

Case Nos. 2008-1511, -1512, -1513, -1514, -1595

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

THERASENSE, INC, (now known as Abbott Diabetes Care, Inc.)
And ABBOTT LABORATORIES,
Plaintiffs-Appellants,

v.

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

and

BAYER HEALTHCARE LLC,
Defendant-Appellee.

APPEALS FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
CONSOLIDATED CASE NOS. 04-CV-2123, 04-CV-3327, 04-CV-3732, AND 05-CV-3117,
JUDGE WILLIAM H. ALSUP

**BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF
AMERICA AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY**

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August 2, 2010

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Pharmaceutical Research and Manufacturers of America certifies the following:

1. The full name of every party or *amicus* represented by me is: Pharmaceutical Research and Manufacturers of America.

2. The name of the real party in interest represented by me is: Pharmaceutical Research and Manufacturers of America.

3. *Amicus Curiae* Pharmaceutical Research and Manufacturers of America is a trade association with no parent corporation and with no publicly held company owning 10 percent or more of its stock.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this Court are:

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STATEMENT OF *AMICUS CURIAE*¹

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is an association of the country’s leading research-based pharmaceutical and biotechnology companies.² PhRMA Members are devoted to inventing medicines that will allow patients to live longer and have healthier and more productive lives. PhRMA’s Members have led the way in the search for new cures – in 2009, PhRMA Members invested an estimated \$45.8 billion in discovering and developing new medicines.³ PhRMA Members are the leading source of medicines discovered throughout the world.

PhRMA submits this brief in support of neither party. In this and other cases, PhRMA Members are on both sides of inequitable conduct allegations. PhRMA Members, however, share a significant interest in the state of the law governing inequitable conduct. In particular, PhRMA Members believe the Court can and should use this opportunity to reset the doctrine firmly on its historical

¹ Pursuant to Fed. R. App. P. 29(a), all parties have consented to the filing of this *amicus* brief.

² A complete list of the members of PhRMA can be found at http://www.phrma.org/about_phrma/member_company_list/members (last viewed July 30, 2010). Plaintiff-Appellant Abbott and Defendant-Appellee Bayer HealthCare LLC are members of PhRMA but did not participate in the preparation of this brief.

³ See PhRMA, *Pharmaceutical Industry Profile 2010*, at 26 (2010) (“Industry Profile”), available at http://www.phrma.org/sites/phrma.org/files/attachments/Profile_2010_FINAL.pdf.

foundations in Supreme Court precedent. Doing so will help to ensure that the doctrine remains an appropriately focused mechanism for deterring and punishing fraudulent conduct, while avoiding the significant deleterious effects of what the doctrine has become: an overused litigation tactic that imposes unjustified burdens and costs on patent owners and courts, as well as downstream burdens on the Patent and Trademark Office (“PTO”).

INTRODUCTION

The oft-cited justification for the inequitable conduct doctrine is to deter fraudulent conduct before the PTO. In its present form, however, the doctrine has spiraled out of control, and is now affirmatively undermining the PTO’s ability to efficiently examine applications and grant high-quality patents, and diminishing the incentive for innovation.

The problems with current law can be traced to the doctrine’s substantial drift from its historical foundation in Supreme Court precedent. That precedent recognized and was based on the inherent authority of the courts to prevent the use of the judicial system to continue a fraud originally perpetrated on the Government. Today’s inequitable conduct doctrine, however, has departed substantially from this foundation: it no longer is grounded in fraud, and it allows parties to portray any blemish in the examination record as misconduct. As a

consequence, it has become an overused litigation tactic, easily pled but rarely proven.

Three fundamental flaws in existing law are the source of the problem. First, the benefit to the party asserting inequitable conduct – complete absolution of liability for infringement of a valid patent – creates an overpowering incentive to assert inequitable conduct, even in cases where the likelihood of success is virtually nil. Moreover, asserting inequitable conduct carries virtually no risks for the party asserting the defense. To be sure, there are litigation costs, but those costs are greatly outweighed by the delays and disruption the defense will impose on the patent holder, and the avoidance of potentially significant economic damages that flow from a finding of infringement.

Second, the varying standards for “materiality” expressed in this Court’s decisions have allowed creative advocates to portray essentially any type of undisclosed or misstated information as capable of influencing the examination of a patent application and therefore “material.” This has made it possible for parties to assert inequitable conduct claims far too readily, and to advance these claims throughout the litigation, to great disruptive effect.

And, third, the requirement for proof of a specific intent to defraud, which is a hallmark of fraud claims, has been undermined by decisions of this Court finding conduct that falls far short of fraud sufficient to establish the requisite intent. A

significant contributor to this last problem has been the Court’s “balancing test,” by which a high degree of materiality (itself defined too loosely) has been allowed to serve as sufficient evidence of specific intent, even when there is no real proof of specific intent to deceive.

In combination, these flaws have caused the inequitable conduct doctrine to become a “plague” on the patent system, as this Court observed two decades ago in *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 n.15 (Fed. Cir. 1988) (en banc in part).⁴

And, the effects of this plague are not limited to patent owners. Because current law induces parties to assert inequitable conduct claims as a routine litigation tactic, despite the remote chance inequitable conduct will be proven, it inappropriately imposes a substantial burden on scarce judicial resources.

The doctrine also perversely handicaps the very institution it is supposed to serve – the PTO. The substantial uncertainty created by current law inhibits a constructive dialogue from occurring between applicants and examiners during examination, and compels applicants to defensively over-disclose information.

⁴ See *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (“[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”); see also *Larson Mfg. Co. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1342 (Fed. Cir. 2009) (Linn, J., concurring) (quoting same); *Aventis Pharma S.A. v. Amphastar Pharms. Inc.*, 525 F.3d 1334, 1350 (Fed. Cir. 2008) (Rader, J., dissenting) (same), *cert. denied*, 129 S. Ct. 2053 (2009).

Together, these effects operate to hinder – rather than improve – the ability of the PTO to efficiently carry out its statutory mandate of examining and issuing high-quality patents.

Ultimately, the uncertainty caused by current law weakens the patent incentive, depriving the American public of the tangible benefits of innovation – new products and services. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1196 (Newman, J., dissenting) (“charges of inequitable conduct [are] a disincentive to technologic innovation”).

To remove the perverse incentives, resolve uncertainty, and restore the doctrine to its historical foundation, this Court should take the following steps.

First, this Court should hold that inequitable conduct can be found only with respect to patent claims that have been asserted in the litigation. This would firmly anchor the doctrine on its common-law foundation as a mechanism to prevent the *continuation* of a fraud originally perpetrated on the PTO by an action in court to enforce a tainted patent claim. It also would respect the Court’s historic appreciation that holding a valid patent unenforceable in a private civil action is an extraordinary remedy, and that courts should have a narrower role than the affected agency (the PTO) in policing fraudulent conduct that occurs before it. *See, e.g.*, 37 C.F.R. § 1.56 (addressing duty of disclosure to PTO); 71 Fed. Reg. 38,808, 38,809 (July 10, 2006) (PTO recognition of the burdens of over-disclosure).

Second, the Court should articulate a clear formulation of materiality that is based in the law governing the patentability of inventions. Specifically, a court should find information material only if that information establishes that one or more of the claims asserted in the litigation is invalid. Employing this clear standard for materiality will properly limit material information to that which actually affects the *patentability* of at least one of the asserted claims, rather than capturing anything that can be portrayed, in an *ex post facto* hypothetical examination, as being “important” to a “reasonable examiner.” See S. Rep. No. 110-259, at 32 & n.152 (2008) (Judiciary Committee Report recognizing that the lack of a clear materiality standard creates uncertainty). And, this clear threshold requirement would provide courts and patent litigants with a predictable and practical test for assessing materiality that would reinforce that the elements of materiality and intent each must be proven.⁵

⁵ It has been noted that this Court has articulated the materiality standard in at least five separate ways: “[1] the objective ‘but for’ standard, where the misrepresentation was so material that the patent should not have issued; [2] the subjective ‘but for’ test, where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so; ... [3] the ‘but it may have’ standard, where the misrepresentation may have influenced the patent examiner in the course of prosecution,” *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006); [4] the “reasonable examiner” standard derived from the 1977 version of PTO Rule 56, 37 C.F.R. § 1.56(a) (1991), “that require[s] a showing that ‘a reasonable examiner would have considered such prior art important in deciding whether to allow the patent application,’” *Digital Control*, 437 F.3d at 1314); and [5] “an arguably narrower standard of materiality,” derived from the 1992 amendments to Rule 56, that

Finally, the Court should make clear that inequitable conduct requires clear and convincing evidence that a person with a duty of candor to the PTO acted with specific intent to defraud that Office. That standard is appropriate for allegations rooted in fraud, which is precisely what inequitable conduct is. In so doing, the Court should firmly reject other formulations that can be read to capture mere negligence, including those based on the Court’s “balancing” test, under which a showing of “high” materiality can obviate or lessen the proofs necessary to establish intent. Because the balancing test is unsupported at common law, and has contributed substantially to the unpredictable character of the doctrine, it should be eliminated.

ARGUMENT

I. Because Of The Disproportionate Incentives And Substantial Burdens Created By Current Law, This Court Should Adopt A New Approach To Inequitable Conduct.

The doctrine of inequitable conduct is rooted in the public’s substantial interest in deterring fraud against the Government. This judge-made doctrine derives from three Supreme Court decisions rendered between 1933 and 1945,

defines materiality as non-cumulative information that either “establishes . . . a prima facie case of unpatentability of a claim” or “refutes, or is inconsistent with, a position the applicant takes in (i) Opposing an argument of unpatentability . . . or (ii) Asserting an argument of patentability.” *Digital Control*, 437 F.3d at 1315 (internal quotation marks omitted).

each of which dealt with overtly fraudulent conduct.⁶ Importantly, in these cases, the parties had not only committed fraud before the PTO in securing the patent, but had continued to exploit and perpetuate the fraud by asserting the tainted patent claims in the federal courts. Since the time the Supreme Court last confronted these issues, however – other than its holding in 1965 that “only the United States may sue to cancel or annul a patent,” *Walker Process Equip. Co. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175 (1965) – the inequitable conduct doctrine has grown far beyond the core principles set out in those early decisions. Today, rather than being raised only in rare or unusual circumstances, assertions of inequitable

⁶ See *Digital Control Inc.*, 437 F.3d at 1315 (doctrine “borne out of a series of Supreme Court cases in which the Court refused to enforce patents whereby the patentees had engaged in fraud in order to procure those patents.”); see also *Larson Mfg. Co. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1343 (Fed. Cir. 2009) (Linn, J., concurring) (“The Supreme Court’s three inequitable conduct cases involved overt fraud, not equivocal acts of omission. *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 809, 819 (1945) (‘patent claims infected with fraud and perjury’ where assignee knew that its employee ‘gave false dates as to the conception, disclosure, drawing, description and reduction to practice’ during interference proceeding and then ‘secured the perjured ... application and exacted promises from the other parties never to question the validity of any patent that might be issued on that application’); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 243 (1933) (false affidavits and deposition testimony obtained ‘for valuable considerations’ averring that the prior art use ‘was an abandoned experiment’ and ‘to keep secret the details of the prior use’); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 240, 243 (1944) (false trade article procured from ‘an ostensibly disinterested expert’ in exchange for \$8,000 to gain patent issuance in spite of previously “insurmountable Patent Office opposition’), *overruled on other grounds by Standard Oil Co. v. United States*, 429 U.S. 17 (1976).” (internal parallel citations omitted)).

conduct have become a standard weapon in the arsenal of those accused of infringing valid patents. *See Larson*, 559 F.3d at 1343 (Linn, J., concurring) (“[t]he ease with which inequitable conduct can be pled, but not dismissed, is a problem of our own making”).

Because the consequences of a finding of inequitable conduct are so profound – complete absolution of liability for a proven infringer of a valid patent claim – it is hardly surprising that the doctrine has become an overused litigation tactic.⁷ Logically, the more pronounced the economic windfall is from defeating a patent – and in Hatch-Waxman cases, for instance, the economic incentives can be immense – the greater incentive there is for inequitable conduct to be alleged.

The doctrine’s perversely high reward to proponents more than offsets the low probability of establishing it in any particular case. Indeed, simply raising an

⁷ In 2008, for instance, inequitable conduct was pled in approximately 40% of all patent cases brought in district court (up from 20% in 2003). C. Mammen, *Controlling the “Plague”: Reforming The Doctrine Of Inequitable Conduct*, 24 Berkeley Tech. L.J. 1329, 1358 (2009). Conversely, the proportion of inequitable conduct claims affirmed on appeal is both low and has declined over the past ten years: in 2001, this Court found inequitable conduct in approximately 1% of all inequitable conduct claims brought at the district court level; by 2008, that figure had declined to 0.35% (and, indeed, in the past fifteen years, this Court has found inequitable conduct in only 0.04 to 0.23% of all patent cases filed in any given year). *Id.* Moreover, this Court affirms the district court’s rejection of inequitable conduct claims in 92% of cases (reversing in only 3%), while reversing or vacating the district court’s finding of inequitable conduct in 59% of cases. *Id.* at 1355.

inequitable conduct claim in litigation delivers significant benefits to its proponent, even if the claim is not ultimately proven:

Although designed to facilitate USPTO examination, inequitable conduct has taken on a new life as a litigation tactic. The allegation of inequitable conduct opens new avenues of discovery; impugns the integrity of [a] patentee, its counsel, and the patent itself; excludes the prosecuting attorney from trial participation (other than as a witness); and even offers the trial court a way to dispose of a case without the rigors of claim construction and other complex patent doctrines.

Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334, 1349-50 (Fed.

Cir. 2008) (Rader, J., dissenting). Charging a patent holder with inequitable conduct is simple, and fundamentally alters the scope and nature of the litigation.

It immediately imposes additional costs on the patent owner through the burden of additional discovery. See D. Kappos, *Building Bridges and Making Connections*

Across the IP System (May 11, 2010) (inequitable conduct allegations create

“expensive, discovery-heavy” litigation that “become a high priced side show to the real issues”), at http://www.uspto.gov/news/speeches/2010/Kappo_GW_Law_Symposium.jsp.

Such discovery also can be unusually dangerous and intrusive.

For example, parties have tried to use inequitable conduct allegations, rather than actual evidence of fraud, to expose otherwise privileged materials to discovery

under the crime-fraud exception to the attorney-client privilege, see *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 808 (Fed. Cir. 2000), or under the advice-of-

counsel exception. *See GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1272-73 (Fed. Cir. 2001). And because inequitable conduct is grounded on highly unpredictable standards and is proven largely by testimonial evidence, its mere invocation places substantial economic pressure on patent owners to settle otherwise meritorious claims of infringement.⁸

By contrast, infringing parties bear little or no risk or cost when they charge inequitable conduct. Losing an inequitable conduct claim does not affect the infringer's position on the infringement action that, after all, is at the heart of the action, nor does it expose the infringer to enhanced damages. The bulk of the additional discovery necessitated by the claim is borne by the patent owner, while virtually no additional discovery burden is imposed on the proponent. And rarely does an unsuccessful assertion of inequitable conduct result in sanctions against its

⁸ These incentives are increased even more by virtue of the fact that inequitable conduct assertions are often cited in private antitrust actions involving pharmaceutical patents. *See, e.g., In re: DDAVP Direct Purchase Antitrust Litig.*, 585 F.3d 677, 687 (2d Cir. 2009) (antitrust suit predicated on prior finding of inequitable conduct), *cert. denied*, 78 U.S.L.W. 3581 (U.S. June 28, 2010) (No. 09-1175); *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1349 (Fed. Cir. 2007) (antitrust and inequitable conduct claims brought together). For instance, in *Purdue Pharma L.P. v. Endo Pharms., Inc.*, No. 00-8029, 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004), the trial court found inequitable conduct. Before that determination was vacated and remanded by this Court two years later, *see* 438 F.3d 1123 (Fed. Cir. 2006), nearly 70 lawsuits were filed, including putative class actions, alleging that the manufacturer's inequitable conduct had violated the antitrust laws. *See, e.g., Complaint, City of New York v. Purdue Pharma, Inc.*, No. 04-3499, 2005 WL 2873297 (S.D.N.Y., Aug. 15, 2005).

proponent – this Court has affirmed a district court’s decision to sanction a party for frivolously asserting inequitable conduct only once in the past ten years.

Takeda Chem. Inds., Ltd. v. Mylan Labs., Inc., 549 F.3d 1381, 1389 (Fed. Cir. 2008), *aff’g* 459 F. Supp. 2d 227, 243 (S.D.N.Y. 2006). In short, the doctrine creates a substantial asymmetry of risk between the parties that overrides the relative merits of the dispute and can unfairly influence its ultimate resolution.

Equally pernicious are the doctrine’s systemic effects on patent prosecution. The risk of having a patent held unenforceable leads patent applicants to adopt the defensive practice of “over-disclosing” information to the PTO for fear of being charged with failing to disclose material information; and to severely constrain their discussions with the PTO examiner, for fear of being charged with misleading the examiner.⁹ These practices impose more work on examiners in each case, thereby decreasing the efficiency and productivity of the PTO.¹⁰ As the PTO itself

⁹ The Supreme Court has recognized in analogous contexts the problems caused by permitting litigation over, and sanctions to be imposed for, conduct before agencies. *See, e.g., Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 351 (2001) (noting that “fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA’s evaluation of an application.”).

¹⁰ *See* S. Rep. No. 110-259, at 32 n.152 (inequitable conduct doctrine “[a]s a practical matter, has led to two types of conduct that frequently occur during patent prosecution [including] ‘dump[ing]’ everything they have on the USPTO

recently noted, the submission of “[s]uch documents add[s] little to the effectiveness of the examination process and, most likely, negatively impact[s] the quality of the resulting Office determinations.” 71 Fed. Reg. at 38,809. Yet, ironically, under today’s inequitable conduct standards, an applicant who helps an examiner navigate a voluminous record will find himself in the same position as an applicant who voluntarily restricts the information it provides to the PTO; both will face an almost certain inequitable conduct challenge when the patent is later litigated.¹¹ This creates an *in terrorem* effect of precluding applicants from

(sometimes many boxes of printed documents”). Over-disclosures compelled by the inequitable conduct doctrine is not a new problem. In 1989, the PTO complained of a similar problem, stating:

an evolving body of case law on fraud and inequitable conduct in the Office has reflected, at times, a lack of cohesive direction. This has led to some uncertainty about the duty of disclosure and to the unproductive use of considerable resources by the Office, the patent bar, patent applicants, and patent owners in addressing issues relating to this duty.

54 Fed. Reg. 11,334, 11,334 (proposed Mar. 17, 1989). The PTO subsequently revised its standards for disclosure of information to the Agency to “specify more precisely the information” that must be disclosed during the examination process. See 56 Fed. Reg. 37,321, 37,323-25 (proposed Aug. 6, 1991).

¹¹ In at least one case, a court has found the submission of too many references to support a claim of inequitable conduct, leading to an impossible-to-satisfy standard under which patent applicants commit inequitable conduct by submitting both too much and too little information. *See, e.g., Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995) (“‘burying’ a particularly material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith”); 71 Fed. Reg. at 38,809 (warning of same).

providing reasonable assistance to patent examiners – such as identifying the most relevant materials – because “anything an applicant does to help the examiner focus on the most relevant information during examination [may] become[] the target of an inequitable conduct challenge in court.” S. Rep. No. 111-18, at 47 (2009) (supp. views of Sen. Hatch). In short, the practical effect of current doctrine is to “discourage[] many applicants from conducting a search and lead[] others to be indiscriminate in the information they submit.” *Patent Reform*, 110th Cong. (2007) (statement of J. Dudas, director of PTO), *available at* http://judiciary.senate.gov/hearings/testimony.cfm?id=2803&wit_id=6506.

These consequences, which flow directly from current doctrine, create significant uncertainty over valid patents defining meritorious and commercially important inventions. And this cloud of unpredictable risk and uncertainty caused by the current doctrine undermines the effectiveness of the patent incentive for PhRMA Members to make the huge investments necessary to discover, develop, and bring new medicines to market. For these reasons, PhRMA urges the Court to cabin the sweep of the doctrine and the manner of proving inequitable conduct to ensure that it remains within the bounds originally set by the Supreme Court.

II. Materiality Should Be Limited To Information That Renders One Or More Asserted Claims Invalid, And Should Be A Threshold Finding In Assessing Inequitable Conduct.

Under current law, materiality is untethered to the merits of the invention – *i.e.*, whether the information affects patentability. Instead, materiality has come to comprise an abstract, hypothetical inquiry into whether the information would have been “important to a reasonable examiner.” Litigants have seized on this amorphous standard and employed it to great effect, portraying a bewildering array of information as the sort of thing a “reasonable examiner” might have wanted to consider during examination – regardless of whether that information would or could actually affect the patentability of any patent claims. Recent examples include: (i) lack of entitlement to a “small entity” discount for certain fees, *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1230-32 (Fed. Cir. 2007); and (ii) withholding extent of declarants’ commercial ties to the applicant, *Ferring B.V.*, 437 F.3d at 1195. Similarly, because the definition of materiality is so broad, litigation over inequitable conduct has been permitted to stray to such peripheral matters as alleged misconduct relevant only to claims that were not granted by the PTO, or that were not asserted in the litigation. *See, e.g., Harris Corp. v. Fed. Express Corp.*, 670 F. Supp. 2d 1306 (M.D. Fla. 2009). To alleviate this fundamental problem, this Court should adopt a materiality standard based on the

core principles and purposes of the inequitable conduct doctrine as originally articulated by the Supreme Court. *Supra* at 7-9.

First, because a court derives its authority to render a patent unenforceable from the patent owner's decision to extend the fraud into the court by enforcing a tainted patent claim, it follows that only information that can affect a patent claim asserted in the litigation can properly be considered material.¹² Thus, if information implicates only an unasserted claim or is incapable of affecting the validity of the asserted claim, the information is *per se* immaterial.

A standard tying materiality to asserted claims, however, will not by itself remedy the problems created by the current overinclusive standard of materiality. To do that, the Court also should hold that information can be found material in the context of patent litigation only if the court finds one or more of the asserted claims invalid for reasons linked to the information at issue – for instance, that omitted information demonstrates an asserted claim to be anticipated or obvious; that mischaracterized information demonstrates a different scope or teaching of the prior art or removes secondary evidence supporting non-obviousness; or that the

¹² Asserted claims are those that the patent holder has put at issue in infringement proceedings. This can occur either by a decision to assert infringement of a claim, or by contesting a counterclaim by an accused infringer seeking a declaration of invalidity or non-infringement of the claim. In the latter case, if the patent owner grants a covenant not to sue under that claim, or otherwise does not contest the declaratory judgment action, the claim is an “unasserted” claim.

information shows that an asserted claim is not enabled or supported by the written description.

An “asserted claims” rule is consistent with the doctrine’s historical foundation: Only asserted claims continue the fraud perpetrated on the PTO into court, and thus give courts a proper basis for imposing sanctions against the patent, *see Precision Instrument Mfg. Co.*, 324 U.S. at 809, 815 ; *Dream Games of Ariz., Inc. v. PC Onsite*, 561 F.3d 983, 990 (9th Cir. 2009) (remedy for fraud should not arise “unless the defendant can show that he has personally been injured by the plaintiff’s conduct”) (internal quotation marks omitted). This rule therefore appropriately shifts the focus away from matters that are collateral to the actual controversy before the court. *See Alcatel USA, Inc. v. DGI Techs., Inc.*, 166 F.3d 772, 797 (5th Cir. 1999) (no fraud or unclean hands where the issue is “merely collateral to the . . . cause of action”). Indeed, a contrary rule raises serious jurisdictional questions. If a patent owner has not asserted a patent claim, it presents no cognizable case or controversy. *See, e.g., Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054 (Fed. Cir. 1995) (covenant not to sue divests court of jurisdiction over affected claims in subsequent declaratory judgment action), *abrogated by, MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), *as recognized in Cat Tech LLC v. Tubemaster, Inc.*, 528 F.3d 871, 879 (Fed. Cir. 2008) (rejecting first prong of *Super Sack*’s declaratory judgment

standard); *but see Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, 1348 (Fed. Cir. 2005) (covenant not to sue does not divest jurisdiction if patent holder has already commenced infringement proceedings on that claim); *cf. Med Immune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (jurisdiction exists for licensees who challenge patent while conforming to license).

Next, an “asserted claims” rule is appropriate because it recognizes the appropriate distinction between the judiciary’s role in deterring and punishing litigation-based misconduct, and an administrative agency’s role in and responsibility for regulating the conduct of parties that appear before it. The agency is clearly better situated to regulate misconduct and should be the primary enforcer of its own rules. *See* PTO Rule § 10.23 (governing misconduct of practitioners before PTO); Br. of *Amicus Curiae Johnson & Johnson et al* at 17-21.

In addition, employing an “asserted claims” rule to assess materiality would deliver a number of tangible benefits to patent litigants, courts, the PTO and the public.¹³ It would focus the determination of materiality on an inquiry that is familiar to courts – patentability – rather than the abstract concept of hypothetical importance to a reasonable examiner.

¹³ This rule also would bring the doctrine into alignment with how other matters are addressed during patent litigation; namely, on a claim-by-claim basis. *See, e.g., 800 Adept, Inc. v. Murex Sec., Ltd.*, 539 F.3d 1354, 1368 (Fed. Cir 2008) (district court erred in entering judgment of invalidity with respect to unasserted claims), *cert. denied*, 129 S. Ct. 1373 (2009).

This determination likewise would fit comfortably into the normal flow of patent litigation, and help the court to preserve materiality and intent as separate inquiries. *Infra* at 20-23. Specifically, if the court found one or more of the asserted claims invalid based on the withheld or misrepresented information, it could then consider whether the evidence demonstrated a specific intent to defraud. If materiality were not established, there would be no basis for proceeding into an inquiry on intent, leaving the matter for appropriate resolution by the PTO as the affected agency, rather than the court.

Finally, employing an “asserted claims” rule for assessing materiality would preserve the inequitable conduct doctrine as an appropriate deterrent to fraud. The claims that a patent owner is most likely to assert in litigation are those most likely to have an impact upon competitors and the public, and thus are the claims as to which the incentive to commit fraud, and the public interest in deterring and punishing it, are greatest. Moreover, the Government has many tools to sanction an individual found to have made false or misleading statements during examination of the patent, or who otherwise takes steps to defraud the PTO, *see, e.g.*, 18 U.S.C. § 1001; *Walker Process Equip.*, 382 U.S. 172 , and the PTO retains ample authority to regulate the conduct of parties appearing before it in an appropriately flexible manner. *See, e.g.*, PTO Rule § 10.23.

III. The Court Should Replace The Balancing Test With An Independent Assessment Of Specific Intent To Deceive.

The problems caused by the overly broad standard of materiality are exacerbated by an intent standard that no longer requires actual proof of fraudulent intent. Moreover, by linking intent to materiality, current law improperly permits parties to prove inequitable conduct with evidence that falls far short of the clear and convincing standard required by law. And, by linking the requirements through a sliding scale, courts have allowed parties to bypass the requirement that the party asserting inequitable conduct prove up each element of that defense.

A. The Court Should Abandon The Balancing Test.

This Court should eliminate the sliding scale of materiality and intent. That balancing test is unsupported in law,¹⁴ and has led to gross distortions in the litigation of inequitable conduct. Although decisions of this Court continue to hold, properly, that materiality “does not presume intent, which is a separate and essential component of inequitable conduct,” *Ferring B.V.*, 437 F.3d at 1190 (quoting *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001)), this requirement is honored in the breach: The balancing test has in numerous cases

¹⁴ This Court’s “balancing” test appears to be the result of a distortion in the evolution of the law. The balancing that is supposed to be performed is an assessment of the nature of the misconduct and its harm to the defendant and public, on the one hand, versus the harm to the patent owner caused by holding all or part of a valid and infringed patent unenforceable, on the other. Moreover, this balancing of equities is supposed to occur at the remedial stage, after intent and materiality have been proven.

effectively obviated the requirement that the “separate” requirement of intent be proven. This shortcut has allowed courts to “infer” an intent to deceive based solely on the *degree* of materiality of the information. *See id.* at 1191 (finding proper the inference of intent if the individual accused of misconduct was aware of information having “a high level of materiality and clear proof that it knew or should have known of that materiality” (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257) (Fed. Cir. 1997)).

Of course, it is axiomatic that factfinders may find intent by drawing reasonable inferences from circumstantial (rather than direct) evidence. But that established evidentiary rule provides no basis to modify the legal standard for proving intent merely because materiality (regardless of its “degree”) has been shown.¹⁵ Yet that is the practical effect of this Court’s balancing test. The balancing test thus represents a marked departure from basic principles of common

¹⁵ Simply asking courts to ascribe a “degree” of materiality to information exacerbates the problems, given that doing so can be a difficult, if not impossible task. For example, patentability standards such as obviousness, enablement, and inventorship turn on the assessment of numerous distinct and independent criteria and facts; it is the exceedingly rare case where one bit of information can provide a dispositive answer. Moreover, there is no practical way to set a “threshold” of materiality, after which the court may justifiably reduce the requirement for additional evidence of intent.

law fraud,¹⁶ and is likewise foreign to the established elements of other forms of fraud on the government.¹⁷

Courts have long applied the traditional standard of determining fraudulent intent without importing materiality into the analysis, and there is no justification for not following this traditional approach in the context of determining inequitable conduct. On the contrary, this shortcut is responsible for some of the doctrine's most glaring distortions and abuses, allowing information labeled "highly" material to substitute for evidence concerning the state of mind or intentions of the person accused of fraud. And, in combination with precedent allowing information irrelevant to patentability to be considered material, this shortcut permits parties to inappropriately leverage the threat of unenforceability during litigation.

By mandating use of basic common law standards governing intent, this Court can alleviate the abuses made possible by current law. And by discarding

¹⁶ See, e.g., 5A Charles Alan Wright & Arthur R. Miller, *Federal, Federal Practice and Procedure* § 1297, at 60, 69 (3d ed. 2004) (“[T]he textbook elements of a fraud action that appear to be reflected in the substantive law of all or almost all jurisdictions [include]: (1) the defendant has made a false representation of or failed to disclose a material fact; . . . (4) an intent on the part of the defendant that the statement or the failure to disclose should be acted upon by the plaintiff.”) (footnotes omitted).

¹⁷ See, e.g., 18 U.S.C. § 1001(a) (False Statements Act, in addition to requiring showing of intent, requires falsification or concealment of a “material fact,” “materially” false statement, or the use of a writing or document with “materially” false statements); 31 U.S.C. § 3729 (False Claims Act requires a showing of materiality in addition to, and analyzed independently of, requisite intent).

the improper linkage between materiality and intent, this Court can prevent situations in which one element of the test or the other becomes the near-exclusive focus of proof, resulting in situations in which “high materiality” effectively substitutes for intent, or bad intent effectively overwhelms the fact that the information at issue is of marginal or no relevance.

B. The Proper Standard For Intent Is Specific Intent To Deceive Or Mislead The PTO Into Issuing An Unpatentable Claim.

In addition to abandoning the sliding scale, the Court should clarify that the appropriate intent standard for inequitable conduct is proof of a specific intent to defraud the PTO. This, too, would restore the doctrine to its historical foundations. As this Court explained in *Digital Control*, the doctrine was judicially created and “borne out of a series of Supreme Court cases in which the Court refused to enforce patents whereby the patentees had engaged in fraud in order to procure those patents.” 437 F.3d at 1315 ; *see also Larson Mfg.*, 559 F.3d at 1343 (Linn, J., dissenting) (“The Supreme Court’s three inequitable conduct cases involved overt fraud, not equivocal acts of omission.”).

Common law fraud requires a showing of fraudulent intent, or intent to deceive. *See, e.g., S. Dev. Co. of Nev. v. Silva* 125 U.S. 247, 250 (1888) (elements of common law deceit include “that such [false] representation was not actually believed by the defendant, on reasonable grounds, to be true [and] that it was made with intent that it should be acted on”); *Froelich v. Erickson*, 96 F. Supp. 2d 507,

522 (D. Md. 2000) (“Maryland courts have emphasized that fraud exists only when the speaker had (i) intent to defraud, and (ii) knowledge that his statement was false at the time it was made.”); *Lazar v. Super. Ct.*, 909 P.2d 981, 984 (Cal. 1996) (“The elements of [common law] fraud [include] . . . (c) intent to defraud, i.e., to induce reliance”). It therefore is appropriate to find inequitable conduct in cases akin to common law fraud. Having gone through a rigorous administrative process to obtain a patent, it is inappropriate to revoke a patent absent proof of intentional misconduct on the part of the patentee – the need to restrict its scope to cases involving specific intent to deceive is crucial “because the penalty for inequitable conduct is so severe, the loss of the entire patent.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 1595 (2009).

But despite the inequitable conduct doctrine’s basis in fraud, and the fact that the penalty for inequitable conduct has not changed, “[s]ubsequent case law has broadened the doctrine to encompass misconduct less egregious than fraud.” *Id.* at 1366. Doing so has not only untethered the doctrine from its original justification as articulated by the Supreme Court, but has also created confusion. In *Kingsdown Med. Consultants*, this Court, sitting *en banc*, appeared to have clarified the issue of intent, holding that even gross negligence does not by itself justify the inference of “deceitful intent” required for inequitable conduct. 863

F.2d at 876. Moreover, this Court has since reiterated that to “successfully prove inequitable conduct, the accused infringer must present ‘evidence that the applicant . . . intended to deceive the [PTO].’” *Star Scientific*, 537 F.3d at 1365. Since *Kingsdown*, however, this Court in reality has often applied a less demanding standard. In *Ferring B.V.*, for example, the Court stated that a sufficient showing of intent would be found where “the applicant knew or should have known of the materiality of the information” and “has not provided a credible explanation for the withholding.” 437 F.3d at 1191. The Court should squarely repudiate such formulations, and clearly state that inequitable conduct requires proof by clear and convincing evidence of a specific intent to deceive. Just as courts will not hold that a defendant has committed fraud on the government without finding that the defendant has acted willfully and intentionally,¹⁸ so too

¹⁸ See *United States v. Lange*, 528 F.2d 1280, 1286 n.10, 1288 (5th Cir. 1976) (violation of the False Statements Act requires “[a]n intent to deceive or mislead” the government must prove that the defendant “had the specific intent to make a false or fraudulent statement”); *United States v. Munoz*, 430 F.3d 1357, 1367 (11th Cir. 2005) (fraud on the FDA “requires specific intent to defraud or mislead”); *United States v. Proffit*, 49 F.3d 404, 406 (8th Cir. 1995) (“specific intent to defraud” is an “essential element[] in the crime of wire fraud”); *United States v. Porcelli*, 865 F.2d 1352, 1358 (2d Cir. 1989) (“The specific intent required under the mail fraud statute is the intent to defraud . . .”); *Russell v. S. Nat’l Foods, Inc.*, 754 So. 2d 1246, 1256 (Miss. 2000) (to establish that an investment decision was induced by fraud, “an affirmative intent to deceive must be shown”); *United States v. Slutsky*, 487 F.2d 832, 844 (2d Cir. 1973) (to prove income tax fraud government must “establish beyond a reasonable doubt that appellants acted wilfully and knowingly with the specific intent to evade their income tax obligations”); *Bender v. Comm’r*, 256 F.2d 771, 774 (7th Cir. 1958) (“Fraud [on

courts should not invalidate patents based on inequitable conduct without finding a specific intent to deceive.

Finally, requiring proof of a specific intent to defraud is necessary to ensure that the doctrine is applied sparingly, while still punishing and deterring bad actors who have willfully committed fraud on the PTO. Specific intent would, of course, continue to encompass deliberate omissions as well as affirmatively deceptive statements. *See Refac Int'l., Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1583 (Fed. Cir. 1996) (“The fact that the conduct here consists of an *omission* rather than a *misrepresentation* does not compel a different result, as either may mislead an examiner.”). Requiring specific intent to deceive will relieve the confusion that recent decisions have created over the standard for intent. It will also result in more evenhanded enforcement of the doctrine by providing a clear, reliable, consistent, and comprehensible standard for lower courts to apply.


the part of the taxpayers] must be proved by clear and convincing evidence and the intent to evade tax is a specific intent.”); 42 C.F.R. § 455.2 (for purposes of healthcare fraud, defining “fraud” as “an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person”).

CONCLUSION

For the foregoing reasons, this Court should clarify that inequitable conduct is limited to asserted claims; that information is material only if it renders an asserted claim invalid; and that specific intent to deceive must be established by clear and convincing evidence, regardless of the “degree” of materiality that has been shown.

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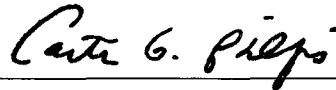

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P.

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1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B) and Fed. Cir. R. 32(b), the brief contains 6,886 words.
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