

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 & CO., 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
in 04-CV-2123, 04-CV-3327, 04-CV-3732, and 05-CV-3117, Judge William H. Alsup

**BRIEF OF *AMICUS CURIAE* THE AMERICAN INTELLECTUAL
PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY**

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CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* American Intellectual Property Law Association certifies the following:

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

American Intellectual Property Law Association
2. The name of the real party in interest represented by us is:

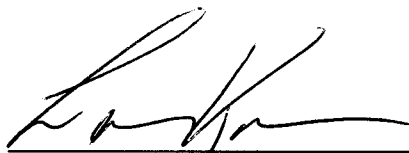
Not applicable.
3. All parent corporation and any publicly held corporations that own 10 percent or more of stock of the party or amicus curiae represented by us are:

None.
4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by us in the trial court or agency or are expected to appear in this Court are:

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TABLE OF CONTENTS

	<u>PAGE</u>
STATEMENT OF INTEREST	1
RESPONSE TO <i>EN BANC</i> QUESTIONS.....	2
INTRODUCTION.....	4
ARGUMENT	8
I. The Basis of the Inequitable Conduct Defense Should Be Fraud on the PTO, Provable Only with Evidence of Specific Intent to Deceive	8
II. Materiality Should Be Found Only Where at Least One Claim Would Not Have Issued “But For” the Alleged Misconduct.....	14
III. The Severe Penalty of Unenforceability Justifies the Proposed Limits on Inequitable Conduct	17
CONCLUSION	19

TABLE OF AUTHORITIES

	<u>Page(s)</u>
Cases	
<i>Akron Polymer Container Corp. v. Exxel Container</i> , 148 F.3d 1380 (Fed. Cir. 1998)	13
<i>Arete Partners, L.P. v. Gunnerman</i> , 594 F.3d 390 (5th Cir. 2010)	10
<i>Aventis Pharma S.A. v. Amphastar Pharms., Inc.</i> , 525 F.3d 1334 (Fed. Cir. 2008)	5
<i>Burlington Indus. v. Dayco Corp.</i> , 849 F.2d 1418 (Fed. Cir. 1988)	4
<i>Consol. Aluminum Corp. v. Foseco Int’l Ltd.</i> , 910 F.2d 804 (Fed. Cir. 1990)	9
<i>Corning Glass Works v. Anchor Hocking Glass Corp.</i> , 253 F. Supp. 461 (D. Del. 1966)	16
<i>Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.</i> , 120 F.3d 1253 (Fed. Cir. 1997)	12
<i>Digital Control, Inc. v. Charles Mach. Works</i> , 437 F.3d 1309 (Fed. Cir. 2006)	14
<i>Driscoll v. Cebalo</i> , 781 F.2d 878 (Fed. Cir. 1984)	12
<i>Eckes v. Card Prices Update</i> , 736 F.2d 859 (2d Cir. 1984)	11
<i>Ferring B.V. v. Barr Labs., Inc.</i> , 437 F.3d 1181 (Fed. Cir. 2006)	12
<i>FMC Corp. v. Manitowoc Co., Inc.</i> , 835 F.2d 1411 (Fed. Cir. 1987)	12
<i>Hazel-Atlas Glass Co. v. Hartford-Empire Co.</i> , 322 U.S. 238 (1944).....	9, 15
<i>Hebert v. Lisle Corp.</i> , 99 F.3d 1109 (Fed. Cir. 1996)	13

<i>Herman & MacLean v. Huddleston</i> , 459 U.S. 375 (1983).....	10
<i>In re Bose Corp.</i> , 580 F.3d 1240 (Fed. Cir. 2009)	11
<i>In re Frost Patent</i> , 398 F. Supp. 1353 (D. Del. 1975)	16
<i>In re Garfinkle</i> , 672 F.2d 1340 (11th Cir. 1982)	9
<i>In re Kingsley</i> , 518 F.3d 874 (11th Cir. 2008)	9
<i>Innogenetics, N.V. v. Abbott Labs.</i> , 512 F.3d 1363 (Fed. Cir. 2008)	17
<i>Japan Telecom, Inc. v. Japan Telecom Am. Inc.</i> , 287 F.3d 866 (9th Cir. 2002)	9
<i>Keystone Driller Co. v. Gen. Excavator Co.</i> , 290 U.S. 240 (1933).....	9, 15
<i>Kingsdown Med. Consultants, Ltd. v. Hollister Inc.</i> , 863 F.2d 867 (Fed. Cir. 1988)	4, 11, 12
<i>Larson Mfg. Co., Inc. v. Aluminart Prods. Ltd.</i> , 559 F.3d 1317 (Fed. Cir. 2009)	5
<i>Lennon v. Seaman</i> , 84 F. Supp. 2d 522 (S.D.N.Y. 2000)	11
<i>Life Techs., Inc. v. Clontech Labs., Inc.</i> , 224 F.3d 1320 (Fed. Cir. 2000)	17
<i>M. Eagles Tool Warehouse v. Fisher Tooling Co.</i> , 439 F.3d 1335 (Fed. Cir. 2006)	13
<i>Manta v. Chertoff</i> , 518 F.3d 1134 (9th Cir. 2008)	10
<i>Merck & Co., Inc. v. Kessler</i> , 80 F.3d 1543 (Fed. Cir. 1996)	17
<i>Monsanto Co. v. Rohm & Haas Co.</i> , 456 F.2d 592 (3d Cir. 1972)	16
<i>Perfumebay.com Inc. v. EBay, Inc.</i> , 506 F.3d 1165 (9th Cir. 2007)	9

Pierre v. Attorney Gen.,
528 F.3d 180 (3d Cir. 2008) 10

Praxair, Inc. v. ATMI, Inc.,
543 F.3d 1306 (Fed. Cir. 2008) 7

Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.,
324 U.S. 806 (1945)..... 8, 9, 15

Russ Berrie & Co., Inc. v. Jerry Elsner Co., Inc.,
482 F. Supp. 980 (S.D.N.Y. 1980) 11

Scanner Techs. Corp. v. ICOS Vision Sys.,
528 F.3d 1365 (Fed. Cir. 2008) 13

Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.,
537 F.3d 1357 (Fed. Cir. 2008) 13, 18

Swift Chem. Co. v. Usamex Fertilizers, Inc.,
197 U.S.P.Q. 10 (E.D. La. Oct. 7, 1977)..... 16

Tafas v. Doll,
559 F.3d 1345 (Fed. Cir. 2009) 17

Tafas v. Kappos,
586 F.3d 1369 (Fed. Cir. 2009) 17

Taltech Ltd. v. Esquel Enters. Ltd.,
604 F.3d 1324 (Fed. Cir. 2010) 5

Trio Process Corp. v. L. Goldstein's Sons, Inc.,
461 F.2d 66 (3d Cir. 1972) 16

United States v. Bailey,
444 U.S. 394 (1980)..... 10

United States v. Boring,
557 F.3d 707 (6th Cir. 2009) 10

United States v. Nguyen,
493 F.3d 613 (5th Cir. 2007) 10

United States v. Philip Morris USA Inc.,
566 F.3d 1095 (D.C. Cir. 2009)..... 9, 10

Other Authorities

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24 BERKELEY TECH. L.J. 723 (2009) 15

David Hricik & Seth Trimble, *Congratulations on Your Hallucinations: Why the
PTO’s 1992 Amendment to § 1.56 Is Irrelevant to Inequitable Conduct*, 38
AIPLA Q.J. 1, 13 (2010)..... 17

Melissa Feeney Wasserman, *Limiting the Inequitable Conduct Defense*,
13 VA. J.L. & TECH. 7 (2008) 11, 12

NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, A PATENT SYSTEM
FOR THE 21ST CENTURY (Stephen A. Merrill et al. eds., 2004)..... 6

Patently-O Patent Law Blog, *Citing References to the USPTO*,
<http://www.patentlyo.com/patent/2010/07/my-entry.html> (Jul. 13, 2010) 14

STATEMENT OF INTEREST

This brief is submitted by the American Intellectual Property Law Association (“AIPLA”).

AIPLA is a national bar association of more than 15,000 members drawn from private and corporate practice, government service, and the academic community. AIPLA represents a diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law as well as other fields of law affecting intellectual property. AIPLA members represent both owners and users of intellectual property. AIPLA’s interest in this case concerns the importance of the legal requirements for inequitable conduct that affect all stages of patent law from procurement through enforcement.

All parties have consented to the filing of this brief pursuant to Federal Rule of Appellate Procedure 29(a) and Federal Circuit Rule 29(c). AIPLA also submits this brief pursuant to the authorization provided in the Court’s April 26, 2010 Order.

RESPONSE TO EN BANC QUESTIONS

AIPLA, *amicus curiae*, responds to the Court's *en banc* questions as follows and as further explained in this brief:

Questions (1), (2), and (5): Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced? If so, how? In particular, should the standard be tied directly to fraud or unclean hands? See *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *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); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933). If so, what is the appropriate standard for fraud or unclean hands? Should the balancing inquiry (balancing materiality and intent) be abandoned?

Answer: Yes. The balancing framework should be replaced to follow the standard for finding fraud on the United States Patent and Trademark Office (PTO) based upon a the totality of the circumstances, as that standard has been established under Supreme Court precedent. Among other things, this standard requires evidence that the applicant made false, material representations of fact, or withheld material information, with knowledge of the falsity and the materiality. Although actual knowledge of materiality may be considered as part of the totality of the circumstances in deciding whether there was any intent to deceive, materiality alone should not.

Question (3): What is the proper standard for materiality? What role should the United States Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?

Answer: The proper materiality standard should require a finding that the PTO issued an invalid claim, which would not have issued "but for" the withholding or submission of the information. This "but for" standard for materiality would provide greater certainty to stakeholders and prevent findings of inequitable

conduct based on information that would not invalidate at least one claim. Courts should not be guided by the current rules of the PTO in defining materiality, as those rules should not apply in litigation for purposes of finding a patent unenforceable.

Question (4): Under what circumstances is it proper to infer intent from materiality? *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (en banc).

Answer: Materiality and intent are separate requirements, and intent should not be inferred from materiality alone. The *Kingsdown* Court correctly decided that a finding of gross negligence is insufficient to support an inference of intent to deceive. Consistent with *Kingsdown*, an inference of intent may not be based on a finding that the applicant “should have known” of that materiality. However, while an intent to deceive may not be inferred from materiality alone, proof that the applicant also had *knowledge of the materiality* may be considered in deciding as part of the totality of the circumstances whether there was any intent to deceive.

Question (6): Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.

Answer: The principles of materiality and intent used in common law fraud should be incorporated into the patent law of inequitable conduct. In other words, inequitable conduct should require fraud on the Patent and Trademark Office. The standards for materiality and intent to deceive used at common law and for other federal agencies, particularly with respect to copyrights and trademarks, are consistent with the standards advocated here in the patent law context, and there is no justification for a separate patent standard.

INTRODUCTION

The duty of candor and good faith protects the public by encouraging patent applicants to disclose information necessary for judging the patentability of claimed inventions. Policing against a breach of this duty serves to deter deceptive behavior before the United States Patent and Trademark Office (“PTO”). AIPLA believes this to be of utmost importance.

But attempts to control applicant misconduct in the PTO have reached a point of diminishing returns. A finding of inequitable conduct results in the ultimate penalty to a patent holder—a determination that an entire patent is unenforceable against all the world. The potency of this defense has led to commonplace and often baseless inequitable conduct allegations, which led this Court to observe that inequitable conduct as a litigation strategy had become a “plague.” *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). Soon thereafter, the Federal Circuit sought to limit the defense by ruling that “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive.” *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc).

Recent precedent has effectively loosened the *Kingsdown* limitations, making the defense once again commonplace in patent infringement actions, drawing renewed criticism from judges, practitioners and scholars. Indeed, Judge

Linn has recently lamented that “this [recent] precedent has significantly diverged from the Supreme Court's treatment of inequitable conduct and perpetuates what was once referred to as a ‘plague’ that our en banc court sought to cure in *Kingsdown*.” *Larson Mfg. Co., Inc. v. Aluminart Prods. Ltd*, 559 F.3d 1317, 1342 (Fed. Cir. 2009) (Linn, J., dissenting). Similarly, Judge Gajarsa has recently referred to “the ongoing pandemic of baseless inequitable conduct charges that pervade our patent system.” *Taltech Ltd. v. Esquel Enters. Ltd.*, 604 F.3d 1324, 1335 (Fed. Cir. 2010) (Gajarsa, J., dissenting). Chief Judge Rader observed that recent decisions have drifted away from the concept that the “atomic bomb” of unenforceability for inequitable conduct is reserved for cases of fraud and deception which require “culpable conduct.” *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting).

The confusion caused by a divergence in the case law has left parties increasingly unable to assess the merits of inequitable conduct allegations. This uncertainty interferes with the ability of stakeholders to make informed business decisions regarding pending disputes and leads parties to endure protracted, expensive litigation. It also encourages charges of inequitable conduct to induce settlements that may bear little relation to the merits of the suit.

In addition, the recent case law has frustrated the purposes of ensuring that the PTO has appropriate, accurate information, to thereby promote the quality of

patent examination. Many patent prosecutors now disclose all known prior art and communications with U.S. and foreign patent offices in related applications regardless of relevance. And where a related patent is involved in litigation, a patent applicant often submits boxes of papers from the litigation. This torrent of paper arrives at the PTO without comment for fear that the comments themselves could be a catalyst for inequitable conduct assertions, leaving the already overburdened examiner unable to locate the most pertinent prior art or information. Excessive disclosures, lack of transparency, unpredictable outcomes, and confused decision making all suggest that the inequitable conduct doctrine needs revision.

The present system of addressing inequitable conduct has produced adverse effects on other aspects of the patent system with easy allegations of inequitable conduct, inferred evidence of deceptive intent from materiality alone, and penalties that are far out of proportion to the offense charged.¹ Therefore, AIPLA believes the Court should modify the existing inequitable conduct framework by applying a focused unclean hands doctrine to deny relief to patent owners found to have committed fraud on the PTO.

¹ See NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, A PATENT SYSTEM FOR THE 21ST CENTURY 123 (Stephen A. Merrill et al. eds., 2004) <http://www.nap.edu/catalog/10976.html> (“In view of its cost and limited deterrent value the committee recommends the elimination of the inequitable conduct doctrine or changes in its implementation.”).

Specifically, the Court should adhere more closely to Supreme Court precedent that only penalizes conduct more readily recognized as common law fraud based on a false representation or omission of a material fact, committed with an intent to deceive, and relied upon by the PTO in issuing the patent claim. AIPLA acknowledges that direct evidence of intent to deceive may not always be available and inferences from circumstantial evidence may be necessary. Intent to deceive may not be inferred from the mere fact of materiality but must be proved with evidence based upon a totality of the circumstances, and one factor to consider may be that such materiality was known to the applicant.

Recent case law has softened the evidentiary standard for intent, leading to sanctions for conduct far less egregious than fraud. For example, this Court has seemingly upheld inferences of intent based on findings of high materiality alone.² Equating high materiality with deceptive intent does not meet standards of common law fraud.

Similarly, the Court should adopt a materiality standard that requires a finding that the PTO issued an invalid claim that would not have issued “but for” the withholding or submission of the information. Without such a showing, there

² *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1318 (Fed. Cir. 2008) (“Based on its predicate findings that the RFO [restrictive flow orifices] art was highly material, that the applicants knew of the RFO art and at least should have known of its

is no assurance of detrimental reliance by the PTO as is typically required under common law fraud. Thus, materiality should require that but for the alleged misconduct, one or more claims would be invalid, thereby providing workable limits for stakeholders and practitioners while protecting the public from unscrupulous applicants. These reforms should reverse the expansion of inequitable conduct and limit the defense to fraudulent conduct before the PTO.

ARGUMENT

I. The Basis of the Inequitable Conduct Defense Should Be Fraud on the PTO, Provable Only with Evidence of Specific Intent to Deceive

The Supreme Court has applied common law fraud principles to inequitable conduct in the procurement and/or enforcement of patents.³ The Supreme Court supported this approach by invoking the equitable maxim that “he who comes into equity must come with clean hands.” *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945). In describing the doctrine, the Supreme Court has said a “willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim by the chancellor.” *Id.* at 814-15. The *Precision* Court applied this doctrine by refusing to enforce a patent issued from a

materiality, ... the district court properly inferred that the applicants intended to deceive the PTO by failing to disclose the RFO art.”).

patent application that was admittedly based upon false data, and the patent owner, “with at least moral and actual certainty if not absolute proof of the facts concerning the perjury, chose to act in disregard of the public interest.” *Id.* at 816.

Following Supreme Court precedent, other circuit courts generally require a showing of fraudulent activity for an unclean hands defense.⁴ Likewise, this Court has stated that “what we have termed ‘inequitable conduct’ is no more than the unclean hands doctrine applied to particular conduct before the PTO.” *Consol. Aluminum Corp. v. Foseco Int’l Ltd.*, 910 F.2d 804, 812 (Fed. Cir. 1990). This should be the standard.

The mental state required to prove fraud is often referred to as specific intent.⁵ Specific intent does not necessarily require direct evidence of deceptive

³ *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814-15 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250 (1944); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933).

⁴ *See In re Kingsley*, 518 F.3d 874, 878 (11th Cir. 2008) (“[T]he equitable doctrine of unclean hands provides that one who has acted in bad faith, resorted to trickery and deception, or been guilty of fraud, injustice or unfairness will appeal in vain to a court of conscience.”) (quoting *In re Garfinkle*, 672 F.2d 1340, 1346 n.7 (11th Cir. 1982)); *Perfumebay.com Inc. v. EBay, Inc.*, 506 F.3d 1165, 1177 (9th Cir. 2007) (“Bad intent is the essence of the defense of unclean hands.”) (quoting *Japan Telecom, Inc. v. Japan Telecom Am. Inc.*, 287 F.3d 866, 870 (9th Cir. 2002)).

⁵ *See United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1118 (D.C. Cir. 2009) (“[T]o determine whether a corporation made a false or misleading statement with specific intent to defraud, we look to the state of mind of the individual corporate officers and employees...”); *see also Consol. Aluminum*, 910 F.2d at 809 (requiring a “sufficiently culpable state of mind”).

intent because the Supreme Court and circuit courts have widely recognized that it is acceptable to infer specific intent from sufficient circumstantial evidence.⁶ But specific intent requires more evidence of subjective purpose than under the current balancing framework. For instance, an applicant’s knowledge of material information alone cannot establish specific intent, regardless of how material that evidence is. In this regard, the Supreme Court and other circuits have interpreted “specific intent” standards in other contexts to require more than mere “knowledge.”⁷ Thus, a finding of specific intent should require not only knowledge of the information but also knowledge of the materiality itself.

⁶ See, e.g., *Herman & MacLean v. Huddleston*, 459 U.S. 375, 390 n.30 (1983) (“[T]he proof of scienter required in [securities] fraud cases is often a matter of inference from circumstantial evidence....”); *Arete Partners, L.P. v. Gunnerman*, 594 F.3d 390, 394 (5th Cir. 2010) (“[A] party’s intent may be inferred by the party’s subsequent acts following the representation.”); *Philip Morris*, 566 F.3d at 1118 (“A person’s state of mind is rarely susceptible of proof by direct evidence, so specific intent to defraud may be, and most often is, inferred from the totality of the circumstances, including indirect and circumstantial evidence.”); *United States v. Boring*, 557 F.3d 707, 711 (6th Cir. 2009); *Manta v. Chertoff*, 518 F.3d 1134, 1142 (9th Cir. 2008).

⁷ See, e.g., *United States v. Bailey*, 444 U.S. 394, 405 (1980) (“In a general sense, ‘purpose’ corresponds loosely with the common-law concept of specific intent, while ‘knowledge’ corresponds loosely with the concept of general intent.”); *Pierre v. Attorney Gen.*, 528 F.3d 180, 190 (3d Cir. 2008) (*en banc*) (overruling suggestion that “mere knowledge is sufficient for a showing of specific intent”); *United States v. Nguyen*, 493 F.3d 613, 624 (5th Cir. 2007) (“The specific intent element of the offense is a slightly more culpable state of mind compared to the knowledge element.”).

Applying these principles, satisfying the element of intent should require clear and convincing evidence of an intent necessary to prove common law fraud. Requiring proof of fraud accords with the approaches by other courts and realigns the inequitable conduct standard with Supreme Court precedent.⁸ The fraud standard is also consistent with the approach taken with other federal agencies.⁹

Contrary to the impression left by recent panel opinions, a specific intent to deceive should not be inferred from the materiality of information alone. Such inference amounts to the “should have known” standard and reverts to the gross negligence approach previously rejected in *Kingsdown*, 863 F.2d at 876. Without evidence that the applicant at least appreciated the materiality of the withheld

⁸ Melissa Feeney Wasserman, *Limiting the Inequitable Conduct Defense*, 13 VA. J.L. & TECH. 7, 17 (2008) (“[L]imiting inequitable conduct to common law fraud will place the inequitable conduct jurisprudence within Supreme Court precedent.”).

⁹ See *In re Bose Corp.*, 580 F.3d 1240, 1245 (Fed. Cir. 2009) (“[A] trademark is obtained fraudulently under the Lanham Act only if the applicant or registrant knowingly makes a false, material representation with the intent to deceive the PTO.”); *Eckes v. Card Prices Update*, 736 F.2d 859, 861-62 (2d Cir. 1984) (“Only the ‘knowing failure to advise the Copyright Office of facts which might have occasioned a rejection of the application constitute[s] reason for holding the registration invalid and thus incapable of supporting an infringement action.’”) (quoting *Russ Berrie & Co., Inc. v. Jerry Elsner Co., Inc.*, 482 F. Supp. 980, 988 (S.D.N.Y. 1980)) ; *Lennon v. Seaman*, 84 F. Supp. 2d 522, 525 (S.D.N.Y. 2000) (“A party seeking to establish a fraud on the Copyright Office ... bears a heavy burden. The party asserting fraud must establish that the application for copyright registration is factually inaccurate, that the inaccuracies were willful and deliberate, and that the Copyright Office relied on those misrepresentations.”) (citations omitted).

information, there should be no finding of specific intent to deceive the PTO based upon materiality alone.¹⁰ Otherwise, courts may potentially infer intent despite a “showing that applicant did not know of its materiality.” *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987).

Compounding the problem, the oft-cited precedent for the “should have known” approach relies on overruled authority. *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997) (citing *Driscoll v. Cebalo*, 781 F.2d 878, 885 (Fed. Cir. 1984), *overruled by Kingsdown*, 863 F.2d at 876).¹¹ Accordingly, the “should have known” approach should be discarded.

Specific intent also cannot be inferred solely from the absence of a credible explanation for withholding material information. While it could affect the totality of the circumstances, the absence of a credible explanation does not by itself create

¹⁰ Wasserman, *supra* note 8, at 13 (“If the defendant did not have the specific intent to defraud the PTO, because the defendant did not know of the materiality of the undisclosed information, then a finding of inequitable conduct does little to curb dishonest conduct.”).

¹¹ *See also Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1202 (Fed. Cir. 2006) (Newman, J., dissenting) (“Thus, this aspect of *Critikon, Inc.* has been correctly identified by practitioners as ‘bad law,’ both because it relies on the overruled *Driscoll* decision and because it is representative of a recent resurgence of the plague that *Kingsdown* had intended to cure.”).

an inference of culpable intent.¹² In fact, inferring intent in such circumstances erroneously shifts the burden to the patentee to provide a credible explanation for the withholding. Permitting a finding of inequitable conduct in these circumstances contravenes established precedent requiring factual support for an intent to deceive.¹³

Without sufficient evidence indicating specific intent, it may be impossible to discern whether intent to deceive is “the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008).¹⁴ Therefore, the intent standard should require clear and convincing evidence of a specific intent to commit fraud on the PTO.

¹² See *M. Eagles Tool Warehouse v. Fisher Tooling Co.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006) (“When the absence of a good faith explanation is the only evidence of intent, however, that evidence alone does not constitute clear and convincing evidence warranting an inference of intent.”); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1368 (Fed. Cir. 2008) (“The patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence.”).

¹³ *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996) (“Intent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.”).

¹⁴ See *Scanner Techs. Corp. v. ICOS Vision Sys.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (“Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”); *Akron Polymer Container Corp. v. Exxel Container*, 148 F.3d 1380, 1384 (Fed. Cir. 1998) (“The intent element of the offense is thus in the main proven by

II. Materiality Should Be Found Only Where at Least One Claim Would Not Have Issued “But For” the Alleged Misconduct

Inequitable conduct allegations typically require a court to decide whether the allegedly withheld or false submitted information is “material.” Ascertaining materiality is rendered more complicated by the arguable existence of as many as five different standards for materiality.¹⁵ These varying standards along with the ease with which courts have inferred an intent to deceive may help explain the apparent dramatic increase in the rate of pleading inequitable conduct in the district courts over the past several years.¹⁶ In addition, the difficulty in determining materiality forces patent prosecutors to disclose numerous references and communications from other, similar U.S. or foreign applications or from litigations involving related patents out of fear that marginally relevant information may later become a basis for inequitable conduct allegations.¹⁷ At least one commentator

inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred.”).

¹⁵ See *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006).

¹⁶ See Christian E. Mammen, *Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct*, 24 BERKELEY TECH. L.J. 1331, 1358-61 (2010) (noting a ten fold increase in the rate of pleading inequitable conduct between 2000 and 2008).

¹⁷ See Patently-O Patent Law Blog, *Citing References to the USPTO*, <http://www.patentlyo.com/patent/2010/07/my-entry.html> (Jul. 13, 2010) (showing that an average applicant discloses more than twenty references per patent).

believes this excessive disclosure practice may undermine any benefits in patent quality attributable to the duty of disclosure.¹⁸

In addressing materiality, as with intent, it is instructive to focus on the three Supreme Court cases rendering patents unenforceable. In each of those cases, the PTO would not have issued one or more of the claims but for the misconduct. The Supreme Court invoked the unclean hands defense not as a “punishment for extraneous transgressions,” *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933), but because the PTO detrimentally relied on the misconduct in order to issue the patents. For example, in *Keystone Driller* the applicant paid an individual to keep secret an invalidating prior use, which caused the issuance of a patent that was otherwise invalid. 290 U.S. at 243-44; *see Precision Instrument*, 324 U.S. at 814-15; *Hazel-Atlas Glass*, 322 U.S. at 240-41. Thus, the Supreme Court found materiality where the PTO relied on alleged misconduct by issuing an invalid claim. This Supreme Court precedent therefore supports an objective “but for” materiality standard that accounts for the reliance element of fraud. In the case of patent prosecution, the PTO and the public detrimentally rely on the misrepresentations of an applicant.

¹⁸ See Christopher A. Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 770 (2009).

This “but for” standard would also bring certainty to both litigating parties and patent prosecutors and is most consistent with the policy and objectives underlying the inequitable conduct doctrine. Applying the objective “but for” standard would require a court to determine whether the claims of the patent would have issued had the misrepresentation or withholding not occurred.¹⁹ By requiring an antecedent showing of invalidity, this standard focuses on highly relevant withheld or falsely submitted information while discouraging allegations based on tangentially relevant information.

Furthermore, Courts should no longer apply the current rules of the PTO in defining materiality, as those rules do not apply the objective “but for” standard that should apply in litigation for purposes of finding a patent unenforceable;

¹⁹ See, e.g., *Swift Chem. Co. v. Usamex Fertilizers, Inc.*, 197 U.S.P.Q. 10, 29 (E.D. La. Oct. 7, 1977) (“I find that the failure of Swift to cite the Pearce patent, had no material effect on the decision of the Patent Office to grant the '808 patent because, even in light of Pearce, I find that the '808 patent is patentable over the prior art.”); *Corning Glass Works v. Anchor Hocking Glass Corp.*, 253 F. Supp. 461, 469 (D. Del. 1966) (“[The] defendant must show that the misrepresentation was material, [i.e.], that the patent would not have issued but for the fraud.”), *rev'd on other grounds*, 374 F.2d 473 (3d Cir. 1967); *In re Frost Patent*, 398 F. Supp. 1353, 1368 (D. Del. 1975) (“Prior to finding this sort of ‘but for’ fraud, a court must, of course, make an independent patentability determination.”), *modified*, 540 F.2d 601 (3d Cir. 1976); *Monsanto Co. v. Rohm & Haas Co.*, 456 F.2d 592, 600 (3d Cir. 1972) (“[Because of the withheld information] it was impossible for the Patent Office fairly to assess Monsanto's application against the prevailing statutory criteria.”); *Trio Process Corp. v. L. Goldstein's Sons, Inc.*, 461 F.2d 66, 73 (3d Cir. 1972) (distinguishing *Monsanto* because there “the patent might not have issued had full disclosure been made.”)

strictly speaking the rules are not controlling in litigation as the PTO lacks substantive rulemaking authority.²⁰ It should be noted, however, that meeting the PTO regulations on the duty of disclosure should create a “safe harbor,” giving an applicant comfort that no inequitable conduct allegation can be sustained in litigation.

The objective “but for” materiality standard would also serve an important gatekeeper function currently lacking in the existing approaches to materiality. For example, the standard would curtail situations where attorney arguments in related prosecutions qualify as material information. This is consistent with earlier decisions finding that attorney arguments are generally not material.²¹

III. The Severe Penalty of Unenforceability Justifies the Proposed Limits on Inequitable Conduct

AIPLA submits that the severe penalty of unenforceability for an entire patent, not just individual claims, justifies these proposed limitations on inequitable conduct, *i.e.*, stricter requirements for proving intent and materiality. A

²⁰ *Tafas v. Doll*, 559 F.3d 1345, 1352 (Fed. Cir. 2009), *appeal dismissed en banc sub nom. Tafas v. Kappos*, 586 F.3d 1369 (Fed. Cir. 2009); *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996); *see also* David Hricik & Seth Trimble, *Congratulations on Your Hallucinations: Why the PTO’s 1992 Amendment to § 1.56 Is Irrelevant to Inequitable Conduct*, 38 AIPLA Q.J. 1, 13 (2010) (“Practical considerations aside, Rule 1.56 should be irrelevant to determining materiality in patent litigation.”).

²¹ *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1378-79 (Fed. Cir. 2008); *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000).

fraud standard—requiring specific intent to deceive apart from materiality and a showing that at least one claim is invalid due to the misconduct (i.e., would not have issued but for the misconduct)—will continue to deter deceptive conduct but will properly focus on the most egregious conduct, reserving the remedy for only rare circumstances. In that regard, former Chief Judge Michel observed that “[j]ust as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability....” *Star Scientific*, 537 F.3d at 1366. Less demanding standards fail to limit application of the defense and do not warrant the penalty of unenforceability for all claims.

Unenforceability is not the only means of policing improper conduct with the PTO. Other protections also serve as backstops against such improper conduct. For example, the PTO’s Office of Enrollment and Discipline has the authority to sanction patent practitioners, inventors are required to sign declarations under penalties of perjury, and third parties can seek reexamination and make prior art submissions. All of these other mechanisms serve as additional checks on an applicant’s behavior before the PTO.

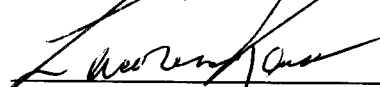
CONCLUSION

In summary, the Court should modify the existing inequitable conduct framework and find intent only where an applicant had specific intent to commit fraud on the PTO and materiality only where but for the alleged misconduct, one or more claims would not have issued. For the foregoing reasons, *amicus curiae* AIPLA respectfully requests that the Court limit the scope of inequitable conduct to only behavior constituting the commission of fraud on the PTO.

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and 32(a)(7)(B) because it contains 4,681 words as measured by the word processing software used to prepare this brief, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).



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