

2008-1511, -1512, -1513, -1514, -1595

**United States Court of Appeals
for the Federal Circuit**

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

Plaintiffs-Appellants,

v.

BECTON, DICKINSON AND COMPANY,
and NOVA BIOMEDICAL CORPORATION,

Defendants-Appellees,

and

BAYER HEALTHCARE LLC,

Defendant-Appellee.

*Appeals from the United States District Court for the Northern District of
California in consolidated case nos. 04-CV-2123, 04-CV-3327, 04-CV-3732,
and 05-CV-3117, Judge William H. Alsup.*

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IN SUPPORT OF NEITHER PARTY**

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Therasense, Inc. (now known as Abbott Diabetes Care, Inc.) and Abbott Laboratories v. Becton, Dickinson and Company and Bayer Healthcare LLC

2008-1511, -1512, -1513, -1514, -1595

CERTIFICATE OF INTEREST

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1. The full names of every party or amicus represented by me is:
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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: **NONE**
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of *amicus curiae* represented by me are: **NONE**
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TABLE OF CONTENTS

TABLE OF AUTHORITIESiv

INTEREST OF AMICUS CURIAE 1

SUMMARY OF ARGUMENT2

ARGUMENT3

 1. THE FRAMEWORK FOR DETERMINING
 INEQUITABLE CONDUCT SHOULD BE MODIFIED TO
 ALIGN BETTER WITH ITS EQUITABLE ROOTS.3

 2. THE INEQUITABLE CONDUCT STANDARD SHOULD
 BE TIED DIRECTLY TO THE EQUITABLE DEFENSE
 OF UNCLEAN HANDS.4

 3. THE PROPER STANDARD FOR MATERIALITY IN
 COURT AND OTHER CONTESTED PROCEEDINGS IS
 AN OBJECTIVE “BUT FOR” STANDARD.6

 A. The “Reasonable Examiner” Standard Has
 Unintended Consequences6

 B. The Materiality Bar Needs to Be Raised to an
 Objective “But For” Standard.9

 C. The Objective “But For” Standard Will Promote
 Beneficial Bifurcation. 11

 4. IT IS IMPROPER TO INFER WRONGFUL INTENT
 SOLELY ON THE BASIS OF A HIGH LEVEL OF
 MATERIALITY. 11

 5. A BALANCING INQUIRY SHOULD OCCUR ONLY
 AFTER CLEAR AND CONVINCING PROOF OF BOTH
 AN INTENT TO DECEIVE AND A HIGH LEVEL OF
 MATERIALITY. 14

6. NEITHER COMMON LAW NOR FEDERAL AGENCY
LAW WILL BE PARTICULARLY HELPFUL IN
DETERMINING INEQUITABLE CONDUCT.....15

CONCLUSION.....16

TABLE OF AUTHORITIES

CASES

<i>Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.</i> , 607 F.3d 817 (Fed. Cir. 2010)	7
<i>American Hoist & Derrick Co. v. Sowa & Sons, Inc.</i> , 725 F.2d 1350 (Fed. Cir. 1984)	9
<i>Ariad Pharm. v. Eli Lilly</i> , 560 F.3d 1366 (Fed. Cir. 2009)	14
<i>Ariad Pharm. v. Eli Lilly</i> , 595 F.3d 1329 (Fed. Cir. 2009)	14
<i>Aventis Pharma v. Amphastar Pharms.</i> , 129 S. Ct. 2053 (2009).....	12
<i>Aventis Pharma v. Amphastar Pharms.</i> , 525 F.3d 1334 (Fed. Cir. 2008)	12
<i>Bien v. Heath</i> 47 U.S. 228, 247 (1848)	4
<i>Dayco Products, Inc. v. Total Containment, Inc.</i> , 329 F.3d 1328 (Fed. Cir. 2003)	9
<i>Digital Control Inc. v. Charles Machine Works</i> , 437 F.3d 1309 (Fed. Cir. 2006)	6, 8, 9
<i>Ferring v. Barr Labs</i> , 437 F.3d 1181 (Fed. Cir. 2006)	12, 13
<i>Hazel-Atlas Glass Co. v. Hartford-Empire Co.</i> , 322 U.S. 238 (1944).....	4
<i>In re Bose Corp.</i> , 580 F.3d. 1240 (Fed. Cir. 2009)	6

<i>J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.</i> , 747 F.2d 1553 (Fed. Cir. 1984)	4
<i>Leviton Mfg. Co., Inc. v. Universal Sec. Instruments, Inc.</i> , 606 F.3D 1353 (Fed. Cir. 2010)	7
<i>Keystone Driller Co. v. Gen. Excavator Co.</i> , 290 U.S. 240 (1933).....	<i>passim</i>
<i>Kingsdown Med. Consultants, Ltd. v. Hollister Inc.</i> , 863 F.2d 867 (Fed. Cir. 1988) (<i>en banc</i>)	7, 12, 15
<i>McKesson Info. Solutions, Inc. v. Bridge Med., Inc.</i> , 487 F.3d 897 (Fed. Cir. 2007)	7
<i>Monsanto Co. v. Bayer BioScience B.V.</i> , 363 F.3d 1235 (Fed. Cir. 2004)	14
<i>Nilssen v. Osram Sylvania, Inc.</i> , 504 F.3d 1223 (Fed. Cir. 2007)	12
<i>Norton v. Curtiss</i> , 433 F.2d 779 (CCPA 1970).....	4
<i>Praxair, Inc. v. ATMI, Inc.</i> , 543 F.3d 1306 (Fed. Cir. 2008)	12, 13
<i>Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.</i> , 324 U.S. 806 (1945).....	<i>passim</i>
<i>Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.</i> , 537 F.3d 1357 (Fed. Cir. 2008)	<i>passim</i>
<i>Symantec Corp. v. Computer Assocs. Int'l, Inc.</i> , 522 F.3d 1279 (Fed. Cir. 2008)	7

ARTICLES

- Christian Mammen, *Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct*, 24 Berkeley Tech. L.J. 1329, 1358-60 (2009).....7
- Patent Application Pendency: Percent of Applications Still Pending*, PatentlyO.com, <http://www.patentlyo.com/patent/2009/07/patent-application-pendency-percent-of-applications-still-pending.html> (last visited July 26, 2010)8
- Update on Patent Pendency*, PatentlyO.com, <http://www.patentlyo.com/patent/2010/04/average-pendency-of-utility-patents-issued-april-27-2010claim-priority-to-foreign-applicationyesnoclaim-priority-to-us-no.html> (last visited July 26, 2010)8

INTEREST OF AMICUS CURIAE

The Intellectual Property Owners Association (“IPO”) submits this brief as *amicus curiae* pursuant to Fed. R. App. P. 29 and Rule 29 of this Court to address the six questions set forth by this Court in its April 26, 2010 Order in this matter. That Order provides that *amicus* briefs may be filed without leave of court.

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in U.S. intellectual property rights. IPO’s membership includes more than 200 companies and a total of over 11,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO members receive about thirty percent of the patents issued by the U.S. Patent and Trademark Office to U.S. nationals. IPO regularly represents the interests of its members before Congress and the USPTO and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO’s Board of Directors, which approved the filing of this brief, are listed in the Appendix¹.

¹ IPO procedures require approval of positions in briefs by a three-fourth majority of directors present and voting. Abbott Laboratories is a member of the IPO Board of Directors; however, it did not participate in the discussions regarding or vote on the decision to file this brief and did not participate in its preparation.

IPO submits this brief because of the frequency with which inequitable conduct issues arise in patent litigation and the resulting need for a clearly articulated and consistently applied standard for determining inequitable conduct. IPO expressly declines, however, to take any position regarding the particular facts of this case.

SUMMARY OF ARGUMENT

1. IPO believes that the current materiality-intent-balancing framework for inequitable conduct should be modified in order to bring additional clarity and consistency to this issue and to align the doctrine more closely with its equitable roots.

2. IPO believes that “unclean hands” is the standard enunciated by the Supreme Court for determining inequitable conduct and is, therefore, the proper standard for adoption by this Court. Consistent with the “unclean hands” doctrine, IPO believes that inequitable conduct should be based on clear and convincing evidence that the applicant intended to deceive the USPTO into issuing an invalid claim.

3. IPO also maintains that this Court should adopt a single standard for materiality for use in court and other contested proceedings. IPO believes that this single standard for materiality should be an objective “but for” standard, i.e., whether but for the alleged inequitable conduct, an issued claim in the asserted patent would not have issued.

4. IPO believes it is not appropriate to infer intent solely from a high level of materiality. Instead, there should be a requirement for clear and convincing evidence of a specific intent to deceive the USPTO.

5. IPO submits that the balancing inquiry should be maintained as an appropriate exercise of the court's equitable discretion in determining the remedy for inequitable conduct after intent and materiality are affirmatively determined. However, the balancing inquiry should not be used to infer intent solely from materiality.

6. Finally, since inequitable conduct is a creature of equity, IPO believes that neither common law nor federal agency law will prove as helpful in determining inequitable conduct standards as decisions addressing equitable issues, particularly in the context of patent prosecution.

ARGUMENT

1. THE FRAMEWORK FOR DETERMINING INEQUITABLE CONDUCT SHOULD BE MODIFIED TO ALIGN BETTER WITH ITS EQUITABLE ROOTS

The materiality-intent-balancing framework for determining inequitable conduct as enunciated by this Court should not be replaced in its entirety. However, IPO believes that this framework, and its application in litigation, needs to be modified in order to bring additional clarity and consistency to the issue and to align the doctrine more firmly within the equitable roots of inequitable conduct.

Suggested modifications to this analytical framework are discussed in more detail below.

2. THE INEQUITABLE CONDUCT STANDARD SHOULD BE TIED DIRECTLY TO THE EQUITABLE DEFENSE OF UNCLEAN HANDS

When the issue has arisen, the U.S. Supreme Court has consistently framed the issue of inequitable conduct in terms of fraud or “unclean hands.” *E.g.*, *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250-51 (1944) (denying relief for claimed infringement due to fraudulent procurement and enforcement of patent); *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) (“The guiding doctrine in this case is the equitable maxim that ‘he who comes into equity must come with clean hands.’”). In *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933), the Supreme Court refers to barring relief for “one who has acted fraudulently, or who by deceit or any unfair means has gained an advantage.” *Id.* at 245 (quoting *Bein v. Heath*, 47 U.S. 228, 247 (1848)). As stated by the Supreme Court, the scope of inequitable conduct may range from outright fraud, to deceit, to gaining an advantage by unfair means. Consistent with this guidance from the Supreme Court, this Court has recognized that “[c]onduct before the PTO that may render a patent unenforceable is broader than ‘common law fraud.’” *J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1559 (Fed. Cir. 1984), citing *Norton v. Curtiss*, 433 F.2d 779, 793 (CCPA 1970).

A patent applicant's ethical duty before the USPTO is not so narrowly defined as to be restricted to truly fraudulent acts; but rather, the applicant bears a duty of candor with respect to all that is potentially inequitable. "Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications at issue." *Precision Instrument*, 324 U.S. at 818. Accordingly, IPO submits that unclean hands is the correct standard for barring relief based on inequitable conduct. This ensures that inequitable conduct, as a defense in equity, is aligned with "one of the fundamental principles upon which equity jurisprudence is founded, that before a complainant can have a standing in court he must first show that not only has he a good and meritorious cause of action, but he must come into court with clean hands." *Id.* at 244.

While the Supreme Court has not established a precise standard for the application of unclean hands, the Supreme Court's statement that "[t]he equitable powers of the court can never be exerted on behalf of one who has acted fraudulently, or who by deceit or any unfair means has gained an advantage," *Keystone*, 290 U.S. at 245, elucidates the basic principles. Applying those principles to patent litigation or other contested proceedings, IPO submits that a finding of inequitable conduct should be based on clear and convincing evidence

that the applicant intended to deceive the USPTO into issuing an invalid claim. IPO believes that this standard is fully consistent with the Supreme Court's pronouncements concerning inequitable conduct and yet provides a clearly articulated standard capable of consistent and more predictable application in litigation.²

3. THE PROPER STANDARD FOR MATERIALITY IN COURT AND OTHER CONTESTED PROCEEDINGS IS AN OBJECTIVE “BUT FOR” STANDARD

As a threshold matter, IPO believes that the patent system would be strengthened were this Court to adopt a single standard for materiality in determining inequitable conduct in litigation. A single standard would provide concrete guidance to the district courts and bring a measure of increased predictability to the inequitable conduct issue.

A. The “Reasonable Examiner” Standard Has Unintended Consequences

Several different standards of materiality have emerged from the courts, including the objective “but for” standard, the subjective “but for” standard, and the “but it may have” standard. *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006). Additionally, various panel decisions of this

² This position is also consistent with the clear and convincing standard that intent to deceive must be proved “to the hilt” when asserting fraud in the acquisition or renewal of a trademark. *See, e.g., In re Bose Corp.*, 580 F.3d. 1240, 1244-46 (Fed. Cir. 2009).

Court have approved of the use of the “reasonable examiner” standard in determining inequitable conduct, a standard that permits a relatively low level of proof for establishing materiality.³ In fact, the “reasonable examiner” standard has become almost the sole standard invoked by this Court, *id.* at 1316, and an unfortunate consequence of reliance on this “reasonable examiner” standard is that inequitable conduct has become a full-blown plague on the patent system. *See, e.g., Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc*). Since 2000, there has been a ten-fold increase in the number of cases in which inequitable conduct has been pled as a percentage of total patent cases.⁴

The exponential increase in inequitable conduct charges has also created its own backlash in the USPTO. In order to minimize the opportunity for allegations of inequitable conduct, patent practitioners now regularly disclose to the USPTO anything that could be alleged to be material, regardless of the relevance of the

³ *See, e.g., Leviton Mfg. Co., Inc. v. Universal Sec. Instruments, Inc.*, 606 F.3d 1353, 1358-59 (Fed. Cir. 2010) (information may be considered material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent); *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 829 (Fed. Cir. 2010), (citing *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007)); *see also Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1297 (Fed. Cir. 2008); *Star Scientific*, 537 F.3d at 1367.

⁴ Christian Mammen, *Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct*, 24 Berkeley Tech. L.J. 1329, 1358-60 (2009). Available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1339259.

reference. Particularly for significant inventions, USPTO examiners are routinely buried under a paper avalanche of prior art references, most of which are of marginal value. Compounding the problem, practitioners are also understandably hesitant to assist the examiners in wading through this mountain of paper, since any statements about the cited references may later be characterized in litigation as material misrepresentations.

The inevitable result of this “cite everything, say nothing” practice forced upon applicants by the current inequitable conduct law is that examiners are frequently overwhelmed with irrelevant references, making the most relevant prior art that much more difficult to identify. The productivity of the examiners declines, the whole patenting process slows down, and pendency periods continue to rise.⁵ The law of inequitable conduct needs to change so that charges of inequitable conduct do not continue to distort the entire patent system.

Moreover, the USPTO amended Rule 56, 37 C.F.R. § 1.56, in 1992 to modify significantly the reasonable examiner standard it had promulgated in 1977. *See Digital Control*, 437 F.3d at 1314. But this Court declined to modify the materiality standard applied in litigation to reflect the USPTO’s amendment. *Id.* at

⁵ *See* Patent Application Pendency: Percent of Applications Still Pending, <http://www.patentlyo.com/patent/2009/07/patent-application-pendency-percent-of-applications-still-pending.html>; Update on Patent Pendency, <http://www.patentlyo.com/patent/2010/04/average-pendency-of-utility-patents-issued-april-27-2010claim-priority-to-foreign-applicationyesnoclaim-priority-to-us-no.html>

1316. Thus, practitioners are left in an untenable position -- they may be found to have committed inequitable conduct even if they complied in full with Rule 56. In practice, this Court's continued reliance on the "reasonable examiner" standard has nullified the PTO's 1992 amendment to Rule 56. Practitioners still over-cite references in order to defend against inequitable conduct charges, regardless of whether the citations are actually required under the current Rule 56. The objective "but for" standard for materiality suggested by IPO, on the other hand, eliminates this practitioner dilemma and the deleterious impact it has on patent prosecution. Under the objective "but for" standard of materiality, compliance with Rule 56 in its current form -- or even with any conceivable amendments -- would negate any charge of inequitable conduct.

B. The Materiality Bar Needs to Be Raised to an Objective "But For" Standard

As currently enunciated, the law of "inequitable conduct" adversely affects the quality of patents being issued by the USPTO. Therefore, IPO urges the Court to take this opportunity to overrule its prior panel decisions indicating that there is no reason for courts to be bound by any single standard of materiality⁶ and to adopt instead a single, objective "but for" standard requiring that "but for" the alleged inequitable conduct an issued claim in the asserted patent would not have issued.

⁶ *E.g.*, *Digital Control*, 437 F.3d at 1316; *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1328, 1368 (Fed. Cir. 2003); *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir. 1984)

IPO believes that the materiality bar needs to be raised and that the objective “but for” standard is the proper standard for materiality in court and other contested proceedings. The “but for” standard also aligns closely with the “unclean hands” underpinnings of inequitable conduct as stated in *Precision Instrument* and *Keystone Driller*. The requirement of “but for” materiality properly limits application of inequitable conduct to those situations where the applicant has in fact “acted fraudulently, or . . . by deceit or any unfair means has gained an advantage.” *Keystone Driller*, 290 U.S. at 245.

The lower “reasonable examiner” test, in contrast, extends the reach of inequitable conduct to situations where there is only the possibility of gaining an unfair advantage, and even to situations where no advantage was gained at all. This Court has previously discussed at length the severity of the inequitable conduct penalty and how courts must be vigilant in enforcing the burden and standard of proof so that the defense is not applied too easily. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365-66 (Fed. Cir. 2008). IPO agrees and believes the same logic supports raising the materiality threshold to an objective “but for” standard. Unenforceability is a drastic remedy and materiality should not be considered in terms of whether it may have possibly affected an examiner’s analysis. Rather, the measure of materiality should be substantial and

based on more than mere possibilities when it is used to bar enforcement of an issued patent.

C. The Objective “But For” Standard Will Promote Beneficial Bifurcation

One expected result of the objective “but for” standard in litigation is that inequitable conduct most commonly will be bifurcated and tried only after the judge or jury finds a claim of the asserted patent to be invalid. If the invalidity finding is based on the same facts as the inequitable conduct charges, then objective “but for” materiality is likely established and the court can proceed on the issue of deceptive intent. This would properly limit the inequitable conduct defense to those circumstances where the applicant has actually “gained an [unfair] advantage”, to use the Supreme Court’s phrase in *Keystone Driller*, 290 U.S. at 245. Therefore, even if the inequitable conduct defense is still pled with excessive frequency, the implementation of an objective “but for” standard of materiality will, over time, significantly reduce the harmful effects of the current inequitable conduct law on the patent system.

4. IT IS IMPROPER TO INFER WRONGFUL INTENT SOLELY ON THE BASIS OF A HIGH LEVEL OF MATERIALITY

IPO believes it is improper to find wrongful intent solely on the basis of a high level of materiality. Inequitable conduct should always require discrete proof of an intentional act of unclean hands. “Any *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 [unclean hands] maxim by the chancellor.” *Precision Instrument*, 324 U.S. at 815 (emphasis added). In 1988, this Court held in *Kingsdown* that gross negligence is not enough to infer intent and specifically required an analysis of the conduct and culpability in the determination of intent. *Id.* at 876 (“the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.”). More recently, a panel of this Court emphasized the discrete nature of the intent element:

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. . . . [T]he alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the *specific intent* to . . . mislead [] or deceiv[e] the PTO. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a known material reference.

Star Scientific, 537 F.3d at 1367 (emphases in original).

IPO is concerned that several panel decisions by this Court have set a lower threshold for intent that appears to be based unduly on a high level of materiality.⁷

⁷ *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. 2008), *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223 (Fed. Cir. 2007), *Aventis Pharma v. Amphastar Pharms.*, 525 F.3d 1334 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2053 (2009), and *Ferring v. Barr Labs*, 437 F.3d 1181 (Fed. Cir. 2006).

In *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. 2008), for example, the panel initially noted that the materiality and intent prongs of inequitable conduct are separate and a finding of materiality alone does not give rise to a presumption of intent. *Id.* at 1313. The majority, however, continued its analysis by stating that an inference of intent to deceive is appropriate when: (1) highly material information is withheld; (2) the applicant knew of the information and knew or should have known of the materiality; (3) and the applicant fails to provide a credible explanation for withholding the information. *Id.* Based on this methodology, the majority held that intent to deceive could be inferred from the failure to disclose the highly material art. *Id.* at 1315.

IPO urges this Court to adopt the intent threshold offered by the panel in *Star Scientific*, which stands in contrast to the *Ferring/Praxair* line of cases. According to the *Star Scientific* panel, 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” *Id.* at 1368. Any inference of intent must be “the single most reasonable inference able to be drawn from the evidence,” *id.* at 1366, and while a court can infer intent from indirect evidence, “no inference can be drawn if there is no evidence, direct or indirect, that can support the inference.” *Id.* at 1368.

To strengthen the requisite proof of intent and to maintain the discrete nature of the materiality and intent prongs, IPO submits that this *en banc* Court should additionally adopt the holding in *Ariad Pharm. v Eli Lilly*, 560 F.3d 1366 (Fed. Cir. 2009), *vacated on other grounds*, 595 F.3d 1329 (Fed. Cir. 2009), in which a panel held that a district court must make “independent findings of both materiality and intent.” *Id.* at 1380. This Court’s panel reasoned that “Lilly cannot prove deceptive intent by clear and convincing evidence simply by relying on the materiality of the errors. Rather, there must be clear and convincing evidence of ‘culpable’ conduct.” *Id.*

5. A BALANCING INQUIRY SHOULD OCCUR ONLY AFTER CLEAR AND CONVINCING PROOF OF BOTH AN INTENT TO DECEIVE AND A HIGH LEVEL OF MATERIALITY

IPO is of the opinion that the balancing inquiry should be maintained. However, before balancing can take place, there should first be independent findings of clear and convincing proof establishing both an intent to deceive the USPTO and objective “but for” materiality. Then, “even if this elevated evidentiary burden is met as to both elements, the district court must still balance the equities to determine whether the applicant's conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable.” *Monsanto Co. v. Bayer BioScience B.V.*, 363 F.3d 1235, 1239 (Fed. Cir. 2004) (cited with approval by *Star Scientific*, 537 F.3d at 1365). Thus, even if both materiality and

an intent to deceive are proven by clear and convincing evidence, the balancing inquiry still permits the court sitting in equity to decline to render the patent unenforceable. *Star Scientific*, 537 F.3d at 1365.

The appropriate place for balancing is in the exercise of the court's inherent discretion in determining whether proven inequitable conduct warrants a holding of unenforceability. As stated by the Supreme Court, the application of the equitable unclean hands doctrine is "not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion." *Keystone*, 290 U.S. at 245-46. This is consistent with inequitable conduct being reviewed under an abuse of discretion standard. *Kingsdown*, 863 F.2d at 872. Balancing should not, however, be used as a backdoor means to conflate intent and materiality by inferring intent solely from a high level of materiality. There should be clear and convincing evidence of "but for" materiality and a specific intent to deceive the USPTO *before* any balancing takes place.

6. NEITHER COMMON LAW NOR FEDERAL AGENCY LAW WILL BE PARTICULARLY HELPFUL IN DETERMINING INEQUITABLE CONDUCT

Inequitable conduct is based in equity. Therefore, neither common law (as opposed to decisions dealing with equitable issues) nor federal agency law would be expected to be a helpful source for determining how inequitable conduct should be applied in court or other contested proceedings. Instead, the Supreme Court's

case law establishing and discussing the equitable doctrine of inequitable conduct based on fraud or unclean hands provides the foundational basis for this issue.

CONCLUSION

IPO urges this Court to take this opportunity to clarify the standards for determining inequitable conduct. By setting a single, higher objective “but for” standard for materiality and by requiring a separate finding of intent to deceive the USPTO, this Court can bring the doctrine of inequitable conduct into closer harmony with Supreme Court precedent and strengthen the patent system.

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APPENDIX

APPENDIX¹

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**United States Court of Appeals
for the Federal Circuit**
Therasense v Becton, 2008-1511, -1512, -1513, -1514, -1595

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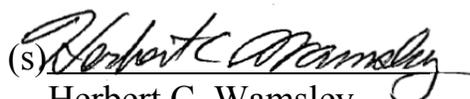
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