

IN THE  
**UNITED STATES COURT OF APPEALS**  
FOR THE FEDERAL CIRCUIT

---

THERASENSE, INC. (now known as Abbott Diabetes Care, Inc.)  
AND ABBOTT LABORATORIES

*Plaintiffs-Appellants,*

v.

BECTON, DICKINSON AND COMPANY,  
and NOVA BIOMEDICAL CORPORATION,

*Defendants-Appellees,*

and

*BAYER HEALTHCARE LLC,*

*Defendant-Appellee.*

---

**On Appeal from the United States District Court  
For the Northern District of California  
Judge William H. Alsup**

---

**BRIEF AND APPENDIX OF THE AMERICAN BAR ASSOCIATION  
AS *AMICUS CURIAE***

---

*Of Counsel:*

MICHAEL A. VALEK  
WILLIAM L. LAFUZE

June 17, 2010

CAROLYN B. LAMM  
*Counsel of record*  
PRESIDENT  
AMERICAN BAR ASSOCIATION  
321 North Clark Street  
Chicago, IL 60610  
(312) 988-5000

---

## CERTIFICATE OF INTEREST

Counsel for the American Bar Association certifies the following:

1. The full name of every party or amicus represented by me is:

American Bar Association

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:

None

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

Carolyn B. Lamm, President  
American Bar Association  
321 North Clark Street  
Chicago, IL 60654  
(312) 988-5000  
Michael A. Valek  
William L. LaFuze

Dated: June 17, 2010



Michael A. Valek  
Vinson & Elkins, L.L.P.

## TABLE OF CONTENTS

STATEMENT OF INTEREST .....	1
I. ARGUMENT .....	4
1. The current legal standard for proving inequitable conduct results in over-assertion of the defense.....	4
2. Excessive assertion of inequitable conduct undermines respect for the legal profession and the patent system itself.....	8
3. Replacing the materiality-intent-balancing standard with one more closely predicated on common law fraud principles would remedy the problems caused by over breadth and ambiguity in the current law.....	11
a. The defense of inequitable conduct has been allowed to expand far beyond the doctrine’s roots in principles of common law fraud and Supreme Court precedent.....	11
b. The ABA supports adoption of a standard more closely predicated on common law fraud principles to remedy the problems caused by the current law. ....	15
II. CONCLUSION .....	19

## TABLE OF AUTHORITIES

### Cases

<i>Agfa Corp. v. Creo Prods. Inc.</i> , 451 F.3d 1366 (Fed. Cir. 2006).....	15
<i>Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.</i> , 525 F.3d 1334 (Fed. Cir. 2008).....	4
<i>Burlington Indus. v. Dayco Corp.</i> , 849 F.2d 1418 (Fed. Cir. 1988).....	5, 9
<i>Corona Cord Tire Company v. Dovan Chemical Corporation</i> , 276 U.S. 358 (1928).....	14, 17
<i>Digital Control Inc. v. Charles Machine Works</i> , 437 F.3d 1309 (Fed. Cir. 2006).....	5, 6, 12, 16
<i>Exergen Corp. v. Wal-Mart Stores, Inc.</i> , 575 F.3d 1312 (Fed. Cir. 2009).....	19
<i>Ferring B.V. v. Barr Labs., Inc.</i> , 437 F.3d 1181 (Fed. Cir. 2006).....	7
<i>Field v. Mans</i> , 516 U.S. 59 (1995).....	12
<i>Hazel-Atlas Glass Co. v. Hartford-Empire Co.</i> , 322 U.S. 238 (1944), overruled on other grounds by 429 U.S. 17 (1976) .....	13
<i>Keystone Driller Co. v. Gen. Excavator Co.</i> , 290 U.S. 240 (1933).....	13
<i>Larson Mfg. of S.D., Inc. v. Aluminart Prods. Ltd.</i> , 559 F.3d 1317 (Fed. Cir. 2009).....	18
<i>Neder v. U.S.</i> , 527 U.S. 1 (1999) .....	12
<i>Nobelpharma AB v. Implant Innovations, Inc.</i> , 141 F.3d 1059 (Fed. Cir. 1998).....	7, 15, 18
<i>Praxair, Inc. v. ATMI, Inc.</i> , 543 F.3d 1306 (Fed. Cir. 2008).....	7, 8, 18
<i>Precision Instr. Mfg. Co. v. Auto Maint. Mach. Co.</i> , 324 U.S. 806 (1945) .....	13

*S.E.C. v. Capital Gains Research Bureau, Inc.*,  
375 U.S. 180 (1963) ..... 12

*Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*,  
537 F.3d 1357 (Fed. Cir. 2008)..... 12, 17

### **Statutes and Rules**

35 U.S.C. § 32..... 17

37 C.F.R. § 1.56..... 6

37 C.F.R. § 1.56(a) ..... 5

37 C.F.R. § 10.130..... 17

### **Other Authorities**

*ABA Report with Recommendation #107B* (Policy adopted Aug. 2009) .....passim

*ABA Report with Recommendation #107D* (Policy adopted Aug. 2009)..... 7, 18

Cotropia, Christopher A., *Modernizing Patent Law’s Inequitable Conduct  
Doctrine*, 24 Berkeley Tech. L.J. 723 (2009) ..... 11

Flores, Edwin S. & Warren, Jr., Sanford E., *Inequitable Conduct, Fraud,  
and Your License to Practice Before the United States Patent &  
Trademark Office*, 8 Tex. Intell. Prop. L.J. 299 (2000) ..... 10

Nolan-Stevaux, Katherine, *Inequitable Conduct Claims in the 21st Century:  
Combating the Plague*, 20 Berkeley Tech. L.J. 147 (2005) ..... 5

Patstats.org, University of Houston Law Center, <http://patstats.org> (last  
visited June 2, 2010)..... 5

Rader, Randall R., *Always at the Margin: Inequitable Conduct in Flux*, 59  
Am. U. L. Rev. 777 (2010) ..... 4, 13

## STATEMENT OF INTEREST

The American Bar Association (“ABA”), as amicus curiae, respectfully submits this brief in support of neither party, in response to this Court’s request for briefs that address whether the Court should modify or replace the materiality-intent-balancing framework that is used to determine when inequitable conduct occurred in obtaining a patent, with the result that the patent is found to be unenforceable. Because of the significant, detrimental impact of the present framework on attorneys, their clients, the Patent and Trademark Office (“PTO”) and the courts, the ABA urges the Court to replace the current framework with a standard predicated on the common law fraud principles of specific intent, injury, and reliance. Specifically, the ABA requests that inequitable conduct be shown only upon proof by clear and convincing evidence that: (1) a person having a duty of candor and good faith to the PTO misrepresented or omitted material information; (2) in the absence of such misrepresentation or omission, the PTO, acting reasonably, would not have granted or maintained in force at least one patent claim; and (3) the misrepresentation or omission was made with a specific intent to deceive the PTO, which intent cannot be established by the mere materiality of the misrepresentation or omission.

The ABA is the largest voluntary professional membership organization and the leading organization of legal professionals in the United States. Its nearly

400,000 members span all 50 states and other jurisdictions, and include attorneys in private law firms, corporations, non-profit organizations, government agencies, and prosecutor and public defender offices, as well as judges, legislators, law professors, and law students.<sup>1</sup>

Of the ABA's members, nearly 23,000 are members of the ABA's Section of Intellectual Property Law ("IPL Section"), which is the world's largest organization of intellectual property professionals and is composed of lawyers representing patent owners, accused infringers, individual inventors, large and small corporations, and universities and research institutions across a wide range of technologies and industries. Formed in 1894, the IPL Section works to advance the development and improvement of intellectual property law. It presents resolutions to the ABA House of Delegates for adoption as ABA policy, which policies then provide the basis for the Section's active role in the consideration of proposed legislation, administrative rule changes and international efforts, and for the preparation of ABA amicus briefs, which are filed primarily in the Supreme Court of the United States and in this Court.<sup>2</sup>

---

<sup>1</sup> Neither this brief nor the decision to file it should be interpreted to reflect the view of any judicial member of the ABA. No member of the Judicial Division Council participated in the adoption or endorsement of the positions in this brief, nor was it circulated to any member of the Judicial Division Council before filing.

<sup>2</sup> Only recommendations adopted by the ABA's House of Delegates ("HOD") become ABA policy. The HOD is composed of more than 500 delegates representing states and territories, state and local bar associations, affiliated

In 2005, when congressional leaders in intellectual property law began a project to revise the patent laws of the United States, the IPL Section formed a Task Force of patent law experts to develop ABA policy to guide the ABA's participation in those efforts. In 2009, following unsuccessful congressional efforts to eliminate or reform the defense of inequitable conduct, the IPL Section directed the Task Force to start from scratch and develop a comprehensive, consensus policy on the defense for use in both legislative and judicial advocacy, since allegations of inequitable conduct continued to be asserted in federal courts and, in particular, in this Court.

After meeting with diverse members of the legal profession and various ABA entities,<sup>3</sup> the IPL Section presented four consensus recommendations for adoption as policy at the ABA's 2009 Annual Meeting. Of these, the policy that addresses the Court's questions is set out in the *ABA Report with Recommendation #107B* (Policy adopted Aug. 2009). This policy is set out in full in the Appendix and is paraphrased in the first and final paragraph of this amicus brief.

---

organizations, sections and divisions, ABA members and the Attorney General of the United States, among others. All amicus briefs filed by the ABA must be supported by ABA policy. See ABA General Information, *available at* <http://www.abanet.org/leadership/delegates.html>, and ABA amicus brief information, *available at* <http://www.abanet.org/amicus>.

<sup>3</sup> The ABA entities consulted included the ABA's Section of Administrative Law and Regulatory Practice, its Section of Science and Technology, its Business Law Section and its Section of Litigation.



The ABA opposes the elimination of the defense of inequitable conduct. Rather, it supports reforming the standard to more closely resemble the doctrine's roots in common law fraud, ending the current use of materiality tests that are broader than the statutory and PTO regulatory standards applicable at the time of prosecution, and requiring proof of a specific intent to deceive the PTO.

Based on its careful study of the impact of the current framework on practitioners, parties, the PTO and the courts, the ABA offers its consensus policy for the Court's consideration, in the belief that adoption of this policy would maintain the defense as a strong deterrent to actual fraud while substantially reducing the burdens that, under the present framework, too often result from allegations based on speculation or harmless mistake.

## **I. ARGUMENT**

### **1. The current legal standard for proving inequitable conduct results in over-assertion of the defense.**

In the ABA's view, the defense of inequitable conduct is raised in far too many cases. From 2004 to 2008, the number of inequitable conduct appeals doubled. *See* Randall R. Rader, *Always at the Margin: Inequitable Conduct in Flux*, 59 Am. U. L. Rev. 777, 779 (2010) (citing statistics compiled by the Stanford Intellectual Property Litigation Clearinghouse); *cf.* *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting) (inequitable conduct, once "a plague," "has taken on a new

life as a litigation tactic.”) (quoting *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)). Statistics and quantitative studies suggest that inequitable conduct is found in less than 25% of those cases where a decision is reached on its merits. See Patstats.org, University of Houston Law Center, <http://patstats.org> (last visited June 2, 2010) (reporting that on a patent-by-patent basis in 2009, patentees prevailed on the issue of inequitable conduct in 32 instances whereas accused infringers won only 6 times, *i.e.*, ~15% of the time); see also Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 Berkeley Tech. L.J. 147, 163-64 (2005) (concluding that from 1995-2004 inequitable conduct was found in only 25% of cases where a decision was made on the merits).

After careful study, the ABA has concluded that the excessive invocation of the inequitable conduct defense has resulted from the vagueness of the existing materiality-intent-balancing test for inequitable conduct. *ABA Report with Recommendation #107B*, at 1. First, this Court has sanctioned the use of at least five standards for determining whether the applicant’s misrepresentation or omission was material. For example, in *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1314-1316 (Fed. Cir. 2006), the Court discussed the PTO’s 1992 amendment of 37 C.F.R. § 1.56(a), which provides for an “arguably narrower standard of materiality,” as well as the PTO’s prior Rule 56 standard based on a

showing that “a reasonable examiner would have considered [a misstatement or omission to be] important,” and the Court’s three older ‘objective but for,’ ‘subjective but for’ and ‘but it may have’ standards. As the *Digital* Court, *id.* at 1316, concluded:

If a misstatement or omission is material under the new Rule 56 standard . . . , under the ‘reasonable examiner’ standard or under the older three tests, it is also material. As we reasoned in *American Hoist [& Derrick Co. v. Sowa & Sons, Inc.]*, 725 F.2d 1350 (Fed. Cir. 1984)], to the extent that one standard requires a higher showing of materiality than another standard, the requisite finding of intent may be lower.

Of these the broadest and most frequently applied is the inherently imprecise ‘important to a reasonable examiner’ standard. Even though the PTO redefined the scope of an applicant’s duty of candor under Rule 56 more than 18 years ago, *see* 37 C.F.R. § 1.56, the fact that this standard is still applied after-the-fact in litigation leads to the untenable situation where a patentee may be found to have committed inequitable conduct even though he or she fully complied with the applicable PTO regulations. *See Digital Control*, 437 F.3d at 1316 (concluding that “the ‘reasonable examiner’ standard and our case law interpreting that standard were not supplanted by the PTO’s adoption of a new Rule 56”). Moreover, the reasonable examiner standard carries no requirement that anyone actually rely on the alleged misrepresentation or omission. Accordingly, the entire patent (and possibly related patents) may be rendered unenforceable based upon the

misrepresentation or omission of anything later deemed to have been “important” even where every requirement for patentability has been met, and there is no injury to the public through the issuance of otherwise invalid claims.

Second, the ABA concluded that over-assertion of the defense has resulted from some ambiguity in the case law that has permitted inequitable conduct to be found based on the mere fact that misrepresented or omitted information is material – in the absence of any other evidence of deceptive intent. *ABA Report with Recommendation #107D*, at 1. Some of this Court’s precedent suggests that the requisite intent may be inferred from the alleged materiality of the misrepresentation or omission. *See Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-14 (Fed. Cir. 2008) (quoting *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006)). The materiality-intent-balancing framework compounds this problem by instructing that a greater showing of materiality can overcome a lesser showing of culpability where clear and independent evidence of actual intent is lacking. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070-71 (Fed. Cir. 1998) (observing that inequitable conduct requires a “lesser” showing of deceptive intent than does fraud, which cannot be shown through the “equitable balancing of materiality and intent,” but rather “must be based on independent and clear evidence of deceptive intent”). Indeed, under a fair reading of current precedent, inequitable conduct can be shown based largely on evidence of

materiality with just a threshold showing of deceptive intent that may itself be largely inferred from the materiality of the alleged misconduct. *See, e.g., Praxair*, 543 F.3d at 1314 (“[A] patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent the drawing of an inference of intent to mislead”) (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997)). The result is a circular overemphasis on materiality that has expanded inequitable conduct doctrine far beyond those instances where the applicant truly acted with fraudulent intent.

**2. Excessive assertion of inequitable conduct undermines respect for the legal profession and the patent system itself.**

The ABA also examined data that suggests that excessive assertion of the inequitable conduct defense has a dramatic and deleterious effect on litigation practice. The extreme nature of the penalties resulting from a finding of inequitable conduct – *i.e.*, unenforceability of the patent-at-issue, potential “infectious” unenforceability of related patents, an exceptional case finding and an award of attorneys’ fees and possible disciplinary proceedings before the PTO – generally requires vigorous litigation of even weak allegations. This leads to relentless discovery on a myriad of issues tangential to the underlying patent infringement claims. Moreover, because communications between the applicant and their prosecution counsel are usually at issue, litigation of inequitable conduct

commonly precipitates disputes as to the scope of privilege and assertions of the crime-fraud exception to that privilege. These disputes tax the trial court's resources and unnecessarily multiply the contentiousness of the proceedings. "All of this results in increasing the complexity, duration and cost of patent infringement litigation that is already notorious for its complexity and high cost." *ABA Report with Recommendation #107B*, at 2.

Moreover, the sharp increase in the number of inequitable conduct appeals in recent years suggests that final resolution of the defense is an increasingly uncertain proposition that requires both extensive litigation below and ultimate disposition on appeal. But by the time such issues are appealed, a high price has already been paid to litigate what is, often, a meritless defense. Even where such allegations fail, the mere assertion that inequitable conduct has occurred is itself harmful to the bar because it is an attack on the reputation of lawyers and their clients. What this Court stated in *Burlington* in 1988 remains true today:

[Lawyers asserting inequitable conduct] get anywhere with the accusation in but a small percentage of the cases, but such charges are not inconsequential on that account. They destroy the respect for one another's integrity, for being fellow members of an honorable profession, that previously made the bar a valuable help to the courts in making a sound disposition of their cases, and to sustain the good name of the bar itself.

*Burlington*, 849 F.2d at 1422; *see also ABA Report with Recommendation #107B*, at 2 ("Weak or poorly supported allegations of inequitable conduct . . .

unnecessarily add to the contentiousness of litigation” because “[r]eputations of attorneys and applicants are sullied and, as a consequence, they develop defensive and uncooperative positions.”).

In addition, the ABA has concluded that the current law is a detriment to the PTO because it encourages behavior that can interfere with the effective and efficient examination of patent applications in that uncertainty as to what might later be alleged to have been “important” to an objectively reasonable examiner “motivates patent attorneys and their clients to disclose every piece of prior art that may be remotely relevant to the subject matter being claimed.” *ABA Report with Recommendation #107B*, at 2; *see also* Edwin S. Flores & Sanford E. Warren, Jr., *Inequitable Conduct, Fraud, and Your License to Practice Before the United States Patent & Trademark Office*, 8 *Tex. Intell. Prop. L.J.* 299, 308 (2000) (“While case law indicates that a practitioner may assume that references that are cumulative or less material than those already before the Examiner do not need to be presented, the better practice is to present the art to the Examiner and allow the Examiner to determine its materiality.”). While over-disclosure might be the safest way to satisfy the courts’ objective legal construct, it is counter-productive for actual patent examiners who must sift through a mountain of duplicative, marginally-pertinent documents looking for what is often the proverbial “needle-in-the-haystack,” *i.e.*, information that substantively impacts patentability of the

applicant's claims. Aside from wasting PTO resources, it has been observed that such behavior has a negative impact on the substantive quality of patent examination. See Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 Berkeley Tech. L.J. 723, 770-71 (2009) (concluding that "information overload" resulting from "overcompliance" with a "doctrine that incentivizes the patent applicant to err on the side of quantity" has a negative impact on patent quality).

The over-disclosure problem facing the PTO is compounded because applicants have a disincentive to say anything of substance about the materials they disclose. Concern that even a well-intentioned effort to advance the examination, e.g., by pointing to the more pertinent references in the record, could later be characterized as misleading or purposefully incomplete keeps applicants quiet. As such, current inequitable conduct doctrine pushes patent prosecution practice towards highly inefficient extremes: *over-disclosure* to avoid any alleged omission and *under-representation* to avoid any alleged misrepresentation.

- 3. Replacing the materiality-intent-balancing standard with one more closely predicated on common law fraud principles would remedy the problems caused by over breadth and ambiguity in the current law.**
  - a. The defense of inequitable conduct has been allowed to expand far beyond the doctrine's roots in principles of common law fraud and Supreme Court precedent.**



Inequitable conduct has its roots in common law fraud. *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365-66 (Fed. Cir. 2008); *Digital Control*, 437 F.3d at 1315 (recognizing that the doctrine of inequitable conduct “was 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.”). Essential to common law fraud are the principles of reliance, injury and intent. *See, e.g., Neder v. U.S.*, 527 U.S. 1, 24-25 (1999) (explaining that fraud includes requirements of “justifiable reliance” and “damages”); *Field v. Mans*, 516 U.S. 59, 70-71 (1995) (discussing the “reliance” requirement for common law fraud); *S.E.C. v. Capital Gains Research Bureau, Inc.*, 375 U.S. 180, 192 (1963) (stating that “intent” and “injury” are “essential elements” of common law fraud). In the context of patent prosecution, these principles are met where the applicant misrepresented or omitted material information with the *specific intent* to deceive the PTO; and the PTO *detrimentally relied* on such by issuing one or more claims that otherwise would not have been allowed.

Indeed, both specific intent and detrimental reliance are found in the facts of *all* of the early Supreme Court cases that gave rise to the judicially-created doctrine of inequitable conduct. For example in *Hazel-Atlas*, the patent applicant manufactured evidence by paying “an ostensibly disinterested expert” to sign a

document purporting to be a trade article praising the claimed invention that had, in fact, been prepared by the applicant's lawyer. *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 240-41 (1944), overruled on other grounds by 429 U.S. 17 (1976). The PTO relied on that manufactured evidence, to the public and its own detriment, to issue the patent over what the Court described as previously "insurmountable Patent Office opposition." *Id.* at 240. The other early Supreme Court cases also involved similar acts of intentional deception and detrimental reliance by the PTO to allow claims that otherwise would not have been allowed. *See Precision Instr. Mfg. Co. v. Auto Maint. Mach. Co.*, 324 U.S. 806, 809, 818-20 (1945) (assignee prosecuted "perjured" application knowing that the named inventor had admitted to lying about the invention date and engaged in a deliberate scheme to keep those facts secret until after the PTO issued the patent); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 243 (1933) (applicant intentionally suppressed evidence of an invalidating prior use by paying a witness "valuable considerations" in exchange for an agreement "to keep secret the details of the prior use," which was not disclosed to the PTO). In each of these cases, the patentee's misconduct had an "immediate and necessary relation to the equity" that was awarded, namely the judgment that the patents-at-issue were unenforceable. *Keystone*, 290 U.S. at 245. *See also* Rader, *supra*, at 779-81 (explaining that "[t]he trilogy of U.S. Supreme Court cases that spawned the doctrine of inequitable

conduct all involved clear-cut scenarios where a witness was paid to suppress or falsify information [*i.e.*, specific intent to deceive] without which the applicant would not have had a chance to obtain a patent [*i.e.*, detrimental reliance].”).

In contrast, other early Supreme Court precedent distinguishes misrepresentations to the PTO where there was no showing that absent those misrepresentations the patent claims would not have issued. *See Corona Cord Tire Company v. Dovan Chemical Corporation*, 276 U.S. 358, 373-74 (1928). In *Corona Cord*, the applicant submitted affidavits to the PTO to antedate certain prior art by establishing a reduction to practice in the “early part of the year 1919.” *Id.* at 373. While it was undisputed that those affidavits overstated the extent of the applicant’s reduction to practice, the evidence showed that a reduction to practice had, indeed, occurred in the early part of 1919. *Id.* at 373-74. As such, the Court reasoned that “the affidavits, though perhaps reckless, were not . . . essentially material to [the patent’s] issue.” *Id.* at 374. Because there was no showing that the claims would not have been granted absent the misrepresentation, the Supreme Court refused to disrupt the presumptive validity of that patent.<sup>4</sup> *Id.*

---

<sup>4</sup> The Supreme Court in *Corona Cord* held that the applicants’ misstatements did not destroy the presumption of validity stemming from the PTO’s grant of the patent. *See id.* at 373-74. While that decision pre-dates the Supreme Court’s unenforceability decisions and the creation of the doctrine of inequitable conduct, it is nonetheless pertinent to the distinction between misrepresentations and omissions that result in injury through the issuance of otherwise invalid claims and those that do not.

The clear distinction found in the common law and early Supreme Court precedent between intentional deception resulting in the issuance of otherwise invalid claims and lesser misconduct where there is no such detrimental reliance is missing from modern inequitable conduct jurisprudence. Indeed, this Court has observed that the concept of inequitable conduct doctrine has expanded over time such that it no longer includes the principles of fraudulent intent and detrimental reliance as absolute requirements. *See Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1375 n 3 (Fed. Cir. 2006) (distinguishing inequitable conduct from common law fraud because, *inter alia*, “reliance and injury are not elements of today’s inequitable conduct defense”); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070-71 (Fed. Cir. 1998) (distinguishing inequitable conduct from fraud which “requires higher threshold showings of both intent and materiality” and “must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance”).

**b. The ABA supports adoption of a standard more closely predicated on common law fraud principles to remedy the problems caused by the current law.**

The consequence of diverging from these common law fraud principles, in the ABA’s opinion, is an overbroad and vaguely-defined inequitable conduct defense. To address the resulting problems, the ABA supports reforming the inequitable conduct doctrine by returning it to the common law fraud principles of

specific intent and detrimental reliance embodied in the early Supreme Court precedent. *ABA Report with Recommendation #107B*, at 3.

The ABA submits that a better standard for determining inequitable conduct is one that requires proof of each of the following by clear and convincing evidence: (1) a person having a duty of candor and good faith to the PTO misrepresented or omitted material information from the PTO; (2) in the absence of such misrepresentation or omission, the PTO, acting reasonably, would not have granted or maintained in force at least one patent claim; and (3) the misrepresentation or omission was made with a specific intent to deceive the PTO, which intent cannot be established by the mere materiality of the misrepresentation or omission.

The first two elements of the ABA's reformed standard reflect the detrimental reliance principles present in common law fraud. By limiting the defense to where it is objectively shown that one or more claims would not have been granted in the absence of the applicant's misrepresentation or omission,<sup>5</sup> the reformed standard insures that inequitable conduct will only be found where the PTO's reliance on such has resulted in actual harm though the issuance of an otherwise invalid claim. This would eliminate assertions of inequitable conduct

---

<sup>5</sup> This part of the ABA's reformed standard is similar to the objective "but for" test for materiality that this Court has already endorsed as one of several different tests for determining materiality. *See Digital Control*, 437 F.3d at 1315.

“where the patentee only committed minor missteps,” *see Star Scientific*, 537 F.3d at 1366, that were not “essentially material to [the patent’s] issue.” *See Corona Cord*, 276 U.S. at 373-74.

It would also reduce the burden on the PTO by removing the incentive to over-disclose information to the examiner. Applicants could conform their disclosures to the applicable PTO regulations without fear of inequitable conduct allegations after-the-fact under the broader “important” to a reasonable examiner standard that is currently applied in litigation. This in turn would give the PTO increased flexibility to tailor the level of disclosure that it requires from those who practice before it. Indeed, under the ABA’s reformed standard it is possible that an applicant’s conduct could violate the PTO’s rules, yet not rise to the level of inequitable conduct that would render the entire patent (and possibly related ones as well) unenforceable. In that event, the PTO would be free to enforce its regulations through disciplinary proceedings and levy a variety of less severe sanctions against patent practitioners.<sup>6</sup> This is analogous to a violation of a local rule in civil litigation, which only rarely results in a “death penalty” sanction, *i.e.*, the loss of the underlying action, and more often leads to the award of lesser sanctions against a party or their counsel. Such flexibility is missing under the

---

<sup>6</sup> The PTO may issue sanctions ranging from a reprimand to case-specific or general suspensions or exclusions from further practice before the PTO. *See* 37 C.F.R. § 10.130; *see also* 35 U.S.C. § 32 (granting the PTO Director authority to issue such sanctions).

current law, where, regardless of whether the applicant's misconduct resulted in the allowance of invalid claims or not, the severe penalty of unenforceability is always the same.

The third element of the ABA's reformed standard is an independent deceptive intent requirement consistent with that required for common law fraud. The specific intent required under this standard requires a greater evidentiary showing than proof of intent under the current materiality-intent-balancing test. *See Nobelpharma*, 141 F.3d at 1070-71 (explaining that fraud requires a higher threshold showing of intent that "may not be based upon an equitable balancing" of intent and materiality, but rather "must be based on independent and clear evidence of deceptive intent"). Such intent may be proven by both direct and circumstantial evidence, but it could not be inferred merely from the materiality of the applicant's misrepresentation or omission. *ABA Report with Recommendation #107D*, at 1. This avoids the overemphasis on materiality – in lieu of culpability rising to actual intent – that is inherent to the materiality-intent-balancing framework and has been further exacerbated by ambiguity in some of this Court's precedent, *see, e.g., Larson Mfg. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1344 (Fed. Cir. 2009) (Linn, J., concurring) (explaining that some of this Court's current precedent allows deceptive "intent" to be inferred from evidence of materiality and negligence); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. 2008) (Lourie,

J., dissenting). Moreover, the reformed standard is a stronger gatekeeper against unsupported allegations of inequitable conduct because it explicitly precludes such where there is no Rule 11 basis for pleading intent other than the alleged materiality of the underlying misrepresentation or omission.<sup>7</sup>

Finally, the ABA's reformed standard proposed is a fair and balanced approach to addressing the many criticisms of current inequitable conduct doctrine. It preserves the defense as a deterrent and remedy for those relatively rare instances where it is proven that the applicant acted with fraudulent intent and the PTO detrimentally relied on such to issue otherwise invalid claims. But it erects the defined boundaries missing from the current law, which has resulted in excessive invocation of the inequitable conduct defense, with deleterious impact not only on litigation, but on the overall patent system. *See ABA Report with Recommendation #107B*, at 1.

## II. CONCLUSION

For the reasons set forth above, the ABA respectfully asks that the Court replace the current materiality-intent-balancing standard with one that reflects the common law fraud principles of detrimental reliance and specific intent. To this end, the ABA submits that a better standard for determining inequitable conduct is

---

<sup>7</sup> This is particularly so given the heightened specificity required to adequately plead inequitable conduct. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-31 (Fed. Cir. 2009).



one where the following elements have been shown, each by clear and convincing evidence: (1) a person having a duty of candor and good faith to the PTO misrepresented or omitted material information from the PTO; (2) in the absence of such misrepresentation or omission, the PTO, acting reasonably, would not have granted or maintained in force at least one patent claim; and (3) the misrepresentation or omission was made with a specific intent to deceive the PTO, which intent cannot be established by the mere materiality of the misrepresentation or omission.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'C. Valek', written over a horizontal line.

Carolyn B. Lamm, President  
American Bar Association  
321 North Clark Street  
Chicago, Illinois 60654  
(312) 988-5000  
Michael A. Valek  
William L. LaFuze

## CERTIFICATE OF SERVICE

I certify that two (2) copies of the foregoing BRIEF AND APPENDIX OF THE AMERICAN BAR ASSOCIATION AS AMICUS CURIAE were served on the 17th day of June, 2010 by Overnight Courier to those addressed below:

ROHIT KUMAR SINGLA  
JASON RANTANEN  
Munger, Tolles & Olson, LLP  
560 Mission Street, 27th Floor  
San Francisco, CA 94105

ANDREW W. SONG  
FRED A. ROWLEY, JR.  
DONALD W. WARD  
Munger, Tolles & Olson, LLP  
355 South Grand Avenue, 35th Floor  
Los Angeles, CA 90071-5160

RACHEL KREVANS  
Morrison & Foerster LLP  
425 Market Street  
San Francisco, CA 94105-2482

MORTON AMSTER  
KENNETH P. GEORGE  
JOSEPH M. CASINO  
Amster Rothstein & Ebenstein LLP  
90 Park Avenue  
New York, NY 10016

BRIAN M. KRAMER  
GREGORY WALTER REILLY  
Morrison & Foerster, LLP  
12531 High Bluff Drive, Suite 100  
San Diego, CA 92130

PARISA JORJANI  
WESLEY E. OVERSON  
JASON R. BARTLETT  
Morrison & Foerster LLP  
425 Market Street  
San Francisco, CA 94105-2482

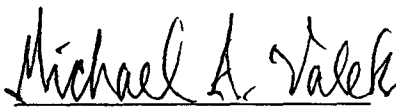
BRADFORD J. BADKE  
SONA DE  
GABRIELLE M. CIUFFREDA  
Ropes & Gray LLP  
1211 Avenue of the Americas  
New York, NY 10036

CAMERON KEITH WEIFFENBACH  
Miles & Stockbridge, P.C.  
1751 Pinnacle Drive, Suite 500  
McLean, VA 22102-3833

CHRISTIAN E. MAMMEN  
c/o UC-Hastings College of the Law  
200 McAllister Street  
San Francisco, CA 94102

LELAND W. HUTCHINSON, JR.  
JONATHAN HILL  
MATTHEW J. KRAMER  
Freeborn & Peters, LLP  
311 South Wacker Drive, Suite 3000  
Chicago, IL 60606-6677

RICHARD SAMP  
DANIEL J. POPEO  
Washington Legal Foundation  
2009 Massachusetts Avenue, N.W.  
Washington, DC 20036

  
Michael A. Valek  
*w/permission  
Lathyn Parvish*

CERTIFICATE OF COMPLIANCE

I certify that the forgoing BRIEF OF THE AMERICAN BAR ASSOCIATION AS AMICUS CURIAE contains 3658 words as measured by the word processing software used to prepare the brief.

Respectfully submitted,

AMERICAN BAR ASSOCIATION

A handwritten signature in black ink, appearing to read "M. A. Valek", written over a horizontal line.

Michael A. Valek

---

**COMBINED APPENDIX**

---

## **TABLE OF CONTENTS**

*ABA Report with Recommendation #107B* (Policy adopted Aug. 2009) .....A-001

*ABA Report with Recommendation #107D* (Policy adopted Aug. 2009).....A-005

AMERICAN BAR ASSOCIATION  
SECTION OF INTELLECTUAL PROPERTY LAW

REPORT TO THE HOUSE OF DELEGATES

RECOMMENDATION

1 RESOLVED, That the American Bar Association urges that any judicially-administered defense  
2 of unenforceability of a patent based on inequitable conduct in the United States Patent and  
3 Trademark Office ("PTO") be predicated on principles of common law fraud, and that any  
4 judgment of such unenforceability be entered only upon proof by clear and convincing evidence  
5 that:

6 (1) a person having a duty of candor and good faith to the PTO in connection with the  
7 patent or an application therefor knowingly and willfully misrepresented a material fact or  
8 material information to the PTO or omitted a known material fact or known material  
9 information from the PTO;

10 (2) in the absence of such misrepresentation or omission, the PTO, acting reasonably,  
11 would not have granted or maintained in force at least one invalid patent claim; and

12 (3) the misrepresentation or omission occurred with a specific intent to deceive the PTO,  
13 and that such intent cannot be established by the mere materiality of the misrepresentation or  
14 omission.

## REPORT

This Recommendation and Report are the second in a series of four, urging Association policy regarding patent infringement cases in which the alleged infringer asserts the affirmative defense that the patent is unenforceable by reason of inequitable conduct in obtaining the patent.

A balanced and fair mechanism for detecting and sanctioning inequitable conduct in the United States Patent and Trademark Office (“PTO”) is of paramount importance to the public, the PTO and the users of the patent system. Patents serve as incentives for innovation and investment in research and development; therefore, it is important that the rules and procedures for deterring inequitable conduct do not unduly burden the system and its users in a way that would diminish those incentives. On the other hand, because patents can and do have significant effects on competition and, therefore, on the public, it is important that their examination, issuance, and maintenance be free of injurious deceit and fraud. Striking the appropriate balance is the goal of various proposals to reform the current law.

Under current law, the standard for what might constitute inequitable conduct is vague and indefinite in its application. The U.S. Court of Appeals for the Federal Circuit, which has exclusive appellate jurisdiction over all patent cases, has stated that, historically, at least five different standards have been applied to the determination of what is material and thus must be disclosed to the PTO. *Digital Control, Inc., v. The Charles Machine Works*, 437 F.3d 1309 (Fed. Cir. 2006). The original goal of the duty to disclose was to assist the PTO in performing its increasingly difficult task. Unfortunately, the opposite has happened because of the uncertain standard for materiality. 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.

The Recommendation supports limiting –by legislation, judicial decision (e.g. by a court, by the ITC, etc.), or PTO rulemaking and subsequent judicial affirmation – the application of the inequitable conduct defense to cases in which a fraud resulted in the PTO’s issuing one or more invalid claims. That clearer standard will enable applicants to focus their disclosure of prior art on that which is most relevant, and to explain that prior art to the PTO in order to make the disclosure more helpful. The National Research Council of the National Academies has recommended that the “inequitable conduct” defense be modified to eliminate this “subjective element” of materiality from most patent litigation.

Patent attorneys and patent bar associations have overwhelmingly, if not unanimously, long taken the position that “inequitable conduct” allegations should be limited to the situations in which the public has actually been harmed as a result of the patentee’s misconduct (e.g., by issuance of at least one invalid patent claim that never should have been issued). The Recommendation proposes to implement this principle – via legislation, judicial decision, or PTO rulemaking and subsequent judicial affirmation – by applying common law fraud principles to the determination of whether misconduct is sufficient to result in a holding that a patent is unenforceable. While lesser forms of misconduct might result in disciplinary or other actions in the PTO, they should not result in unenforceability of a wholly valid patent.



### Reform of the Law of Inequitable Conduct Is Needed

The defense of inequitable conduct is raised in far too many cases. The Federal Circuit has referred to it as a “plague” on the system. *Burlington Industries, Inc. 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. 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.”)

Allegations of inequitable conduct often are based on speculation or harmless mistake and, in most cases, are unsuccessful. Nevertheless, the defense adds substantially to the complexity and cost of litigation. It leads to relentless discovery in hopes of finding supportive evidence. Because the target of the discovery is usually the applicants’ patent attorney and inventors and others who assisted the attorney in preparing and prosecuting the patent application, the defense frequently involves disputes about the scope and applicability of the attorney-client privilege and allegations of a crime-fraud exception to the privilege.

Accused infringers’ aggressive discovery demands lead in turn to resistance to those demands by the patentee, with the attendant discovery disputes and motion practice. All of this results in increasing the complexity, duration and cost of patent infringement litigation that is already notorious for its complexity and high cost.

Weak or poorly supported allegations of inequitable conduct also unnecessarily add to the contentiousness of litigation. Reputations of attorneys and applicants are sullied and, as a consequence, they develop defensive and uncooperative positions. *See Burlington Indus. v. Dayco*, 849 F.2d at 1422 (“[Lawyers asserting inequitable conduct] get anywhere with the accusation in but a small percentage of the cases, but such charges are not inconsequential on that account. They destroy the respect for one another's integrity, for being fellow members of an honorable profession, that used to make the bar a valuable help to the courts in making a sound disposition of their cases, and to sustain the good name of the bar itself.”)

The current law of inequitable conduct also interferes with the effective and efficient examination of patent applications by the PTO. Apprehension about being accused of inequitable conduct motivates patent attorneys and their clients to disclose every piece of prior art that may be remotely relevant to the subject matter being claimed. Thus, patent examiners must devote a large percentage of the time allowed for examination of an application to dealing with mountains of prior art references, many of which may have little to do with the patentability of the claimed subject matter. Moreover, applicants and their counsel are reluctant to assist examiners by pointing out the relevant teachings of the prior art and explaining how their claims distinguish over that prior art. This reluctance stems from the fact that any such assistance may later be criticized as incomplete or misleading (and intentionally deceitful) when an action is brought to enforce the patent. The fear of being later accused of inequitable conduct is a strong disincentive to applicants’ and their attorneys’ providing the assistance that the PTO needs to improve the examination process.

A balanced and fair approach to the detection and sanctioning of inequitable conduct also is important for the certainty required in business transactions involving patents. Investments and business transactions involving patents are based on the perceived value of the assets. The value of a patent is related not only to the innovation that it protects, but also to the prospects that its validity and enforceability can be successfully defended in litigation. An adequate deterrent to inequitable conduct that functions without the unnecessary litigation burdens that currently exist will contribute to the certainty and value that facilitate such transactions.

This Recommendation supports legislation to codify – or judicial decision to modify – the inequitable conduct defense in accordance with common law fraud principles. Such fraud requires a knowing and willful misrepresentation or omission of material information and further requires that the recipient of the information relied on the misrepresentation or omission to its detriment. The Recommendation embodies these concepts in paragraphs (1) and (2). Paragraph (2) expresses the detrimental reliance requirement in objective terms, requiring that the PTO’s reliance be judged by a reasonableness standard.

Paragraph (3) would require that a finding of an intent to deceive be based on evidence beyond the mere materiality of the information that has been misrepresented or concealed. This concept was recently emphasized by the Court of Appeals for the Federal Circuit in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366-67 (Fed. Cir. 2008) (“With regard to the deceptive intent prong, we have emphasized that ‘materiality does not presume intent, which is a separate and essential component of inequitable conduct.’” [citation omitted]). This requirement warrants emphasis, because there has been some ambiguity in court decisions concerning the extent to which intent may be inferred from other evidence. *See, Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. 2008) (Lourie, J., dissenting).

Although the Section of Intellectual Property Law already has blanket authority to urge – on behalf of the Section – this position to Congress, this Recommendation, if adopted, would establish policy of the full ABA (not merely the Section) to be urged in Congress and also would provide ABA policy potentially to support an *amicus curiae* brief in an appropriate case.

Respectfully submitted,

Gordon T. Arnold, Chair  
Section of Intellectual Property Law  
August 2009

**AMERICAN BAR ASSOCIATION  
SECTION OF INTELLECTUAL PROPERTY LAW**

**REPORT TO THE HOUSE OF DELEGATES**

**RECOMMENDATION**

1 RESOLVED, That the American Bar Association urges that the defense of unenforceability of a  
2 patent based upon inequitable conduct arising from proceedings in the United States Patent and  
3 Trademark Office ("PTO") can be established only by proof by clear and convincing evidence of  
4 a specific intent to deceive the PTO by knowingly and willfully misrepresenting a material fact  
5 or material information to the PTO or by failing to provide a known material fact or known  
6 material information to the PTO, and that such intent cannot be established by only the  
7 materiality of the fact or information that was misrepresented or not provided.

## REPORT

This Recommendation and Report are the fourth in a series of four, urging Association policy regarding patent infringement cases in which the alleged infringer asserts the affirmative defense that the patent is unenforceable by reason of inequitable conduct in obtaining the patent.

This Recommendation separately addresses the issue of deceptive intent discussed in connection with the second of the four Recommendations. Specifically, this Recommendation reaffirms the position that deceptive intent requires proof by clear and convincing evidence of a knowing and willful misrepresentation or concealment of material information and that such intent cannot be established by the mere materiality of the information that was misrepresented or concealed.

The law has long recognized that intent can rarely be proven by direct evidence and that circumstantial evidence is admissible to prove this element of inequitable conduct. This Recommendation would not disturb that precedent. Rather, this recommendation addresses a narrower issue, namely, whether inequitable conduct can be found based on the *mere* fact that misrepresented or omitted information is material – in the absence of any other evidence of deceptive intent. This Recommendation is consistent with Federal Circuit precedent, as recently articulated in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366-67 (Fed. Cir. 2008); but this Recommendation is warranted because there has been some ambiguity in the Federal Circuit cases before and after *Star Scientific*. See, e.g., *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. 2008) (Lourie, J., dissenting).

Although the Section of Intellectual Property Law already has blanket authority to urge – on behalf of the Section – this position to Congress, the Recommendation, if adopted, would establish policy of the full ABA (not merely the Section) to be urged in Congress and also would provide ABA policy potentially to support an *amicus curiae* brief in an appropriate case.

Respectfully submitted,

Gordon T. Arnold, Chair  
Section of Intellectual Property Law  
August 2009