturalization Service”; it is not necessary to show that the nondisclosure or misrepresentation in question actually had such an effect. *See Kungys v. United States*, 485 U.S. 759, 772 (1988). The Supreme Court noted in that case that it “has never been the test of materiality that the misrepresentation or concealment would *more likely than not* have produced an erroneous decision, or even that it would *more likely than not* have triggered an investigation.” *Id.* at 771 (emphasis in original).

Even with respect to the common law action for fraud, deceit, and misrepresentation, which is more exacting than the doctrine of inequitable conduct, see *J.P. Stevens & Co.*, 747 F.2d at 1559, the “but for” test does not apply to the element of materiality. In that setting, as the Restatement of Torts explains, a matter is material if “a reasonable man would attach importance to its existence or nonexistence in determining his choice of action,” or if the maker of the representation “knows or has reason to know that its recipient regards or is likely to regard the matter as important in determining his choice of action.” *Restatement (Second) of Torts* § 538 (1977); see *Neder v. United States*, 527 U.S. 1, 22 & n.5 (1999) (citing the Restatement as setting forth the materiality requirement for common-law fraud). In order for a material misrepresentation to satisfy the causation requirement needed for an award of damages, it is necessary for the plaintiff to show reliance on the misrepresentation. However, the “but for” test does not apply even to tort actions for damages, as it is not necessary for the plaintiff to show “that he would not have acted or refrained from acting as he did unless he had relied on the representation.” *Restatement (Second) of Torts* § 546, cmt. b. In none of these settings

has the test for materiality been set at the high “but for” level adopted by the majority in this case.⁴

⁴ The majority argues that the “but for” test is applied in both copyright and trademark law to claims of fraudulent registration. To the contrary, in the copyright context, courts have rejected the “but for” test in favor of a rule that a federal registration will be invalidated if the claimant willfully misstates or fails to state a fact that, if known, “*might have occasioned* a rejection of the application.” *Eckes v. Card Prices Update*, 736 F.2d 859, 861-62 (2d Cir. 1984) (emphasis added); *see generally* 2 Melville B. Nimmer & David Nimmer, *Nimmer on Copyright* § 7.20[B][1], at 7-212,4(1) & n.21 (rev. ed. 2010) (“If the claimant wilfully misstates or fails to state a fact that, if known, might have caused the Copyright Office to reject the application, [it] may be ruled invalid.”) (citing numerous cases). In 2008, Congress adopted a “but for” test to govern the effect of errors on the right to bring a civil action and the right to heightened remedies, *see* 17 U.S.C. § 411 (Supp. III 2009), but that provision was not made applicable to the presumption of copyright validity set forth in 17 U.S.C. § 410(c), which remains subject to the pre-2008 standards. *See* 2 *Nimmer on Copyright* § 7.20[B][1], at 7-212.4(2) n.25.2.

As for trademarks, it is true that in deciding whether fraud on the PTO will result in the cancellation of a mark on the federal register, courts apply a “but for” test of materiality. *See, e.g., Orient Express Trading Co. v. Federated Dep’t Stores, Inc.*, 842 F.2d 650, 653 (2d Cir. 1988) (defining material fact as “one that would have affected the PTO’s action on the applications”); *Citibank, N.A. v. Citibanc Grp., Inc.*, 724 F.2d 1540, 1544 (11th Cir. 1984) (requiring “false, material statement by the plaintiff of a fact that would have constituted grounds for denial of the registration had the truth been known.”). As the author of the leading treatise on trademark law has pointed out, however, cancellation of a mark from the federal register does not extinguish the trademark rights of the mark’s owner or defeat the owner’s right to sue infringers. 6 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 31.60 (4th ed. 2008).

The course charted by the majority is thus contrary to the Supreme Court decisions that gave rise to the doctrine of inequitable conduct, to a long line of our own precedent, and to the principles of materiality that courts have applied in other contexts. Under this court’s new rule, an applicant who conceals information with the intent to deceive the PTO will be free to enforce his patent unless it can be proved by clear and convincing evidence that the patent would not have issued but for the fraud. Even though the majority justifies its new rule in part by asserting that it will improve the prosecution of patents before the PTO, I am convinced that the new rule is likely to have an adverse impact on the PTO and the public at large, a view that—significantly—is shared by the PTO itself.

IV

The facts of this case, as found by the district court, illustrate why the materiality standard of Rule 56 is a suitable test for inequitable conduct claims based on disclosure violations. A central issue during the examination that led to the issuance of the ’551 patent was whether the prior art had taught that glucose sensors could be used to test whole blood without a protective membrane. The examiner focused on whether the prior

Unlike the effect of a trademark registration, the issuance of a patent grants a right which, but for the examination and allowance at the PTO, would not exist. For those reasons, as McCarthy has explained, the “standard of disclosure and hence of ‘fraud’ in the procurement of federal trademark registrations should be, and is, quite different from that in patent procurement. The stringent standard[s] of disclosure applicable to patent applications are . . . not appropriate to applications for trademark registration.” *Id.* at § 31.65 (internal quotation and citation omitted).

art '382 patent taught the use of sensors without membranes. On its face, the '382 patent seemed to teach that sensors could be used without membranes when testing whole blood because the specification of the '382 patent, when discussing the use of sensors with whole blood, stated the following:

Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.

'382 patent, col. 4, ll. 63-66. A central issue before the examiner was whether the use of the term “optionally” in that passage indicated that it was possible to use the sensors in whole (or live) blood without a protective membrane.

The district court found that the persons involved in prosecuting the '551 application, Abbott's attorney Lawrence Pope and its expert, Dr. Gordon Sanghera, made representations to the examiner that the pertinent passage in the '382 patent should not be taken at face value. In particular, Dr. Sanghera submitted a declaration in which he stated that even though the '382 patent referred to the use of a protective membrane surrounding the enzyme and mediator layers of the glucose meter as “optionally, but preferably” present, “one skilled in the art would have felt that an active electrode comprising an enzyme and a mediator would require a protective membrane if it were to be used with a whole blood sample.” For that reason, he stated, he was “sure that one skilled in the art would not read [the '382 patent] to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred.” Mr. Pope, the prosecuting attorney, added his own remarks when

submitting Dr. Sanghera's declaration. He stated: "One skilled in the art would not have read the disclosure of the [382 patent] as teaching that the use of a protective membrane with whole blood samples was optional. He would not, especially in view of the working examples, have read the optionally, but preferably language . . . as a technical teaching but rather mere patent phraseology." Mr. Pope added: "There is no teaching or suggestion of unprotected active electrodes for use with whole blood specimens in [the '382] patent or the other prior art of record in this application." Shortly after those submissions were made, the examiner allowed the claims for a membraneless sensor.

The problem, the district court found, is that Abbott had made directly contradictory representations to the European Patent Office ("EPO") concerning the teaching of the '382 patent in connection with the prosecution of a European patent application and had not disclosed those contradictory representations to the PTO. Before the EPO, Abbott represented that the European counterpart to the '382 patent referred to a "protective membrane optionally utilized with the glucose sensor of the patent," and that the membrane was "preferably to be used with in vivo measurements." With specific reference to the language from the patent reciting the use of the protective membrane "optionally, but preferably when being used on live blood," Abbott told the EPO: "It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor."

The district court found that Abbott's representations to the EPO contradicted its representations to the PTO,

made through Dr. Sanghera and Mr. Pope. The court's finding on that issue, made after a detailed analysis of the representations to the two bodies, cannot be held to be clearly erroneous. The district court also found that Abbott's failure to disclose to the examiner that it had made inconsistent statements to the EPO regarding the teaching of the '382 patent was highly material. In particular, the court found that the failure to disclose the inconsistency in those statements was the kind of nondisclosure covered by PTO Rule 56, as being nondisclosure of information "inconsistent with a position the applicant takes in . . . [a]sserting an argument of patentability." That finding, too, cannot be regarded as clearly erroneous in light of the central role of the pertinent portion of the '382 patent in the examination of the application that led to the issuance of the '551 patent.

Turning to the issue of intent, the district court found that Abbott's failure to disclose material information was intentional, i.e., it was made with the specific intent to deceive the PTO. The district court heard live testimony from Mr. Pope and Dr. Sanghera and conducted a detailed analysis of their testimony in light of the record. Based on that analysis, the court concluded that their efforts to justify their conduct were unpersuasive. The court found that Mr. Pope and Dr. Sanghera were aware of the contrary representations made to the EPO and consciously chose to withhold them from the PTO. The court carefully considered their explanations for their failure to disclose the references and found each witness's explanation to be lacking. The court discredited Mr. Pope's explanation that he understood the term "unequivocally clear" in the EPO submission to relate to the permeability of the membrane, not to the text immediately following the words "unequivocally clear," where it is plainly stated that the membrane is optional. The court was not per-

sued by Mr. Pope's statement that he believed "optionally, but preferably" meant, in the context of patents, "optionally, but always."

The court then considered possible alternative reasons for Mr. Pope's decision not to disclose the contradictory EPO statements, such as the possibility that Mr. Pope had misunderstood the meaning of the terms "whole blood" and "live blood." Ultimately, however, the district court could identify no plausible reason for the non-disclosure and therefore found that Mr. Pope had acted with deceptive intent. That finding, based on the court's consideration of Mr. Pope's demeanor and overall credibility, as well as the court's analysis of the record as a whole, cannot be said to be clearly erroneous.

For similar reasons, the court found that Dr. Sanghera also acted with intent to deceive the PTO. The court considered and rejected the possibility that Dr. Sanghera believed that Mr. Pope, Abbott's counsel before the PTO, would disclose the material information. The court began by finding that Dr. Sanghera's declaration before the PTO contained representations that were misleading by omission. The court explained that finding as follows:

He did not have to take this extra step. Having done so, he was obligated to avoid intentional deception. His sworn statements to the PTO about the meaning of the "optionally but preferably" sentence were known by him to be inconsistent with his own company's statements to the EPO—statements he had himself helped craft.

As to Dr. Sanghera's testimony that he believed that statements he made to the PTO did not contradict the statements made to the EPO, the court found that Dr.

Sanghera knew that a representation had been made to the EPO that the '326 patent did not require a membrane when used with whole blood. Noting that Dr. Sanghera's trial testimony had been impeached by his prior inconsistent statements on certain points, and finding that Dr. Sanghera exhibited an "unconvincing trial demeanor," the district court found that he acted with the requisite intent to deceive. As in the case of Mr. Pope, the district court's findings as to Dr. Sanghera are not clearly erroneous.

Viewed in light of the district court's findings, this case is a compelling one for applying the principles of inequitable conduct. The district court found that Abbott's representatives deliberately withheld material from the PTO that directly refuted Abbott's contention that one skilled in the art would have believed that the '382 patent taught that a membrane was required for whole blood analysis. Abbott's inconsistent position on the teachings of this critical reference falls squarely within the scope of information of the sort referred to in PTO Rule 56(b)(2), i.e., information that "refutes, or is inconsistent with, a position the applicant takes in . . . [a]sserting an argument of patentability." Given the examiner's focus on the issue of whether the protective membrane in the prior art patent was optional or not, the issue was of critical importance in the prosecution of the application that issued as the '551 patent, even though the undisclosed information, if revealed, may not have resulted in the rejection of the claims at issue. Accordingly, the district court made all the findings necessary to support its holding that the '551 patent was unenforceable for inequitable conduct.⁵

⁵ Understandably relying on this court's prior case law, the district court stated at one point that Mr. Pope "knew or should have known" that the withheld information would have been highly material to the examiner, and at another point the court referred to "balancing the

Because the district court's factual findings are not clearly erroneous and because its legal analysis comports with the proper role of the doctrine of inequitable conduct in patent law, the district court's judgment that the '551 patent is unenforceable for inequitable conduct should be affirmed.

I respectfully dissent.

levels of materiality and intent." Although those remarks suggest a looser standard than that advocated here, they do not undermine the district court's ruling on inequitable conduct, because the district court elsewhere made findings that clearly satisfied the requirements of the more restrictive standard for inequitable conduct set forth above. In particular, the court found that Mr. Pope "acted with specific intent to deceive Examiner Shay and the PTO," that Mr. Pope and Dr. Sanghera "made a conscious and deliberate decision to withhold disclosure to the PTO of these prior statements" to the EPO, and that both of them "knew that the EPO materials made affirmative statements inconsistent with the declaration and the attorney remarks [to the PTO]." With respect to Dr. Sanghera, the court found that he "consciously made sworn statements to the [PTO] that were deliberately misleading." With respect to the issue of "balancing," moreover, the district judge did not find it necessary to balance intent against materiality, because he explicitly found that the evidence was strong as to both materiality and intent.