

Appeal Nos. 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

PLAINTIFF-APPELLANT,

v.

BECTON, DICKINSON AND COMPANY
and NOVA BIOMEDICAL CORPORATION,

DEFENDANT-APPELLEES

and

BAYER HEALTHCARE LLC,

DEFENDANT-APPELLEE,

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF CALIFORNIA
JUDGE WILLIAM H. ALSUP

BRIEF OF THE FEDERAL CIRCUIT BAR ASSOCIATION AS *AMICUS CURIAE* IN
SUPPORT OF NO PARTY

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Date: August 2, 2010

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

TERASENSE, INC. AND ABBOTT LABORATORIES v. BECTON, DICKINSON AND CO. AND NOVA BIOMEDICAL

No. 2008-1511

CERTIFICATE OF INTEREST

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

THE FEDERAL CIRCUIT BAR ASSOCIATION 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:

The Federal Circuit Bar Association

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

N/A

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

None

4. [X] 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:

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August 2, 2010
Date

[Handwritten Signature]
Signature of counsel
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Printed name of counsel

Please Note: All questions must be answered
cc: _____

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STATEMENT OF INTEREST

The Federal Circuit Bar Association (“FCBA”) is a national bar association with over 2600 members from across the country, all of whom practice before or have an interest in the Federal Circuit’s decisions. The FCBA offers a forum for common concerns and dialogue between the bar and the Federal Circuit judges. One of the FCBA’s objectives is to offer assistance and advice to courts, including through *amicus curiae* briefs, on issues affecting practice before the Federal Circuit and lower tribunals.

A great many FCBA members practice in patent law, which falls within the Federal Circuit’s exclusive appellate jurisdiction. The FCBA and its members therefore have a particular interest in this case.¹

The FBCA submits this brief to respond to the six questions provided in the Court’s April 26, 2010 Order and is submitted pursuant to the authorization of that Order and with the consent of all parties pursuant to Federal Rule of Appellate Procedure 29(a).

¹ The FCBA is composed of private, government, academic, and other members of the bar with an interest in the United States Court of Appeals for the Federal Circuit. The government members of the Association did not participate in the preparation of this amicus brief.

ARGUMENT

Over two decades ago, this Court stated that “the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.” *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 n.15 (Fed. Cir. 1988) (quoting *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)). According to some commentators, unsupportable allegations of inequitable conduct represent an immediate and urgent jurisprudential problem demanding attention, reform and the development of new standards.² For lawyers practicing before the United States Patent and Trademark Office (“USPTO”), a compelling need exists for clarity and continuity between regulations governing practice before the USPTO and the substantive law of inequitable conduct. In light of these concerns and others discussed more fully below, the FCBA believes that the state of inequitable conduct jurisprudence will benefit by clarifying the current analytical framework, not replacing it with an entirely new analysis.

As this Court did with its *Kingsdown* and *Burlington* decisions in 1988, the FCBA believes that the Court should again clarify the standards for proving

² See, e.g., Christian E. Mammen, *Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct*, 24 Berkeley Tech. L. J. 1329 (2009); Gerald Sobel, *Reconsidering the Scope of the Inequitable Conduct Doctrine In View of Supreme Court Precedent and Patent Policy*, 18 Fed. Circuit B. J. 169 (2006).

inequitable conduct within its existing analytical framework. In particular, this Court should:

- (i) adopt a single materiality test based on the current Rule 1.56(b) standard set forth by the Patent Office in 1992;
- (ii) clarify the proof needed to establish intent to deceive;
- (iii) reiterate the holding of *Kingsdown* that gross negligence or “knew or should have known” is not the standard to prove intent to deceive by clear and convincing evidence;
- (iv) clarify the relationship between the materiality and intent elements, stating that each must be proven by clear and convincing evidence and that the degree of materiality may affect the amount of evidence of intent to deceive required; and
- (v) clarify the importance of the final balancing step in which the evidence of both materiality and intent to deceive are weighed to determine whether the equitable remedy of unenforceability is warranted.

The FCBA believes that clarifying the current framework in this way will address legitimate concerns over consistency and predictability of the doctrine while at the same time preserving decades of useful precedent and an important defense that protects the public interest in patent prosecution free of inequitable conduct.

I. This Court's Materiality-Intent-Balancing Framework for Inequitable Conduct Should Not Be Modified or Replaced But Should Be Clarified and Restated.

In response to Questions 1 and 2 of the Court's April 26, 2010 en banc Order,³ the current framework for determining inequitable conduct should be retained. Generally, that framework requires proof of materiality and intent to deceive elements, and then a weighing of the proof of these elements to determine whether, in equity, the patent at issue should be declared unenforceable. This framework retains the flexibility to address varying fact patterns involving evidence of different degrees of materiality or intent to deceive in the context of this equitable doctrine. The FCBA believes that decades of precedent applying this framework—which in and of itself provides clarity as to the metes and bounds of inequitable conduct—should not be discarded to experiment with entirely new standards. Moreover, the adoption of a narrow “but for” fraud-based requirement may be inconsistent with the trilogy of Supreme Court cases from which the inequitable conduct doctrine developed — *Keystone Drilling*, *Hazel-Atlas Glass*, and *Precision Instrument Mfg.*

³ *Therasense, Inc. v. Becton, Dickinson and Company*, slip op. 2010 WL 1655391 (Fed. Cir. April 26, 2010) (1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?, 2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? (citations omitted)).

Genuine questions exist whether limiting the doctrine of inequitable conduct to fraud comports with Supreme Court law. The fact patterns in *Keystone Drilling*, *Hazel-Atlas Glass*, and *Precision Instrument Mfg* all involved bad acts (e.g., fraud, bribery and perjury); however, the cases rest upon public policies and legal doctrines that would not require a finding that the patent would not, or should not, have issued but for the misconduct. Rather, these cases applied the equitable maxim that “he who comes into equity must come with clean hands.” *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945); *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 243-44 (1933); *Hazel-Atlas Glass*, 322 U.S. 238, 248 (1944). Explaining the burden this equitable maxim places on parties seeking equitable relief, the Supreme Court stated it does require “that they shall have acted fairly and without fraud or deceit as to the controversy in issue.” *Precision Instrument Mfg.*, 324 U.S. at 814-15 (citing *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245 (1933); omitting other citations). Criminal or fraudulent conduct, while sufficient to invoke the maxim, apparently was not necessary. As the Supreme Court explained:

Accordingly one’s misconduct need not necessarily have been of such a nature as to be punishable as a crime or as to justify legal proceedings of any character. 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 maxim by the chancellor.

Precision Instrument, 324 at 815. In short, the doctrine, as applied in the context of patent unenforceability by the Supreme Court in *Precision Instrument*, is not strictly limited to fraud and may be invoked for any intentional act that transgresses equitable standards of conduct.

The Supreme Court, applying this maxim in the context of patent unenforceability, additionally emphasized the breadth of the doctrine underlying inequitable conduct:

The maxim necessarily gives wide range to the equity court's use of discretion in refusing to aid the unclean litigant. It is 'not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion.'

Precision Instrument, 324 U.S. at 815 (quoting *Keystone Driller*, 290 U.S. at 246 (1933)). In this context, the Court also emphasized the importance of the proper application of this doctrine to patent cases, given the considerable public interest in patents being free from fraud or other inequitable conduct:

The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds **free from fraud or other inequitable conduct** and that such monopolies are kept within their legitimate scope.

Precision Instrument, 324 U.S. at 816 (emphasis added). Thus, the equitable maxim, and resulting patent unenforceability defense, as applied in *Precision*

Instrument, exists at its core to make sure patents “spring from backgrounds free from fraud or other inequitable conduct.” *Id.* It is not strictly limited to fraud, and any such limitation imposed by this Court in the form of a new fraud-based standard would seem to exclude “other inequitable conduct” and as a result, may be inconsistent with *Precision Instrument*. See also *Hazel-Atlas Glass*, 322 U.S. 238, 246 (1944) (the possession and assertion of patent rights are “issues of great moment to the public”).

The Supreme Court’s *Corona Cord Tire* decision has been cited to suggest that its precedent does not support the materiality of misrepresentations concerning an issue peripheral to patentability and consequently that the current materiality standards may be too broad. See, e.g., Gerald Sobel, *Reconsidering the Scope of the Inequitable Conduct Doctrine In View of Supreme Court Precedent and Patent Policy*, 18 Fed. Cir. B.J. 169, 183 (2008) (citing *Corona Cord Tire Co.*, 276 U.S. at 374). This case, however, preceded the trilogy of cases based on the unclean hands doctrine. As discussed, *supra*, it was the application of this doctrine that led to the inequitable conduct defense. Although the affidavits at issue in *Corona Cord Tire* misstated certain details on how the alleged invention had been reduced to practice, the affidavits were accurate in reporting that it had been reduced to practice and were characterized by the Court as “perhaps reckless.” *Id.* at 374. The issue in *Corona Cord Tire* concerned only whether the misrepresentation affected the

presumption of validity in the context of an invalidity defense at a time before the inequitable conduct defense existed. *Id.* at 374. It cannot fairly be read to abrogate the broader (and later) language of, for example, *Precision Instrument*, which based the inequitable conduct doctrine on “fraud or other inequitable conduct” and “any willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct.” *Precision Instrument*, 324 U.S. at 815-16.

There is no reason to abandon decades of Federal Circuit precedent developing this materiality-intent-balancing framework in favor of a narrower standard that would exclude “other inequitable conduct” from the defense. This is particularly so given the real potential that the Supreme Court may find such a test too narrow and restrictive to allow just application of this doctrine in various circumstances.

Instead, concerns about the overuse or “plague” of the inequitable conduct defense are better addressed by restating and clarifying its application, in the context of the materiality-intent-balancing test, as this Court did in its en banc treatment and rejection of a gross negligence standard in *Kingsdown*.

Tightening the substantive standards on what must be proven to establish inequitable conduct—particularly in conjunction with this Court’s heightened

*Exergen*⁴ pleading standards for inequitable conduct—should effectively deal with existing concerns without abandoning decades of important precedent.

II. A Single Standard for Materiality Based on Rule 56 Should Be Adopted.

In response to Question 3 of the en banc order,⁵ a single test for materiality should be adopted and it should be based on current Rule 56. *See* 37 C.F.R. § 1.56(b) (1992). Doing so would simplify the current analysis, under which this Court recognizes five different materiality standards. *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006). Other currently-accepted materiality tests—based on the prior Rule 56 or the common law—should be abandoned. Such tests are confusing, more difficult to apply, too subjective and unnecessarily duplicative.

As background, three of the currently-recognized materiality standards are based on common law and have been described by this Court as (i) an objective “but for” standard, (ii) a subjective “but for” test, and (iii) a subjective “but it may have” standard under which omissions or misrepresentations may be material if

⁴ *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009).

⁵ *Therasense, Inc. v. Becton, Dickinson and Company*, slip op. 2010 WL 1655391 (Fed. Cir. April 26, 2010) (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?).

they may have resulted in a rejection of the patent application. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362-63 (Fed. Cir. 1984).

Additionally, two materiality standards are based on the Patent Office regulations concerning the duty of disclosure under Rule 56. In 1984, this Court described the pre-1992 version of Rule 56 as a materiality standard “strikingly similar” to the common law standard (“but it may have”), and the Court found the pre-1992 version of Rule 56 “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.” *American Hoist & Derrick*, 725 F.2d at 1362-63. This materiality standard, known as the “reasonable examiner” standard, provides that information “is material where there is [1] a *substantial likelihood* that [2] a reasonable examiner [3] would consider it important [4] in deciding whether to allow the application to issue as a patent.” *American Hoist & Derrick*, 725 F.2d at 1362.

In 1992, the Patent Office amended this standard with a new Rule 56, re-defining the materiality of omissions or misrepresentations before the Patent Office as follows:

Under this section, 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 application takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.”

37 C.F.R. § 1.56(b) (1992). This section further defines prima facie case:

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(b) (1992). This rule was “amended to present a clearer and more objective definition of what information the Office considers material to

patentability.” Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (January 17, 1992).

Under the current Rule 56 standard, new information is material if it establishes either “a prima facie case of unpatentability” or “refutes, or is inconsistent with a position the applicant takes.” *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed. Cir. 2003).

While this Court has continued to recognize all five materiality standards, it has recognized that they are genuinely different, and that the kind and nature of the proof of intent must be higher where only the lower materiality standards are met:

[W]here ‘a reasonable examiner would merely have considered particular information to be important but not crucial to his decision’ the requisite finding of intent must be high. Conversely, where an objective ‘but for’ standard of materiality is shown, ‘a lesser showing of

facts from which intent can be inferred may be sufficient.’

Digital Control, 437 F.3d at 1315-16 (citations omitted). This Court has explained “[t]here is no reason [] to be bound by any single standard,’ as a finding of inequitable conduct requires a balancing of materiality and intent.” *Id.* at 1315 (citation omitted). But to the extent this balancing of materiality and intent is maintained within the current framework, as recommended herein, there is no reason not to adopt a single standard that is appropriately broad and not unduly subjective. In other words (and as discussed in section IV *infra*), a threshold materiality determination should be made based on a single standard and then, if materiality is found, the degree of materiality may be considered to determine the evidence needed to establish the intent element.

The adoption of a single standard will improve consistency in the litigation of materiality. The PTO’s current Rule 56 is the best choice for various reasons. This rule has been in place—governing practice before the Patent Office—for nearly twenty years. Its adoption as the single standard would appropriately conform the standard for determining the materiality of alleged misconduct before the Patent Office with the standard that applies to those appearing before the Patent Office. This standard encompasses, but is appropriately broader than, the objective “but for” materiality standard. Nevertheless, it is an objective standard that is

preferable and more easily applied than the subjective “reasonable examiner” standard.

Abandoning the “reasonable examiner” standard in litigation of inequitable conduct claims—as the Patent Office did long ago for ascertaining misconduct—will provide a more objective and consistent framework that would be more easily and consistently applied by courts. Uniformity will be promoted. While a violation of Rule 56 is not dispositive of inequitable conduct because materiality is but one element in the analysis, it should be determinative of materiality. The standard for materiality should be the same in litigation as before the Patent Office.

III. Intent to Deceive Should Not Be Inferred Solely From Circumstantial Evidence of Materiality.

In response to Question 4 of the en banc order,⁶ this Court should use this en banc rehearing, as it did *Kingsdown*, to clarify the standard for proving intent to deceive.

The *Kingsdown* Court decided, en banc, that an intent to deceive may not be inferred from a finding of gross negligence:

“Gross negligence” has been used as a label for various patterns of conduct. It is definable, however, only in terms of a particular act or acts viewed in light of all the circumstances. We adopt the view that a finding that

⁶ *Therasense, Inc. v. Becton, Dickinson and Company*, slip op. 2010 WL 1655391 (Fed. Cir. April 26, 2010) (4. Under what circumstances is it proper to infer intent from materiality? (citation omitted)).

particular conduct amounts to “gross negligence” does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.

Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) (citing *Norton v. Curtiss*, 433 F.2d 779 (C.C.P.A 1970)).

Some recent cases of this Court raise serious concerns about a lowered threshold of proof for the intent to deceive element, making inferences apparently inconsistent with *Kingsdown*. See, e.g., *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1350 (Fed Cir. 2008), *cert. denied*, 129 S. Ct. 2053 (2009) (finding intent to deceive concerning affidavit that compared compound half life measurements without disclosing dosage differences, where the inference of intent was made without expressly finding it was the single most reasonable inference); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. 2008) (finding inference of deceptive intent when “(1) highly material information is withheld; (2) ‘the applicant knew of the information [and] ... knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding”); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1194 (Fed. Cir. 2006) (finding intent to deceive by failing to disclose affiliation between declarant and applicant apparently based on finding that applicant should have known of the materiality of the withheld affiliation); *Novo Nordisk Pharm.*,

Inc. v. Bio-Technology Gen. Corp., 424 F.3d 1347 (Fed. Cir. 2005) (finding intent to deceive by Danish inventor who “should have known” a patent regulatory requirement not to use the past tense in prophetic patent example, even though the Court found the inventor did not know the requirement and “did not intentionally breach his duty of candor and good faith”); *Critikon, Inc. v. Becton Dickinson Vascular Access*, 120 F.3d 1253 (Fed. Cir. 1997) (holding “intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO’s consideration of the patent application”).

The post-*Kingsdown* application of this “should have known” materiality standard dates at least to *Critikon*. But *Critikon* relied on *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed Cir. 1986)—a case explicitly overruled by *Kingsdown*⁷—to apply its “knew or should have known” negligence standard to infer intent. *Critikon*, 120 F.3d at 1256 (“For example, intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO’s consideration of the patent application”); see also *Larson Mfg. Co. of S.D. v. Aluminart Prods.*, 559 F.3d 1317, 1343 (Fed. Cir. 2009) (Linn,

⁷ *Kingsdown*, 863 F.2d at 876 (“Some of our opinions have suggested that a finding of gross negligence compels a finding of an intent to deceive [citing, among other cases, *Driscoll v. Cebalo*] ... 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;...””).

J. concurring) (recognizing *Critikon* and other cases have introduced a “should have known” standard to prove intent that is lower than the gross negligence standard rejected by *Kingsdown*); *Ferring*, 437 F.3d at 1202 (Newman, J., dissenting) (recognizing that *Critikon*’s knew or should have known standard was based on *Driscoll*, which had been overruled, en banc, by *Kingsdown*).

Notwithstanding the burden of proof, the *Critikon* decision also required an applicant to come forward with a good faith explanation for an act or omission after an accused infringer has shown that it was material and that the applicant should have known it was material. *Critikon*, 120 F.3d at 1259. The *Novo Nordisk* decision similarly inferred intent to deceive by imputing knowledge of U.S. patent regulations from an attorney to an applicant and, based on this imputation, found that the applicant “should have known” the materiality. *Novo Nordisk*, 424 F.3d at 1361-62. The *Ferring* decision inferred intent to deceive where an applicant cannot give a reasonable explanation for an act or omission. *Ferring*, 437 F.3d at 1191. These decisions, among others, seem at odds with *Kingsdown*.

Other recent Federal Circuit decisions, however, have applied strict proof requirements for the intent element, consistent with *Kingsdown*. See, e.g., *Larson Mfg. Co. of S.D. v. Aluminart Prods., Inc.*, 559 F.3d 1317 (Fed. Cir. 2009); *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008); *Abbott*

Labs. v. Sandoz, Inc., 544 F.3d 1341 (Fed. Cir. 2008). In *Star Scientific*, this Court explained the rationale for maintaining a high standard of proof:

The need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability. ... As a result, courts must ensure that an accused infringer asserting inequitable conduct has met his burden on materiality and deceptive intent with clear and convincing evidence before exercising its discretion on whether to render a patent unenforceable.

Star Scientific, 537 F.3d at 1355-56. The Court also explained that materiality and intent are separate elements requiring separate proof, and that proof of materiality cannot alone satisfy the proof requirements of the intent element. *Id.* at 1366.

Moreover, the Court, recognizing that intent may be established through circumstantial evidence, warned that such “inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.” *Id.* at 1366 (citing *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008)).

In *Larson*, this Court once again applied a high threshold for proving the intent element and vacated the lower court’s finding of intent based, in part, on applicant’s failure to explain certain omissions. This Court explained that “materiality does not presume intent, and nondisclosure, by itself, cannot satisfy

the deceptive intent element.” *Larson*, 559 F.3d at 1340. The *Larson* Court, citing *Star Scientific*, also held that the inference of intent to deceive “must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.” *Id.* at 1340.

In restating *Kingsdown* and raising the standard of proof needed to establish the intent to deceive element, this Court should expressly reverse *Critikon* and its progeny. *Star Scientific* and *Larson* appropriately raise the bar and tighten the standards by which deceptive intent must be proved. By adopting the holdings of these cases and restating adherence to *Kingsdown*, this Court will effectively address the overuse of inequitable conduct without abandoning decades of useful precedent. Consistent with these cases and *Kingsdown*, this Court should clarify the law of proving the intent element of inequitable conduct in at least the following three ways.

First, this Court should clarify that intent to deceive is an independent element that must be separately proven, by clear and convincing evidence; it may not be inferred from materiality only, and absent contemporaneous knowledge of materiality, an inference of intent to deceive would be inappropriate. The degree of materiality should determine the type and quality of evidence needed to prove intent by clear and convincing evidence.

Second, this Court should remove the concepts of gross negligence or “knew or should have known” that have crept into the inequitable conduct analysis in some post-*Kingsdown* cases.

Third, this Court should clarify that, to the extent circumstantial evidence is relied on to prove intent to deceive by clear and convincing evidence, the court must also find that an intent to deceive the PTO is the single most reasonable inference, and not merely one of many permissible or plausible inferences.

IV. The Approach of Balancing Materiality and Intent Should Not Be Abandoned But Its Application Should Be Clarified.

In response to Question 5 of the en banc order,⁸ this Court should not abandon its long-standing approach of balancing materiality and intent. This balancing takes place in two respects. First, the degree of materiality should be considered in determining the evidence needed to prove intent to deceive by clear and convincing evidence. Second, if both elements are established by clear and convincing evidence, there remains a critical balancing step where the court must determine, in equity, whether to declare the patent in question unenforceable.

Both steps are important to the flexible application of the framework and should be retained. The long-standing approach of balancing materiality and intent

⁸ *Therasense, Inc. v. Becton, Dickinson and Company*, slip op. 2010 WL 1655391 (Fed. Cir. April 26, 2010) (5. Should the balancing inquiry (balancing materiality and intent) be abandoned?).

has generated decades of precedent on the relationship between the elements. The Court should take this opportunity to clarify the application of this materiality-intent-balancing-framework, both in the context of determining the degree and kind of evidence needed to establish the intent element, as well as in determining the balancing done to determine whether to declare a patent unenforceable.

Concerning the effect that the degree of materiality has on the evidence needed to prove intent, this Court should, as discussed above, make clear that intent may not be inferred from a mere misrepresentation or omission, no matter how material, and that it must be separately proven by clear and convincing evidence. In this context, the Court should clarify that the “balancing” step should take place only after the court has concluded that there is clear and convincing evidence of materiality. *See, e.g., Star Scientific*, 557 F.3d at 1367. If materiality is not established by this standard, the analysis ends. Only after the misrepresentation or omission is found material, should the *degree* of materiality be evaluated. The type and quality of evidence then needed to establish intent by clear and convincing evidence may depend on the degree of materiality. As an example, if the information withheld was indisputably material and the evidence establishes that the actor actually knew of this information and knew it was material, little evidence will be needed to support a finding that there was an intent

to deceive. That said, intent to deceive may never be inferred from a mere finding of materiality, and must be separately proven by clear and convincing evidence.

The balancing of materiality and intent to determine whether, in equity, the patent is unenforceable takes place only after both elements have been found by clear and convincing evidence. *See, e.g., Norberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 398 (Fed. Cir. 1996) (holding that the district court properly refrained from balancing materiality and intent when a showing of one element had not been clearly and convincingly made). Even if materiality and intent to deceive are found by clear and convincing evidence, however, courts must still balance the equities to determine whether the applicant's conduct before the Patent Office was egregious enough to warrant holding the entire patent unenforceable. In this step,

the district court must balance the *substance* of those now-proven facts and all the equities of the case to determine whether the severe penalty of unenforceability should be imposed. It is this balancing that is committed to the district court's discretion.

Star Scientific, 537 F.3d at 1367 (citation omitted).

This Court should reinforce the importance of this step in the application of the doctrine. To the extent this additional step is deliberately taken, the tough case where materiality and intent to deceive exist but the conduct does not warrant a finding of patent unenforceability can be addressed, as will any concerns about the harsh nature of the remedy.

V. Standards for Materiality and Intent Before Other Federal Agencies Should Not Be Determinative of Inequitable Conduct Before the U.S. Patent and Trademark Office.

In response to Question 6 of the en banc order,⁹ the standards for materiality and intent in other federal agency contexts are not determinative in the context of inequitable conduct. Those standards are unlikely to be useful, as the objectives of other agencies are so disparate from those of the U.S. Patent and Trademark Office. To the extent that the rights at issue and the circumstances that exist before the Patent Office are comparable to the rights at issue and circumstances that exist before another federal agency, that agency's standards may be considered and may be relevant. But if the current framework is retained and clarified, there is ample precedent on materiality and intent in the specific context of allegations of inequitable conduct to make it unnecessary to search for possibly analogous rights and standards concerning practice before other federal agencies.

⁹ *Therasense, Inc. v. Becton, Dickinson and Company*, slip op. 2010 WL 1655391 (Fed. Cir. April 26, 2010) (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).

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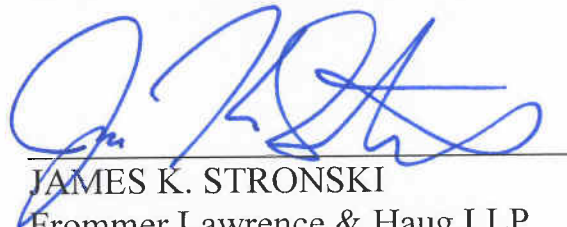
⁹ *Therasense, Inc. v. Becton, Dickinson and Company*, slip op. 2010 WL 1655391 (Fed. Cir. April 26, 2010) (6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context).

CONCLUSION

For the aforementioned reasons, *amicus curiae* FBCA respectfully submits that this Court should tighten the existing framework and substantive standards for proving inequitable conduct, including the adoption of a single standard for the materiality element, the clarification of the proof required to satisfy the intent to deceive element, and the clarification of how materiality and intent are balanced to determine whether, in equity, a patent should be declared unenforceable.

Dated: August 2, 2010

Respectfully Submitted,



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PROOF OF SERVICE

I hereby certify that on August 2, two copies of the foregoing “Brief Of The Federal Circuit Bar Association As *Amicus Curiae* in Support of No Party” were served by Federal Express on the other parties in this appeal by sending the copies to the following attorneys for the other parties:

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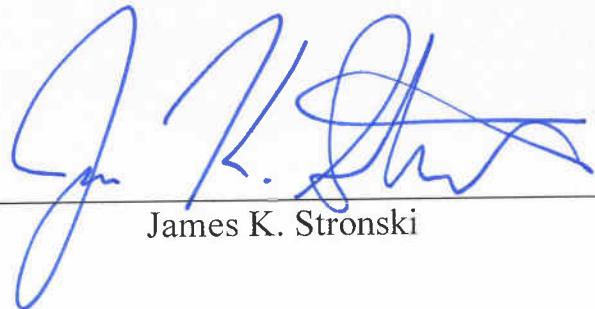
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**CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 32(a)(7)(B)**

I certify that the foregoing “Brief of *Amicus Curiae* The Federal Circuit Bar Association In Support of Neither Party” complies with the type-volume limitation in Federal Rule of Appellate Procedure 32(a)(7)(B). In particular, excluding the parts exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii), this brief contains 4,748 words as reported by the word-processing program Microsoft® Office Word 2003.

I also certify that the foregoing “Brief of *Amicus Curiae* The Federal Circuit Bar Association In Support of Neither Party” complies with the typeface requirements in Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements in Federal Rule of Appellate Procedure 32(a)(6). In particular, this brief has been prepared in a proportionally spaced typeface, i.e., Times New Roman, in 14-point font.



James K. Stronski