

[Therasense, Inc. v. Becton, Dickinson and Company](#)  
2008-1511, -1512, -1513, -1514, -1595 (Fed. Cir. 2011)(en banc)

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.

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 electro-chemical 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: “Option-ally, 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 media-tor 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 dis-closure 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 evidence. *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, Auto-motive 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 suppression 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 anti-trust 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": Re-forming 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. Dovan 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.

\* \* \* \* \*

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 encompasses 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. \* \* \* \* \*

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); Citi-bank, N.A. v. Citibanc Group, Inc., 724 F.2d 1540, 1544 (11th Cir. 1984) (trademarks). \* \* \* \* \*

## VII

In this case, the district court held the ’551 patent un-enforceable 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.

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 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.

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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.

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 adjustment. 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.

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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 in-tended 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.<sup>1</sup> 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)

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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.