

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.

Appeal 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

**BRIEF OF *AMICUS CURIAE* APOTEX, INC.
NOT SUPPORTING ANY PARTY**

Shashank Upadhye
APOTEX, INC.
150 Signet Drive
Toronto, ON M9L 1T9
416.401.7701

Robert Gould
Else Hanson
DUANE MORRIS LLP
190 S. LaSalle St.,
Suite 3700
Chicago, IL 60603
312.499.6700

Matthew C. Mousley
DUANE MORRIS LLP
30 S. 17th St.
Philadelphia, PA 19103
215.979.1000

Ian Scott
Principal Attorney
DUANE MORRIS LLP
1540 Broadway
New York, NY 10036
212.692.1000

Joseph M. Bennett-Paris
DUANE MORRIS LLP
Atlantic Center Plaza,
Suite 700
1180 W. Peachtree St. NW
Atlanta, GA 30309
404.253.6900

JULY 30, 2010

Counsel for Amicus Curiae Apotex, Inc.

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Therasense, Inc. and Abbott Laboratories v. Becton, Dickinson and Co. et al.

No. 2008-1511, -1512, -1513, -1514, -1595

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party)

Apotex, Inc. certifies the following (use "None" if applicable; use extra sheets if necessary):

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

Apotex, Inc.

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:

Apotex, Inc.

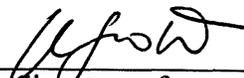
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

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

See Attachment A, annexed hereto.

July 29, 2010
Date


Signature of counsel
IAN SCOTT
Printed name of counsel

Please Note: All questions must be answered

cc: _____

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Defendant-Appellee.

CERTIFICATE OF INTEREST

ATTACHMENT A

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

1. Shashank Upadhye – Apotex, Inc.
2. Ian Scott – Duane Morris LLP
3. Robert Gould – Duane Morris LLP
4. Elese E. Hanson – Duane Morris LLP
5. Joseph M. Bennett-Paris – Duane Morris LLP
6. Matthew C. Mousley – Duane Morris LLP

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I. INTEREST OF AMICUS CURIAE

Apotex, Inc. (“Apotex”) is a manufacturer of generic pharmaceutical products. As a generic pharmaceutical company, Apotex makes business decisions based on its evaluation of U.S. patents, particularly those patents listed in the FDA’s Orange Book. Those decisions include whether or not to attempt to launch a generic drug and, if so, when to attempt such a launch, and whether to challenge the validity and enforceability of patents that may cover relevant pharmaceutical products. Apotex is also the owner of a number of U.S. patents and patent applications.

In deciding whether to challenge patents and to obtain patent protection itself, Apotex—like the public in general—relies on this Court’s precedent. In order for Apotex’s own decisions to have predictable consequences, the Court’s precedent must include clear and consistent decisions. As this Court has recognized, the U.S. Court of Appeals for the Federal Circuit was created, in part, for the purpose of achieving uniformity in the exposition and application of substantive patent law. *Atari Inc. v. JS & A Group Inc.*, 747 F.2d 1422 (Fed. Cir. 1984); *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564 (Fed. Cir. 1984). In furtherance of that purpose, Apotex submits this *amicus curiae* brief to urge the Court to maintain and clarify its precedent regarding inequitable conduct. Apotex does not intend this brief to support any particular party to the appeal.

II. ARGUMENT

A. Summary

The Court should retain the established balancing framework for evaluating inequitable conduct without substantive modification, as it is a well suited framework for evaluating a doctrine rooted in equity. However, in light of recent Federal Circuit panel decisions, *see, e.g., Optium Corp. v. Emcore Corp.*, 603 F.3d 1313 (Fed. Cir. 2010), the *en banc* Court should clarify this framework by confirming the following points:

- Inequitable conduct is broader than common law fraud.
- As an element of an equitable defense, materiality should continue to be assessed by any of the several prevailing standards, including those derived from practical PTO rules and those derived from conventional legal principles. *See Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1237 n.11 (Fed. Cir. 2008).
- Although materiality is often discussed in the context of prior art references and their materiality to the language of allowed patent claims, inequitable conduct can occur with respect to the breach of *any* rule of patent prosecution.
- Because questions of “materiality” and “culpability” are often interrelated and intertwined, courts should be permitted to “expressly consider[] the level of materiality of a withheld reference in determining whether an inference of deceptive intent is appropriate.” *Optium*, 603 F.3d at 1323 (Prost, J., concurring).

- Intent may be established by a “known or should have known” standard.
- Because intent is often proved only by circumstantial evidence, materiality may be one of several considerations. To the extent that undue focus on materiality raises concerns with regard to any alleged overpleading of inequitable conduct in patent cases generally, such concerns are allayed by this Court’s decision in *Exergen Corp. v. Wal-Mart Stores, Inc.*, which requires a strict pleading standard pursuant to FRCP 9(b) and should ensure that inequitable conduct is pled only in factually appropriate cases. 575 F.3d 1312, 1326-27 (Fed. Cir. 2009).

B. The Materiality-Intent Balancing Framework Is Well Suited as a Means for Evaluating an Equitable Defense and Should Not Be Replaced or Modified.

The inequitable conduct doctrine developed from a series of Supreme Court decisions in which the Court refused to enforce patents obtained by patentees who had engaged in fraud during their procurement. *See Precision Instr. Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 251 (1944) (“To grant full protection to the public against a patent obtained by fraud, that patent must be vacated.”); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933). The defense arose out of considerations of equity and the public interest. *Precision Instr.*, 324 U.S. at 818 (“Public interest demands that all facts relevant to [matters before the Patent Office] be submitted formally or informally to the Patent Office, which can then

pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies.”) (citations omitted). Where fraud is committed, injury to the public through a weakening of the patent system is manifest. *See id.* at 816.

Accordingly, courts following this precedent developed the doctrine as an equitable defense to infringement by applying general principles of common law fraud to the particulars of the patent prosecution process, specifically requiring a showing that the patentee affirmatively misrepresented information to the patent examiner, or withheld material information from the examiner, and requiring a showing of wrongfulness, such as deceptive intent, willful misconduct, or gross negligence. *Norton v. Curtiss*, 433 F.2d 779, 793-96 (CCPA 1970) (discussing elements of “technical” or “affirmative” fraud and applying them to patent context).

The Supreme Court has recognized that “[t]hose 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 in issue.” *Precision Instr.*, 324 U.S. at 818. In a similar fashion, the Federal Circuit’s predecessor, the CCPA, has concluded that applicants must pursue their patent applications with the highest standards of honesty and candor in order for the patent system to work. *Norton*,

433 F.2d at 793-94. The CCPA approved of the expansion of the types of misconduct for which applicants could be penalized beyond common law or “technical” fraud to include a broader range of conduct warranting the equitable remedy of patent unenforceability. *Id.*

Equitable relief has always been a flexible remedy which must be able to meet new situations and provide whatever relief is necessary to correct injustices that arise. *Hazel-Atlas*, 322 U.S. at 248. In various areas of patent law, the Supreme Court has found that a flexible test, rather than a rigid standard, is appropriate. *See, e.g., KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415, 427 (2007) (explaining that obviousness should be evaluated by “an expansive and flexible approach”); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 737-38 (2002) (explaining that doctrine of prosecution history estoppel should be applied “in a flexible way, not a rigid one”); *eBay Inc. v. MercExchange LLC*, 547 U.S. 388, 393-94 (2006) (holding that evaluation of requests for permanent injunctions under the Patent Act should be guided by “traditional equitable principles,” not a “categorical rule”); *see MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007) (holding that Article III of the Constitution does not require a licensee to break or terminate its license agreement before seeking a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed, and therefore indicating that no unique jurisdictional standard exists for patent cases);

Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 102 (1993) (holding that the court should not automatically vacate an invalidity counterclaim upon finding non-infringement and, rather, the court should evaluate the totality of the circumstances regarding the appropriateness of reaching the merits of such a counterclaim after the infringement claim has been dismissed); *see also Bilski v. Kappos*, No. 08-964, 130 S. Ct. 3218, 2010 U.S. LEXIS 5521, at *18 (June 28, 2010) (holding that “the machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible ‘process’”). Because the materiality-intent balancing framework is a flexible test, it is appropriate and should be retained.

C. The Standard for Establishing Inequitable Conduct Should Be Informed by, but Not Be Tied Directly to, Fraud, and Should Continue to Be Interpreted as a Form of Unclean Hands.

Just as the materiality-intent framework has been developed by the courts, the standard for establishing inequitable conduct should not now be revised to be strictly tied to common law fraud. Rather, the standard is more properly viewed as a form of unclean hands, a standard that is more suited to the unique *ex parte* nature of the patent prosecution process. *See Norton*, 433 F.2d at 793 (“[T]he courts appear to look at the equities of the particular case and determine whether the conduct before them—which might have been admittedly less than fraudulent in the technical sense—was still so reprehensible as to justify the court’s refusing to enforce the rights of the party guilty of such conduct. It might be said that in

such instances the concept of fraud becomes intermingled with the equitable doctrine of ‘unclean hands.’ A court might still evaluate the evidence in light of the traditional elements of technical fraud, but will now include a broader range of conduct within each of those elements, giving consideration to the equities involved in the particular case.”).

With respect to the distinction from common law fraud, it should be noted that the Federal Circuit has expressed a clear preference for the term “inequitable conduct” to identify generically a breach of the duty of candor and good faith to the United States Patent Office that is sufficient to render a patent unenforceable. This diction itself was intended to distinguish “inequitable conduct” from common law fraud. *Korody-Colyer Corp. v. General Motors Corp.*, 828 F.2d 1572, 1578 (Fed. Cir. 1987) (citing *Argus Chemical Corp. v. Fibre Glass-Evercoat Co.*, 812 F.2d 1381, 1384-85 (Fed. Cir. 1987)). The Court’s discussions of this subject make clear that it is the need to impute harm that distinguishes “inequitable conduct” in procuring a patent from common law fraud. *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1454-57 (Fed. Cir. 1984) (noting that “[d]efendants and the trial judge have had little or nothing to say, in discussing the breach of duty to disclose issue, about the limited claims finally patented; they have not shown that non-disclosure of prior art would have had any effect on their allowance”).

This Court's decisions have broadened the doctrine of inequitable conduct to encompass misconduct less egregious than fraud. *See, e.g., Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069-71 (Fed. Cir. 1998). Notwithstanding the broader scope of the doctrine, the severity of the penalty has not changed, and thus courts must be vigilant not to permit the defense to be applied too lightly. *See, e.g., Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008) ("Just 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 or in good faith."). Nevertheless, the Federal Circuit has held that although inequitable conduct is broader than fraud, the pleading requirements of Rule 9(b) require "identification of the specific who, what, when, where, and how of the material misrepresentation or omission [was] committed before the PTO." *Exergen*, 575 F.3d at 1326-27 (internal citations omitted). Although the effects of *Exergen* are still to be measured, that decision should help to limit the assertion of inequitable conduct to appropriate factual circumstances, thereby reducing any alleged "plague" of inequitable conduct counterclaims in patent cases.

D. The Balancing of Materiality and Intent Should Not Be Abandoned, but the Standards by Which the Thresholds of These Elements Are Established and How a Strong Showing of Materiality May Evidence Intent Should Be Clarified.

The established balancing framework should be applied without modification. From a very early time in the history of the Federal Circuit, the balancing inquiry has been a part of the inequitable conduct analysis. *See Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1364 (Fed. Cir. 1984). More recently, this Court has stated that “a patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the Patent Office during prosecution.” *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006) (citing *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1330-31 (Fed. Cir. 2004)). Once threshold levels of materiality and intent are proven, the court must engage in a balancing inquiry, “with a greater showing of one factor allowing a lesser showing of the other.” *Id.* at 1313 (quoting *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001)).

The Federal Circuit should clarify the inequitable conduct balancing framework with particular attention to establishing the requisite “threshold level” of intent which must be proved in order to successfully establish the defense. This clarification is necessary in light of the recent panel decision in *Optium Corp. v.*

Emcore Corp., 603 F.3d 1313 (Fed. Cir. 2010). In *Optium*, the panel affirmed the district court’s grant of summary judgment of no inequitable conduct, stating that Optium had offered “no evidence that could succeed in proving deceptive intent by clear and convincing evidence” and had “simply argued that the ‘high materiality’ of the Willems reference relieved it of the burden to produce any affirmative evidence of intent.” *Id.* at 1322.

While the result of *Optium* may have been correct, the articulated rationale only further blurs the standard for intent. As the panel notes in its decision, Emcore did not dispute that the inventors knew of the non-disclosed reference and did not dispute that the reference was cited in multiple internal memos, including the invention disclosure form submitted by the inventors to their employer. *Id.* at 1318. Nonetheless, Emcore’s patent attorneys did not include the reference in the information disclosure statement submitted to the Patent Office. *Id.*

The Federal Circuit’s case law has established intent may be found by examining conduct “in light of all the evidence, including evidence indicative of good faith” to determine whether “sufficient culpability” exists. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (“We adopt the view that a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive; 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.”). Direct evidence of intent is rarely available,¹ and as Judge Prost noted in her concurring opinion in *Optium*, this Court has in previous cases “expressly considered the level of materiality of a withheld reference in determining whether an inference of deceptive intent is appropriate.” *Optium*, 603 F.3d at 1322-23 (Prost, J., concurring) (citing *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1366-67 (Fed. Cir. 2007)).² However, “[s]uch consideration of materiality in determining intent does not mean that a high level of materiality *alone* presumes intent without *other* evidence as to the patentee’s state of mind.” *Id.* at 1323-24

¹*Star Scientific*, 537 F.3d at 1366 (“[B]ecause direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence.”); *Critikon Inc. v. Becton Dickinson Vascular Access*, 120 F.3d 1253, 1256 (Fed. Cir. 1997) (“Direct evidence of intent or proof of deliberate scheming is rarely available in instances of inequitable conduct, but intent may be inferred from the surrounding circumstances.”); *Jack Frost Labs., Inc. v. Physicians & Nurses Mfg. Corp.*, Nos. 96-1114, -1430, -1543, 1997 U.S. App. LEXIS 26138, at *17-18 (Fed. Cir. Sept. 23, 1997) (UNPUBLISHED OPINION) (“Unfortunately, the intent prong of the inequitable conduct determination almost never includes a ‘smoking gun,’ and this case is no exception.”).

²*See also Critikon*, 120 F.3d at 1257 (“We have never held that materiality is irrelevant to the question of intent. To the contrary, we have recognized that 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.”) (internal quotation omitted); *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1134-35 (Fed. Cir. 2006) (“[W]hen the materiality of the undisclosed information is relatively low, there is less basis for inferring intent from materiality alone.”); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1315-16 (Fed. Cir. 2008); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1190-91 (Fed. Cir. 2006).

(Prost, J., concurring) (citing *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1340 (Fed. Cir. 2006)) (emphasis added).

While the instant case may not present mere nondisclosure of a highly material reference, in light of the undisputed, internal discussion of the nondisclosed reference in *Optium*, including its discussion in the inventors' information disclosure form to their employer, *Optium* was also not a case of mere nondisclosure.

E. As an Element of an Equitable Defense, Materiality Is Appropriately Assessed by Any of the Several Prevailing Standards.

Several standards have developed for assessing materiality since the inception of the inequitable conduct doctrine. *See Digital Control*, 437 F.3d at 1316 (discussing historic development of inequitable conduct and material to patentability standards). Given that the determination of whether information is material to patentability depends on facts and context, it is appropriate to evaluate materiality under each case's peculiar circumstances by any or several of these standards, including those derived from practical PTO rules and those derived from conventional legal principles. *See Monsanto Co.*, 514 F.3d at 1237 n.11 ("A misstatement or admission can be material for purposes of showing inequitable conduct even if it does not meet the standard for Rule 56 if, in the totality of circumstances, a reasonable examiner would have considered such information

important in deciding whether to allow the parent application.”). As this Court once wisely observed, “[t]here is no reason . . . to be bound by any single standard, for the answer to any inquiry into fraud in the PTO does not begin and end with materiality, nor can materiality be said to be unconnected to other considerations.” *Am. Hoist*, 725 F.2d at 1363 (noting that questions of “materiality” and “culpability” are often interrelated and intertwined).

1. Materiality standards historically included in PTO rules should endure.

Since 1977, the PTO rules have included a test for materiality of information to patentability. The first such test provided that information “is material where 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.” 37 C.F.R. § 1.56(a) (1977). In *American Hoist*, one of the first cases of inequitable conduct addressed by this Court, this Rule 56 standard was identified as an “official standard” for materiality. 725 F.2d at 1362. As the Court explained, “[t]he PTO ‘standard’ is an appropriate starting point for any discussion of materiality, for it appears to be the broadest, thus encompassing the others, and because that materiality boundary most closely aligns with how one ought to conduct business with the PTO.” *Id.* at 1363.

The “reasonable examiner” standard is an important enduring standard for materiality in this Court’s case law. *See, e.g., Akzo N.V. v. ITC*, 808 F.2d 1471,

1481 (Fed. Cir. 1986) (“Our major standard for materiality is whether a reasonable examiner would consider the omission or misrepresentation important in deciding whether to issue the patent.”); *see also Monsanto Co.*, 514 F.3d at 1237 n.11 (“A misstatement or [omission] can be material for purposes of showing inequitable conduct even if it does not meet the standard for Rule 56 if, in the totality of circumstances, a reasonable examiner would have considered such information important in deciding whether to allow the parent application.”); *Digital Control*, 437 F.3d at 1316 (“[I]f a misstatement or omission is material under the new Rule 56 standard, it is material. Similarly, if a misstatement or omission is material under the ‘reasonable examiner’ standard or under the older three tests, it is also material.”). The reasonable examiner test should be retained as one means of evaluating materiality. The test is flexible enough to “meet new situations,” *Hazel-Atlas*, 322 U.S. at 248, and courts applying the test have instructive precedent to consult in so doing.

In 1992, the PTO amended Rule 56 to create an arguably narrower standard of materiality. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363-64 (Fed. Cir. 2003) (noting that the PTO “amended its rules to provide a different standard for materiality”). The new, and current, Rule 56 reads, in relevant part, as follows:

Information is material to patentability when it is not cumulative to information already of record or being made of record in the

application, and

(1) it establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) it refutes, or is inconsistent with, a position the applicant takes in:

(i) opposing an argument of unpatentability relied on by the Office, or

(ii) asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56 (1992).

This Rule 56 materiality standard has more structure and includes elements that are more objective in nature than the reasonable examiner standard. As such, it is particularly helpful in those cases where the facts make application of this standard straightforward (e.g., where an applicant made an argument during patent prosecution that is clearly contradicted by a reference that is not cumulative to the references before the examiner). Nevertheless, that this standard calls for the establishing and rebutting of a prima facie case allows a court applying it to consider the totality of the circumstances in working toward a conclusion. For these reasons, the current Rule 56 standard should also be retained as an available standard for evaluating materiality.

2. A finding of materiality should not require that “but for” the alleged misconduct, one or more claims would not have issued.

A relatively more strict “but for” standard has also been recognized in the case law. Under this standard:

Indications in the record that the claims at issue would not have been allowed *but for* the challenged misrepresentations must not be overlooked due to any certainty on the part of the reviewing tribunal that the claimed invention, viewed objectively, should have been patented. If it can be determined that the claims would not have been allowed *but for* the misrepresentation, then the facts were material regardless of their effect on the objective question of patentability.

Norton, 433 F.2d at 795 (emphasis added). Although this standard may also be helpful to a court evaluating certain facts and weighing certain equities in any given case, this standard should not be the only means for evaluating materiality. *See Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 716 (1st Cir. 1981) (“This is not to say that a strict ‘but for’ test of materiality must be applied in every instance, or that it would necessarily be inappropriate to test the materiality of misrepresentations or nondisclosures against a standard somewhat different from the formulation used in *Norton*.”).

3. The Court should clarify that materiality standards should not be limited to the validity of claims, but should apply to any aspect bearing on patentability.

Although materiality is often discussed in the context of prior art references and their materiality to the language of allowed patent claims, the Court should clarify that inequitable conduct can occur with respect to *any* part of patent

prosecution, and the materiality of an applicant's misrepresentation or omission should be evaluated with respect to patentability *generally*, not just with respect to the validity of the claims over prior art. Given the *ex parte* nature of patent prosecution, much of the decision making is in the hands of the applicant and prosecuting attorney. As a result, the applicant and prosecuting attorney should have a high obligation to be forthright, particularly in cases where the examiner cannot independently verify the information provided by the applicant and prosecuting attorney. For example, when a declaration or affidavit is submitted, the examiner will have no independent ability to verify the information, thus the examiner ought to be made aware of any information that could call the affidavit or declaration into question. *See* Shashank Upadhye, *Generic Pharmaceutical Patent and FDA Law* § 4.16 (West 2010) (citing *Paragon Podiatry Lab., Inc. v. KLM Labs, Inc.*, 984 F.2d 1182, 1191 (Fed. Cir. 1993)). Those who are involved in the prosecution of patent applications should follow all the rules adopted by the PTO, and the intentional failure to follow those rules in any material manner should be sanctioned by holding any resulting patent unenforceable.

F. A Showing of a High Degree of Materiality Should Be a Proper Component of Finding Intent, and Intent Should Be Able to Be Satisfied by a “Known or Should Have Known” Standard.

In order to prove inequitable conduct, the alleged infringer must prove with clear and convincing evidence that the patentee concealed material information

with the specific intent to mislead or deceive the PTO. *Star Scientific*, 537 F.3d at 1366. The deceptive intent element cannot be established by information that was only later, after prosecution, found to be material. *See M. Eagles Tool Warehouse*, 439 F.3d at 1340-41. However, questions of “materiality” and “culpability” are often interrelated and intertwined. As noted above, the Federal Circuit “has expressly considered the level of materiality of a withheld reference in determining whether an inference of deceptive intent is appropriate.” *Optium*, 603 F.3d at 1323 (Prost, J., concurring).

The Federal Circuit’s own case law regarding the inequitable conduct defense starts with *Kingsdown*, wherein the Court recognized that deceitful conduct, rather than mere mistake or negligence, is necessary for establishing intent. *Kingsdown*, 863 F.2d at 873. The Court stated that “intent ... cannot always be inferred from a pattern of conduct that may be described as gross negligence.” *Id.* The “conduct must be sufficient to require a finding of deceitful intent in light of all the circumstances.” *Id.*³ Since *Kingsdown*, however, this Court has considered several cases where it did infer intent to deceive based in part

³ *Kingsdown* dealt with a patent attorney’s mistake in transferring the claims in a continuing application. *Id.* at 871. The attorney misrepresented that a new claim in the continuation application corresponded to an allowed claim in the parent application. *Id.* The Federal Circuit found this insufficient to establish intent to deceive, particularly “[i]n view of the relative ease with which others also overlooked the differences in the claims.” *Id.* at 873. Moreover, the Court was “not convinced ... that [the patent attorney’s] conduct even [rose] to a level that would warrant the description ‘gross negligence.’” *Id.*

on materiality, repeatedly recognizing that direct evidence of intent is rarely available. *See In re Metoprolol Succinate Patent Litig.*, 494 F.3d 1011, 1020 (Fed. Cir. 2007).

For example, in *Critikon*, the Court found that a “relatively high degree of intent” could be inferred based on the patent counsel’s knowledge of a prior art patent. 120 F.3d at 1256. The Court stated that Critikon “knew or should have known” of the materiality of the reference, yet it did not disclose the reference to the patent office. *Id.* Similarly, the Federal Circuit has considered materiality as evidence of intent within the context of a patentee’s failure to disclose the sale of a sample device and related test results. In *Jack Frost*, the Court noted that while “no single factor or combination of factors can be said always to require an inference of intent to mislead, 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.” 1997 U.S. App. LEXIS 26138, at *18. (quoting *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1416 (Fed. Cir. 1987)). In that case, the Court recognized that the district court based its intent determination in part on the fact that the prosecuting attorney had not disclosed “unquestionably material” sales activity to the PTO. *Id.* (noting that the district court “based its intent determination, not *merely* . . . on the fact that [the prosecuting attorney] had

not disclosed the sales activity to the PTO, but in large part on [his] lack of candor and his continued failure to disclose good faith reasons for the lack of disclosure”) (emphasis added). Thus, in two different contexts of “nondisclosure” where the applicant knew of the material information—i.e., *Critikon* and *Jack Frost*—the Federal Circuit has used materiality as an indicator of intent.

The Federal Circuit again found intent under the facts presented in *Digital Control*,⁴ where the applicants made misstatements in a Rule 131 declaration. 437 F.3d at 1320. In *Digital Control*, the Federal Circuit noted several factors relied upon by the district court relevant to the intent analysis. *Id.* at 1319-20. First, the applicant was an “‘extremely experienced inventor,’ who, at the time of his Rule 131 declaration, had applied for numerous patents and had testified as an expert witness in patent litigation.” *Id.* The inventor was clearly aware of the duty of candor to the PTO and had control over the contents of his declaration, even though it was drafted by an attorney. *Id.* at 1320. The inventor had also drafted a summary document, which was nearly identical to the Rule 131 declaration with the exception of the misstatements. *Id.* The district court found evidence that the inventor had a reason to mislead the PTO in that he was under pressure from a customer to acquire and enforce the patent rights at issue. *Id.* Finally, the district

⁴ This Court vacated the district court’s finding of inequitable conduct because the district court did not separate its analysis of the misstatements in the declaration from its analysis of the failure to disclose the prior art reference. 437 F.3d at 1321.

court found the applicant's testimony regarding his intent (good faith) to lack credibility. *Id.* The Federal Circuit found that the misstatements in the Rule 131 declaration were material and there were "ample factual findings" of intent. *Id.* at 1321. The Federal Circuit further noted that "a false affidavit, standing alone, is sufficient to render a patent unenforceable." *Id.* (citing *Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1583 (Fed. Cir. 1996); *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983); *Gen. Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994)). Accordingly, *Digital Control* is another case where the finding of intent was informed by the materiality of the information withheld from or misrepresented to the PTO.

Thus, the Federal Circuit's post-*Kingsdown* case law applies a "known or should have known" standard that considers good faith. As the Federal Circuit explained in *Critikon*, "[n]o single factor or combination of factors can be said always to require an inference of intent to mislead, ... 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. A mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice in such circumstances." 120 F.3d at 1257 (citing *FMC Corp.*, 835 F.2d at 1415).

This standard is similar to that used in the induced infringement analysis. In that context, liability is premised on “specific intent to encourage another’s infringement.” *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 699 (Fed. Cir. 2008) (quoting *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006)). Within the context of induced infringement, this Court has required the plaintiff to show “that the alleged infringer knew or should have known that his actions would induce actual infringements.” *SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360, 1376 (Fed. Cir. 2010) (citing *DSU Medical*, 471 F.3d at 1304). This Court has stated that “‘specific intent’ in the civil context is not so narrow as to allow an accused wrongdoer to actively disregard a known risk that an element of the offense exists.” *Id.* (citing *Crawford-El v. Britton*, 951 F.2d 1314, 1318 (D.C. Cir. 1991) (equating specific intent and deliberate indifference); *Boim v. Holy Land Found. for Relief & Dev.*, 549 F.3d 685, 693 (7th Cir. 2008) (equating intentional misconduct with knowledge and deliberate indifference)). In *SEB S.A.*, this Court held that inducement can be found even when the patentee has not set forth direct evidence that the accused infringer actually knew of the patent, further stating that “the standard of deliberate indifference of a known risk is not different from actual knowledge, but is a form of actual knowledge.” *Id.* at 1377 (citing *United States v. Carani*, 492 F.3d 867, 873 (7th Cir. 2007) (“Deliberate avoidance is not a standard less than knowledge; it is simply another way that

knowledge may be proved.”); *Woodman v. WWOR-TV, Inc.*, 411 F.3d 69, 84 n.14 (2d Cir. 2005) (“We note that a party’s knowledge of a disputed fact may also be proved through evidence that he consciously avoided knowledge of what would otherwise have been obvious [to] him.”)). Much of this reasoning should be applied to the materiality-intent balancing framework in order to clarify the minimum level of intent which is necessary to prove inequitable conduct. Failing to disclose or accurately portray material information should be considered a “known risk...not different from actual knowledge.” *See id.* (internal citations omitted); *see also Critikon*, 120 F.3d at 1257 (“It is axiomatic that ‘close calls should be resolved by disclosure, not unilaterally by applicant.’”) (citing *Labounty Mfg., Inc. v. ITC*, 958 F.2d 1066, 1076 (Fed. Cir. 1992)). For the foregoing reasons, this Court should explicitly hold that materiality may be one piece of indirect evidence indicative of intent to deceive the PTO.

G. The Court Should Consider the Standards for Materiality and Intent in Other Federal Agency Contexts and at Common Law to the Extent Such Standards Are Analogous and Helpful.

To the extent other areas of federal agency law provide analogous and helpful standards for evaluating materiality and intent, the Court should consider them and take advantage of any insight such consideration may provide. As stated above with respect to materiality, “[t]here is no reason . . . to be bound by any single standard.” *Am. Hoist*, 725 F.2d at 1363. The availability of multiple

standards to evaluate materiality and intent ensures that the materiality-intent balancing framework, and the inequitable conduct defense specifically, remain flexible and able to meet new situations.

III. CONCLUSION

For the foregoing reasons, the Court should retain the established balancing framework for evaluating inequitable conduct. Materiality should continue to be assessed by any of the several prevailing standards, including those derived from practical PTO rules and those derived from conventional legal principles, and circumstantial evidence of intent should continue to include, as piece of that evidence, materiality. Clarifying this flexible approach to inequitable conduct while maintaining a strict pleading standard will ensure that the defense is raised only under appropriate circumstances.

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Shashank Upadhye
APOTEX, INC.
150 Signet Drive
Toronto, ON M9L 1T9
416.401.7701

Respectfully submitted,



Ian Scott
Principal Attorney
DUANE MORRIS LLP
1540 Broadway
New York, NY 10036
212.692.1000

Robert Gould
Else Hanson
DUANE MORRIS LLP
190 S. LaSalle St., Suite 3700
Chicago, IL 60603
312.499.6700

Joseph M. Bennett-Paris
DUANE MORRIS LLP
Atlantic Center Plaza, Suite 700
1180 W. Peachtree St. NW
Atlanta, GA 30309
404.253.6900

Matthew C. Mousley
DUANE MORRIS LLP
30 S. 17th St.
Philadelphia, PA 19103
215.979.1000

*Counsel for Amicus Curiae
Apotex, Inc.*

CERTIFICATE OF COMPLIANCE

This brief complies with the length limitation of Fed. R. App. P. 29(d) because this brief is no more than one-half the maximum length authorized by Fed. R. App. P. 32(a)(7)(B)(i). Specifically, this brief contains 5,916 words, excluding the portions exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2007 in fourteen-point Times New Roman font.



Ian Scott

CERTIFICATE OF SERVICE

I certify I am today filing this **Brief of Amicus Curiae Apotex, Inc. Not Supporting Any Party** with the Office of the Clerk of the U.S. Court of Appeals for the Federal Circuit by hand delivery and serving two (2) copies of the same on the below-listed counsel by Federal Express overnight delivery:

ROHIT KUMAR SINGLA

Munger, Tolles & Olson, LLP

560 Mission Street, 27th Floor, San Francisco, CA 94105

Tel: (415)512-4000

Fax: (415)512-4077

Counsel for Plaintiff-Appellant Abbott Laboratories and Plaintiff-Appellant TheraSense, Inc. (n/k/a Abbott Diabetes Care, Inc.)

RACHEL KREVANS

Morrison & Foerster LLP

425 Market Street, , San Francisco, CA 94105-2482

Tel: (415) 268-7178

Fax: (415) 276-7522

Counsel for Defendant-Appellee Bayer HealthCare LLC

BRADFORD J. BADKE

Ropes & Gray LLP

1211 Avenue of the Americas, , New York, NY 10036

Tel: (212) 596-9031

Fax: (646) 728-1793

Counsel for Defendant-Appellee Becton, Dickinson and Co. and Defendant-Appellee Nova Biomedical Corp.

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