

**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

**BRIEF FOR *AMICI CURIAE*
22 PATENT PROSECUTION FIRMS AND PRACTITIONERS
SUPPORTING NEITHER PARTY**

(Amici listed on inside cover)

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CERTIFICATE OF INTEREST

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2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the parties represented by me are:

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<http://ssrn.com/abstract=1588916>.....6
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- The Statement of Jon Dudas, Director of the PTO, in *Patent Reform: The Future of American Innovation, Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007), available at http://judiciary.senate.gov/hearings/testimony.cfm?id=2803&wit_id=6506 13
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STATEMENT OF INTEREST AND STATEMENT OF CONSENT

Amici Curiae 22 Patent Prosecution Firms and Practitioners provide patent prosecution services to hundreds of companies in all areas of technology. Because findings of inequitable conduct have a crippling impact on the reputation and career of an accused patent attorney, the *Amici* represented here have an interest in advocating for predictable rules of conduct that both punish improper practice and shield ethical practitioners.

The parties have consented to the filing of this brief. *Amici* 22 Patent Prosecution Firms and Practitioners have no direct stake in the result of this appeal, and the parties have not contributed to the preparation of this brief.

I. SUMMARY OF ARGUMENT

The materiality-intent-balancing framework for inequitable conduct should be replaced with clear standards that encourage an open dialog with the Patent Office and allow practitioners to exercise reasonable latitude in advocacy and in deciding which references are relevant enough to disclose.

Although in other contexts it may benefit a party to conceal information, it is in the best interests of patent attorneys to disclose the most relevant prior art references to the PTO. There is a powerful incentive to do so, because pending claims may be amended to distinguish over those references, and a patent is more likely to survive a validity challenge if the best prior art references had been considered by the Examiner.¹ But the assumption driving inequitable conduct jurisprudence – at least those cases involving the failure to disclose a reference – is that the attorney is strongly motivated to conceal the closest art. The result is a doctrine that makes it too easy to establish deceptive intent where none exists.

Compared to the proof of fraud needed to establish a *Walker Process* antitrust counterclaim, inequitable conduct is a “lesser offense” that “includes types of conduct less serious than ‘knowing and willful’ fraud.”² The explanation for this distinction has been that inequitable conduct defense acts merely as a “shield” in an infringement litigation,

¹ See, for example, *KSR International Co. v. Teleflex, Inc. et al.*, 127 S. Ct. 1727, 1745 (2007); *Lindemann Maschinenfabrik v. Am. Hoist and Derrick*, 730 F.2d 1452, 1459 (Fed. Cir. 1984).

² *NobelPharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 876 (1998).

whereas the more serious finding of fraud acts as a “sword” in that it may expose the patentee to antitrust damages.³

In litigation, the inequitable conduct defense acts as a sword (sometimes even called an “atomic bomb”)⁴ against the accused practitioner, who suffers from severe substantive and procedural disadvantages at the District Court and on appeal. Little attention is paid to the impact of the defense on a practitioner caught in the crossfire of litigation: sullied reputation, job loss, suspension from practice, disbarment – frequently the result of inference built upon inference, or the inability to remember the thinking underlying one decision among thousands made over the course of a career.

The impact of a mistaken finding of inequitable conduct is so severe that at a minimum, the issues of materiality and intent must be decided separately. A return to the doctrine’s roots in common law fraud as

³ *Id.* at 1070.

⁴ *Aventis Pharma SA v. Amphastar Pharmaceuticals*, 525 F.3d 1334, 1349 (Rader, J., dissenting) (Fed. Cir. 2008).

articulated in the *Keystone* trilogy⁵ – and consistent with *Walker Process* fraud – would provide a more equitable analytical framework to decide questions of misconduct. The test for *Walker Process* fraud described in *NobelPharma* and *Dippin' Dots* is also the proper one to apply here:

[a finding of *Walker Process* fraud] must be based on *independent and clear evidence* of deceptive intent together with a clear showing of reliance, *i.e.*, that the patent would not have issued but for the misrepresentation or omission. Therefore, for an omission such as a failure to cite a piece of prior art to support a finding of *Walker Process* fraud, the withholding of the reference must show evidence of fraudulent intent. A mere failure to cite a reference to the PTO will not suffice.⁶

This test as applied in *NobelPharma* would lessen the likelihood of mistaken findings of inequitable conduct, provide clear guidance to the practitioner, and encourage an open and efficient dialog with the PTO that the current rule makes impossible.

⁵ *Keystone Driller Co. v. Gen. 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); *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945).

⁶ *NobelPharma* 141 F.3d at 1071 (emphasis added); see also *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1348 (Fed. Cir. 2007), *cert. denied*, 552 U.S. 948 (2007).

II. ARGUMENT

A. In response to questions 1, 2, 4, and 5, the materiality-intent-balancing framework should be abandoned, and the standard for inequitable conduct should be tied to common law fraud.

1. Patent attorneys accused of inequitable conduct suffer from severe substantive and procedural disadvantages at the District Court.

Concealing information is the antithesis of practice before the PTO. Patent attorneys are strongly motivated to disclose the closest prior art during prosecution – this allows claims to be drafted or amended to distinguish over the relevant art, and results in a robust and properly vetted patent that benefits from a strong presumption of validity.⁷

But the assumption underlying the current materiality-intent balancing test is that patent attorneys have powerful incentives to conceal the closest art. This places the accused practitioner at a severe disadvantage, most commonly when a finding that a withheld reference has “high materiality” (although often not high enough to impact patentability) leads to a finding of inequitable conduct. These findings may take place even absent any circumstantial evidence of intent to

⁷ See, for example, *KSR* 127 S. Ct. at 1745; *Lindemann*, 730 F.2d at 1459.

deceive; the *Ferring* case – in which the Court’s holding that an attorney “should have known” of the materiality of withheld information justified an inference of deceptive intent – is a widely cited example of this so-called “bleed through” or “snowball” effect.⁸

Despite the Court’s recognition in *Exergen* that knowledge of a reference’s existence is not the same as knowledge of “the specific material *information* contained in that reference,”⁹ and the acknowledgement in *Dippin’ Dots* that an omission could happen for any number of nonfraudulent reasons,¹⁰ the snowball effect occurs because once it is shown that a prior art reference with some threshold level of materiality was withheld, the burden shifts to the accused patent practitioner to give a good faith explanation.¹¹ This requires the

⁸ *Ferring B.V. v. Barr Labs, Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006), *cert. denied*, 549 US 1015 (2006). For commentary on this case, see, for example, Dolak, *Inequitable Conduct: A Flawed Doctrine Worth Saving* (March 17, 2010), page 22; Available at SSRN: <http://ssrn.com/abstract=1588916>; see also, Rader, *Always at the Margin: Inequitable Conduct in Flux*, *American University Law Review*, Vol. 59, 777-786 (2010).

⁹ *Exergen Corp. v. Wal-Mart Stores, Inc. et al.*, 575 F.3d 1312, 1330 (Fed. Cir. 2009) (emphasis in original).

¹⁰ *Dippin’ Dots*, 476 F. 3d at 1347.

¹¹ *Star Scientific, Inc. v. RJ Reynolds Tobacco Company*, 537 F.3d 1357, 1368 (Fed. Cir. 2008), *cert. denied*, 129 S.Ct. 1595 (2009).

attorney to actually remember the decision to withhold the reference; attempts at reconstructing the events are insufficient.¹²

Because litigation sharply focuses on one or more choices made during a patent's prosecution, the accused attorney is expected to recall those events with the same clarity that one might remember an automobile accident or the birth of a child. But memory of a particular decision to withhold a reference may be physiologically impossible.¹³ On any given day, a typical patent attorney may work on a half-dozen or more separate matters; in the years between the patent prosecution and the litigation in which the allegation of inequitable conduct is first made, the attorney may have prosecuted hundreds of patents and reviewed thousands of references. And yet the inability to remember the basis for a single decision among thousands is equated by the courts with a lack of credibility – even in the case of a prosecutor with an

¹² *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1318 (Fed. Cir. 2008).

¹³ See, for example, Wixted, *The Psychology and Neuroscience of Forgetting*, Annual Review of Psychology 2004, 55:235–69.

otherwise stellar reputation, decades of experience, and no reason to jeopardize their integrity, reputation, and license to practice.¹⁴

2. Substantive and procedural disadvantages for the accused prosecution attorney continue on appeal.

Not only are the district court's credibility findings "virtually unreviewable,"¹⁵ but members of the patent bar are given far less ability to fight a judge's reprimand than their litigating colleagues. For instance, a group of sanctioned litigators was allowed to appear as nonparty appellants in *Medtronic*; the panel decision in that case recognized the devastating effect of a Court's rebuke:

Despite our reluctance to second-guess the judgment of trial judges who typically have intimate knowledge of the case, we have the responsibility, *in light of the substantial economic and reputational impact of such sanctions*, to examine the record with care to determine whether the trial court has committed clear error in holding the case exceptional or has abused its discretion with respect to the fee award.¹⁶

¹⁴ *Praxair*, 543 F.3d at 1318; see also, Migliorini, *Lessons for Avoiding Inequitable Conduct and Prosecution Laches in Patent Prosecution and Litigation*, 46 IDEA 221, 260 (2006).

¹⁵ *Hamsch v. Department of the Treasury*, 796 F.2d 430, 436 (Fed. Cir. 1986).

¹⁶ *Medtronic Navigation, Inc. et al. v. Brainlab Medizinische Computersysteme GmbH et al.*, 603 F.3d 943, 953 (Fed. Cir. 2010) (emphasis added).

But when accused of inequitable conduct, the affected patent attorney is typically not permitted to intervene in the appeal, nor even granted leave to an amicus brief on his or her own behalf. The failed attempts of the patent attorney accused of inequitable conduct in the original *Therasense* appeal are a good example.¹⁷

3. Post-decision consequences to the accused prosecution attorney are crippling.

Prosecution attorneys who are unable to reverse adverse inequitable conduct findings on appeal are treated as though they had committed common law fraud, rather than a “lesser offense” as described in *NobelPharma*. One study revealed that many attorneys found to have committed inequitable conduct resign the practice altogether.¹⁸ Other attorneys (like the one involved in this case) lose their jobs, lose clients, and are subject to costly and traumatic disciplinary proceedings both before the PTO and their state bar organizations.¹⁹ All suffer damage to reputation from the harsh language in opinions finding inequitable

¹⁷ Order dated October 23, 2008 denying Lawrence S. Pope’s motion for leave to intervene; Order dated January 5, 2009 denying Lawrence S. Pope’s motion for leave to file brief *amicus curiae*.

¹⁸ Flores and Warren, *Inequitable Conduct, Fraud, and Your License to Practice Before the United States Patent and Trademark Office*, 8 Tex. Intell. Prop. L.J. 299, 322 (2000).

¹⁹ *Id.* at 321-325.

conduct, which are easily accessible on the Internet. And patent attorneys sued for malpractice based on their “intent to deceive” the PTO must struggle with professional liability insurance policies that frequently have exclusions for “intentional” acts.

A rule that requires proof of *Walker Process* fraud – in the sense that the PTO was actually deceived by one with an (independently proven) intent to deceive – will protect ethical practitioners and still prevent patents infected with fraud from being asserted and enforced.

B. In response to question 3, the standard for materiality should be clear enough for practitioners to know what conduct is prohibited, and high enough to give them a reasonable amount of discretion in dealing with the PTO.

1. The current standards for materiality are too vague to provide any real guidance to the patent practitioner.

The fundamental problem faced by attorneys while prosecuting patents is that the current “reasonable examiner” and other standards for materiality articulated in *Digital Control*²⁰ provide no reliable guidance as to what a court will ultimately find to be material; and in many cases, a withheld reference is found to be material even if it would

²⁰ *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-1316 (Fed. Cir. 2006).

have no effect on patentability.²¹ Although a District Court must find at least a threshold level of materiality and intent before performing the materiality-intent balancing test, there is no guidance from the Federal Circuit as to what the threshold levels are. These decisions are left to the district court, and reviewed here for abuse of discretion.²²

As was discussed above, attorneys found to have committed inequitable conduct are frequently subject to disciplinary proceedings before the PTO and their state bar; these proceedings are quasi-criminal in nature.²³ In the criminal context, the Supreme Court has found due process violations where a rule fails “to provide a person of ordinary intelligence fair notice of what is prohibited, or [as being] so standardless that [they] authoriz[e] or encourag[e] seriously discriminatory enforcement.”²⁴ Under the current inequitable conduct rules, patent attorneys have no clear guidance or fair notice as to the extent of the duty of candor; the consequence is they can be accused of

²¹ See, for example, *Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010), *rehearing and rehearing en banc denied*, (Jul. 16, 2010).

²² *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1255 (Fed. Cir. 1997).

²³ *In Re Gault*, 387 US 1, 33 (1967).

²⁴ *Skilling v. United States*, 561 U.S. __ (June 24, 2010), *citing United States v. Williams*, 553 U.S. 285, 304 (2008).

deception for withholding a reference they believe to be irrelevant, and accused of deception for disclosing too much.

2. Attempts to comply with the various materiality standards are both difficult and wasteful.

In addition to rendering unenforceable many otherwise valid patents, the current inequitable conduct doctrine strips the practitioner of any latitude in exercising professional judgment and places unjustified burdens on their clients and the PTO. Many firms listed as amici here use databases to ensure that all art and office actions in related applications are cross-cited, regardless of actual relevance. Even this may not be enough, as the Court has required cross-citation in co-pending applications with “substantially similar” claims;²⁵ there is no limitation to applications that are related or even in the same technology classification.

The patent bar’s focus on defending against false charges of inequitable conduct ultimately leads to (among other inefficiencies) compromised patent quality, as the Examiner may not even find the most relevant references among the large number of cumulative

²⁵ *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003).

references that are submitted.²⁶ The citation problem is particularly notable in biotech practice, where some practitioners submit not just a prior art reference cited by an examiner in a related case, but also the articles cited in that reference. A return to the doctrine's roots in common law fraud could limit the impact of this flood of prior art by allowing an applicant to identify the most relevant references without fear that characterizing the references will be viewed as an attempt to deceive the PTO.

Finally, the threat of an inequitable conduct accusation compels practitioners to withdraw allowed applications from issue by filing a request for continued examination ("RCEs") whenever any art, regardless of its relevance, is cited in a related foreign or domestic application; the problem becomes intractable when there are many related applications. An overwhelming number of these RCEs are allowed unamended on a first office action, further clogging the PTO's

²⁶ Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 Berkeley Tech. L.J. 723, 770-771 (2009); see also, The Statement of Jon Dudas, Director of the PTO in *Patent Reform: The Future of American Innovation, Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007), available at http://judiciary.senate.gov/hearings/testimony.cfm?id=2803&wit_id=6506.

examination process and at significant cost to the patentee both in attorney fees and in shortened patent terms.

A requirement that a misrepresentation or omission must affect the patentability of at least one claim as required by *Walker Process* would provide clarity, ensure consistent application of the defense, and provide patent attorneys with sufficient latitude to exercise the professional judgment that is expected in all other areas of the legal profession.

III. CONCLUSION

The current inequitable conduct doctrine places an unjust burden on patent attorneys and goes far beyond punishing improper practice. The materiality-intent-balancing framework for inequitable conduct must be replaced with a test that, at a bare minimum, requires independent and clear evidence of deceptive intent and provides unambiguous guidance as to what is material to the prosecution of a patent. Only then may a patent attorney confidently satisfy his or her duty of candor to the PTO.

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BRIEF FORMAT CERTIFICATION

Pursuant to Fed. R. App. P. 32 (a)(7)(C), I certify that the attached brief is proportionally spaced, has a typeface of 14 points and contains 2,782 words as calculated by the word processing program (Microsoft Word 2008 for Mac) used to prepare the brief.

Dated: July 30, 2010

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CERTIFICATE OF SERVICE

I hereby certify that an original and 30 copies of the foregoing **BRIEF FOR AMICI CURIAE 22 PATENT PROSECUTION FIRMS AND PRACTITIONERS** were filed by hand, on July 30, 2010, addressed to the Clerk's Office, U.S. Court of Appeals for the Federal Circuit, 717 Madison Place, N.W., Washington, D.C. 20439, and that two true and correct copies of the same were served via Federal Express, next day delivery, on July 30, 2010, to each of the principal counsel of record as follows:

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