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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EN BANC BRIEF OF DEFENDANTS-APPELLEES BECTON, DICKINSON AND COMPANY AND NOVA BIOMEDICAL CORPORATION

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FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Therasense, Inc. and Abbott Laboratories v. Becton, Dickinson & Co. and Nova Biomedical Corp.

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

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Becton, Dickinson & Co. and Nova Biomedical Corp. 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:

Becton, Dickinson and Company;
Nova Biomedical Corp.

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 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:

Please see the attached sheet

7 Oct. 2010
Date

Signature of counsel

BRADFORD J. BADKE
Printed name of counsel

Please Note: All questions must be answered

cc: Rohit Singla, Esq.; John Whealan, Esq; Rachel Krevans, Esq.

CERTIFICATE OF INTEREST - Attachment

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:

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Abbreviation	Meaning
’551 patent	U.S. Patent No. 5,820,551
’382 patent	U.S. Patent No. 4,545,382
’636 counterpart	EPO No. 078636B2
EPO	European Patent Office
PTO	United States Patent and Trademark Office
Abbott	Abbott Diabetes Care, Inc. (formerly Therasense, Inc.) and Abbott Laboratories
Bayer	Bayer Healthcare LLC
BD	Becton, Dickinson and Co.
Gov’t __	Page __ of Brief For The United States as Amicus Curiae On Rehearing *En Banc* In Support Of Neither Party
LifeScan	LifeScan, Inc.
Medisense	Medisense, Inc.
Nova	Nova Biomedical Corp.
Roche	Roche Diagnostics Corp.
Pope	Attorney Lawrence Pope
Sanghera	Dr. Gordon Sanghera

Emphasized Text

Unless otherwise noted, all emphasis in quoted text has been added

STATEMENT OF RELATED CASES

No appeal in or from this civil action was previously before this Court or any other appellate court. The Court decided another appeal from the same District Court proceedings on January 25, 2010 in *Therasense, Inc. (now known as Abbott Diabetes Care, Inc.) and Abbott Laboratories v. Becton, Dickinson and Company and Nova Biomedical Corporation*, Nos. 2009-1008, -1009, -1010, -1034, -1035, -1036, -1037. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325 (Fed. Cir. 2010) (Linn, Friedman, Dyk).

SUMMARY OF ARGUMENT

The District Court's finding that Abbott's U.S. Patent No. 5,820,551 ("the '551 patent") on blood glucose sensors was procured by inequitable conduct was correctly decided and properly affirmed by this Court. Abbott's misconduct in prosecuting this patent was inequitable, even fraudulent, under any standard. If ever a case clearly and convincingly compelled a conclusion of inequitable conduct, this is it.

The *Therasense* Case

Over thirteen years of prosecution, the '551 patent-in-suit had been rejected eleven times in view of Abbott's own prior art U.S. Patent No. 4,545,382 ("the '382 patent"), or its European counterpart, EPO No. 078636B2 ("the '636 counterpart").[1] Faced with these repeated rejections, in 1997, Attorney Pope took over the prosecution and brainstormed with Abbott's Director of R&D, Dr. Sanghera, to devise a plan to secure the '551 patent. Both were highly sophisticated in patent prosecution and highly motivated to obtain a patent at any cost in the face of growing competitive pressure. Indeed, not only did they successfully procure the '551 patent, but they eventually helped enforce it against competition once it issued.

[1] The '636 and '382 disclosures are virtually identical. Trial Op. at 1108.

The plan Pope and Sanghera devised to distinguish Abbott's prior art '382 patent was to submit, for the first time in the '551 prosecution, new claims directed to a glucose sensor that lacked a membrane. But, as the Examiner noted, Abbott's '382 patent already taught that membranes were optional. To overcome the Examiner's rejections, Pope convinced him to accept Sanghera's declaration swearing that a person of ordinary skill in the art would not read the '382 patent as the Examiner originally understood it, but instead would understand the '382 patent to "require" a membrane, contrary to its plain language. Pope made the same argument in support of allowance.

But Pope and Sanghera did not tell the PTO the whole story. They did not tell the Examiner about Abbott's prior submissions to the EPO to save the '636 counterpart to the '382 patent, which said the exact opposite: that the '382/'636 prior art "does not require a membrane." Pope and Sanghera were well aware of those admissions. Sanghera helped draft those EPO papers, and discussed their content and meaning with Pope. Although PTO Rule 1.56 at that time required disclosure of these inconsistent statements as material information,[2] Pope and Sanghera made the deliberate decision to withhold them to get the '551 patent allowed.

[2] 37 C.F.R. § 1.56(b)(2) deems information that "refutes, or is inconsistent with" an applicant's position in opposing unpatentability or asserting patentability is material.

Abbott claims this case was wrongly decided, yet avoids the facts for the first 47 pages of its brief. It then omits Sanghera's role in drafting the EPO papers and the critical fact that they explicitly state that a membrane was "not require[d]" by Abbott's prior art. Likewise, no *amici* fully analyze the facts in *Therasense* to defend Pope or Sanghera's misconduct. Doing so would only reveal that the conduct is inequitable under any standard proposed.

Abbott's argument that District Court Judge William H. Alsup, who presided over the trial, found Pope and Sanghera not to be credible witnesses only because he disagreed with their explanation for withholding is incorrect. The District Court searched long and hard for any exculpatory evidence of good faith, and found none. Pope and Sanghera's implausible excuses were a moving target contradicted by their own admissions. They tried to twist the plain language of the EPO papers to ignore Abbott's admission that membranes were "optional," but ultimately admitted that their tortured reading contradicted plain English. The District Court, having observed their demeanor, found that Sanghera, in particular, "was impeached on substantive points with his prior inconsistent statements" and that neither he nor Pope was credible. *Therasense v. Becton, Dickinson & Co.*, 565 F. Supp. 2d 1088, 1113, 1115-16 (N.D. Cal. 2008) (hereinafter "Trial Op.").

This is not a case of mere attorney argument to the PTO about prior art that the Examiner can assess for himself. It is instead a case of a strategic decision to

conceal inconsistent EPO admissions to deceive the Examiner into relying on Sanghera's declaration that a skilled person has a contrary view of the art. In this area of extrinsic evidence, the PTO was unable to fend for itself. This Court's affirmance of invalidity based on the '382 patent confirms the '551 patent would not have issued over that art absent Pope and Sanghera's deception. *Therasense v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1299-1300 (Fed. Cir. 1010) (hereinafter "Panel Op.").

The Legal Standard For Inequitable Conduct

Therasense exemplifies the proper standard for the inequitable conduct doctrine. The District Court correctly found, and the Panel affirmed, inequitable conduct using the materiality-intent-balancing test, where the version of Rule 1.56 in effect at the time of the conduct in question established materiality, and deceptive intent was the single most reasonable inference based on the totality of the evidence. The balance of equities weighed heavily in favor of finding inequitable conduct.

This Court should affirm this materiality-intent-balancing test as the standard to be applied where withheld information bears on patentability. It is the most practical standard, and best promotes the public policy interest in the issuance of valid patents, while providing a defined, reasonable standard for practitioners.

Materiality: The materiality standard should be defined by PTO Rule 1.56 in effect at the time of the conduct in question. While Abbott argues that this Court *need not* pay heed to the PTO's Rule, (Abbott 36-37),[3] it does not explain why this Court *should not* do so. Given that the charge of inequitable conduct effectively is that the applicant did not disclose what he was duty-bound by PTO Rules to submit, the most logical measure of whether he breached that duty is the Rule that defines what information the PTO requires to do its job. Any disconnect between the PTO's Rule and what the courts later enforce will undermine the duty of disclosure that forms the lynchpin of the U.S. patent system. As the PTO itself warns in its *amicus* brief, if the materiality standard is broader than the Rule (*e.g.*, "reasonable examiner") "dumping" is likely to occur. (Gov't 17).[4] If it is narrower (*e.g.*, "but/for"), there is no need to comply with the Rule, rendering it meaningless.

Abbott misreads the trilogy of Supreme court cases -- *Keystone*, *Hazel-Atlas*, and *Precision*[5] -- to argue for a "but/for" materiality standard on the theory that

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[3] "Abbott __" refers to the specified page(s) of Abbott's August 3, 2010 Brief on Rehearing.

[4] "Gov't __" refers to the specified page(s) of the August 2, 2010 *amicus* brief of the United States. Other *amicus* arguments are addressed without reference to the specific *amicus*.

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

unenforceability is limited to cases of overt fraud. While fraud on the PTO undoubtedly qualifies as inequitable conduct, *Precision* created the latter as a defense distinct from fraud. *Precision*, 324 U.S. at 816. The Court could not have intended the two to be redundant. A "but/for" materiality standard violates this precedent.

The "but/for" test is ill-advised. In cases where the prosecution record is less clear than here, it may be difficult to prove "but/for" causation despite deceptive behavior. Many more improperly procured patents would survive litigation and suppress competition under this test.

Even if the "but/for" test applied, the record here nonetheless clearly establishes materiality - "but/for" Sanghera's misleading declaration and the concealed EPO papers, the '551 patent would not have issued.

Intent: The parties agree that deceptive intent should be the single most reasonable inference based on the totality of the evidence, including any evidence of good faith, as set forth in *Star Scientific*.[6] This high bar for showing intent is the standard the District Court and this Court applied. It gives the patentee the benefit of every doubt because he need not offer any explanation for his conduct in the first instance. If, however, he elects to rebut the evidence of intent, his explanation

[6] *Star Scientific, Inc. v. Reynolds Tobacco Co.*, 537 F.3d 1357, 1367 (Fed. Cir. 2008).

can, and should, be subject to scrutiny. Abbott confuses this opportunity for the patentee to rebut as burden shifting. It is plainly different.

Nor is there any dispute that intent and materiality are separate elements that must each be shown. Intent cannot be inferred from high materiality alone, although evidence of materiality may also be circumstantial evidence of intent. For example, the withheld inconsistent EPO statements in *Therasense* provide both evidence of high materiality under Rule 1.56 and evidence of deceptive intent because they show why Pope and Sanghera were motivated to conceal them. Abbott mistakes this commonality of relevant *facts* as conflating the *elements* themselves. It does not. Excluding certain facts from the intent analysis because they also show materiality ignores reality.

Balancing: Abbott argues that balancing the equities dilutes the materiality and intent elements. (Abbott 41-47). But balancing is not reached until each element is first proven by clear and convincing evidence. If either is missing, there is nothing to balance, and therefore no inequitable conduct. Contrary to Abbott's assertions, the balancing step can only help patentees because courts may still decline to find inequitable conduct, even if both materiality and intent are present, if the equities so require.

* * *

To the extent inequitable conduct is raised in cases where the facts are less compelling than in *Therasense*, it is not due to any flaw in the materiality-intent-balancing framework. Rather, it reflects confusion as to what constitutes inequitable conduct because courts continue to raise outdated and inconsistent materiality and intent standards. This uncertainty causes over-assertion of the defense.[7] Clarifying *en banc* that the *Therasense* analysis is correct for cases where the information at issue bears on patentability should significantly reduce meritless inequitable conduct charges, and assist courts in disposing of non-meritorious allegations early in litigation.

The PTO, at this Court's invitation, filed an *amicus* brief in this appeal. The materiality-intent-balancing standard it advocates is the same as that applied in *Therasense*. As the agency tasked with the issuance of valid patents, it is in the best position to determine what it needs to do its job.

This Court can use *Therasense* to exemplify the proper application of the materiality-intent-balancing test. The District Court correctly found, and the Panel properly affirmed, inequitable conduct here. Sanghera's declaration and the

[7] For all of Abbott's complaints that the inequitable conduct standard is somehow deficient, the infrequency of actual findings of inequitable conduct suggests otherwise. Between 2000 and 2008, this Court affirmed inequitable conduct in less than 0.5% of the cases where it was pled. Christian Mammen, "Controlling The 'Plague': Reforming The Doctrine Of Inequitable Conduct," 24 Berkeley Tech. L.J. 1329, 1358-59 (2010).

withheld inconsistent EPO admissions were highly material under Rule 1.56 at the time of the misconduct. The overwhelming evidence of intent to deceive leaves no doubt that this was the single most reasonable inference that could possibly be drawn. The District Court was well aware that the defense is susceptible to abuse, and ought to be viewed with skepticism. Trial Op. at 1117. Yet, it found "every inch of the clear and convincing standard" met such that the present case was not an abuse, but far from it. *Id*.

Even if this Court deviates from the materiality-intent-balancing standard *Therasense* applied, the misconduct here was so egregious that it warrants affirmance of inequitable conduct under any standard. The District Court warned that if the conduct here was blessed, "we would in effect be issuing licenses to deceive patent examiners in virtually all cases" such that PTO Rule 1.56 "would be a dead letter." Trial Op. at 1114, 1117. The Majority agreed, noting that *Therasense* is "one of those rare cases in which a finding of inequitable conduct is appropriate." Panel Op. at 1300; *see also* Trial Op. at 1116-17. Any other result would condone such deceitful action and completely "eviscerate the duty of disclosure." Panel Op. at 1305.

STATEMENT OF ISSUES

As discussed in detail below, the answers to the Court's questions on rehearing *en banc* are as follows:

Q1: The materiality-intent-balancing framework should remain in place for cases in which the information at issue bears on patentability of claims. The few cases in which the conduct has no bearing on patentability are better referred to the PTO for disciplinary action or analyzed under the unclean hands doctrine.

Q2: The inequitable conduct standard should not be tied to fraud. The Supreme Court created this defense as a specific act of unclean hands for patents, separate from fraud. This distinction is binding.

Q3: The materiality standard should be the version of PTO Rule 1.56 in effect at the time of the conduct in question.

Q4: Intent cannot be inferred from materiality alone, but evidence of high materiality is circumstantial evidence of intent.

Q5: Materiality and intent must each be found by clear and convincing evidence first. Courts should then balance the equities to avoid finding inequitable conduct when the overall circumstances require a different outcome.

Q6: Standards in other federal agencies or other areas of common law are ill-suited for patents.

The ultimate issue before the Court is whether the District Court correctly found, and this Court properly affirmed, that Pope and Sanghera procured the invalid claims of the ’551 patent by inequitable conduct.

ARGUMENT

I. THE VERSION OF PTO RULE 1.56 IN EFFECT AT THE TIME OF THE CONDUCT IN QUESTION SHOULD DEFINE MATERIALITY AS *THERASENSE* EXEMPLIFIES

This Court asks what the proper standard for materiality should be and what role the PTO's Rules should play in defining materiality. (Order for *En Banc* rehearing, Q3). Because the materiality issue in the inequitable conduct analysis is whether an applicant failed to disclose material information to the PTO, the proper standard to determine whether the information in question was actually material so as to have warranted disclosure should be PTO Rule 1.56 at the time of the conduct in question.[8] As discussed below, this approach consistently serves both purposes of the materiality standard: (1) to guide applicants as to their duty of disclosure in prosecution, and (2) to serve as a benchmark for determining inequitable conduct in litigation.

The best authority on what the PTO needs to fulfill its statutory mandate of issuing valid patents is the PTO itself. Rule 1.56 constitutes what the PTO deems necessary to allow it to perform this function. Indeed, the PTO urges this Court to adopt this standard to enable it to evaluate patent applications fairly and efficiently. (Gov't 8-12).

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[8] This materiality requirement should relate only to what is material to patentability, not to other acts unrelated to patentability. (*Infra*, p. 50-51).

When the PTO receives the art it requires -- nothing more and nothing less -- it can best assess whether an invention is worthy of patent protection. The courts should apply the same materiality standard as the PTO. A broader standard than what the PTO requires (*e.g.*, "reasonable examiner") may cause applicants to overdisclose during prosecution. A narrower standard (*e.g.*, "but/for") may result in underdisclosure. (*Infra*, p. 18-19). There should be a common standard of materiality, and that standard should track PTO Rule 1.56. This provides a consistent rule of conduct and gives fair notice to prosecutors and litigants alike.

The notion that PTO Rule 1.56 at the time of the conduct should govern when assessing whether that conduct was inequitable is nothing new. That logic has been acknowledged by this Court over the past quarter century, including this one. *See, e.g.*, Panel Op. at 1305; *see also Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363-1364 (Fed. Cir. 1984); *Taltech Ltd. v. Esquel Enters.*, 604 F.3d 1324, 1329, 1333 (Fed. Cir. 2010); *Rothman v. Target Corp.*, 556 F.3d 1310, 1323 (Fed. Cir. 2009).

A. A Uniform Materiality Standard For The PTO And The Courts Will Limit The Number Of Inequitable Conduct Cases

The reason inequitable conduct is frequently raised is not because Rule 1.56 is defective, but because courts apply different materiality standards than what governed prosecution in the PTO. This disconnect is due to the fact that although the current version of Rule 1.56 has governed prosecution for nearly two decades,

prior tests for materiality have not been overruled and continue to be enforced by the courts. *See Digital Control Inc. v. Charles Mach. Works,* 437 F.3d 1309, 1314-16 (Fed. Cir. 2006); *Am. Hoist,* 725 F.2d at 1362-1363; *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363-64 (Fed. Cir. 2003); *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1354 (Fed. Cir. 2008).

In 1977, the PTO promulgated the "reasonable examiner" standard in Rule 1.56. In 1992, the PTO narrowed its Rule to require information that raises a "prima facie case of unpatentability" or is "inconsistent" with a position the applicant takes in prosecution. M.P.E.P. §2001.4 (noting "37 CFR 1.56 has been amended to present a *clearer and more objective* definition of what information the Office considers material to patentability" and "to address criticism concerning a perceived lack of certainty in the materiality standard"). Because current Rule 1.56 is more precise than the "reasonable examiner" standard (Gov't 8-12), certain information may be material under the previous rule, but not under the current rule. Yet the pre-1992 "reasonable examiner" standard has been raised with respect to conduct that occurred after the Rule changed. *See, e.g., Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1367 (Fed. Cir. 2008); *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1366 (Fed. Cir. 2007).

The result of applying a different standard in litigation than what governed prosecution is unfair because a patentee who complied with Rule 1.56 during

prosecution may nonetheless face an allegation of inequitable conduct at trial. The uncertainty as to which materiality standard will apply in litigation – notwithstanding full compliance with the PTO's Rule at the time of the conduct – contributes to the frequency of the inequitable conduct defense. Moreover, this disconnect creates uncertainty and inefficiency during prosecution. It forces applicants to submit information that may be required under any rule, flooding the PTO with more information than it needs to do its job. (Gov't 17).

B. The Standard Of Inequitable Conduct Should Remain Separate From Fraud

The answer to the Court's question of whether the materiality-intent-balancing framework for inequitable conduct standard should be replaced by something tied directly to fraud is no. The Supreme Court created the inequitable conduct defense as a specific form of unclean hands separate from fraud in *Precision* to redress misconduct involving a patent. *Precision*, 324 U.S. at 816. (Order for *En Banc* rehearing, Q1 and Q2). Prior to that case, under *Keystone* and *Hazel-Atlas*, a challenger had to rely solely on either a more general application of unclean hands or fraud, both of which suffered shortcomings in the patent context. Inequitable conduct overcame those shortcomings by providing specific guidance for the application of unclean hands in the patent context, and an alternative to fraud. Its materiality-intent-balancing framework should remain.

1. The Creation Of The Doctrine

In *Keystone*, the Supreme Court dismissed the patentee's infringement claims for unclean hands because it had suppressed evidence in related litigation. 290 U.S. at 244. But *Keystone's* general unclean hands doctrine is amorphous. It merely requires "some unconscionable act of one coming for relief" that has "immediate and necessary relation to the equity that he seeks." *Id.* at 245. Even then, a court is not bound by any formula in applying this maxim. *Id.* at 245-46. It thus provides little guidance to courts or litigants.

In *Hazel-Atlas*, the Supreme Court held that the patentee committed fraud to overcome "insurmountable Patent Office opposition" by paying an expert to falsely claim authorship of an article that the patentee wrote. The patentee then used the same article to prevail in litigation. 322 U.S. at 245 (this was a "deliberately planned and carefully executed scheme to defraud not only the Patent Office but the Circuit Court of Appeals"). But fraud requires showing that there was reliance on a misrepresentation and resulting harm, which may not be evident in the prosecution record in every case. *See* Restatement (Second) of Torts § 525 (1977). The total effect of the fraud in *Hazel-Atlas* was a complete a denial of relief to the patentee, as required by *Keystone's* unclean hands doctrine. *Id.* at 250-51.

In *Precision*, the Supreme Court created the inequitable conduct doctrine as distinct from fraud. The plaintiff there asserted a patent knowing it was based on a false invention date. 324 U.S. at 815-18. The Court vacated the patent because of "inequitable conduct," which it described as a particular act of unclean hands. *Id.* at 814-16, 819 (stating that plaintiff's "inequitable conduct impregnated [the] entire cause of action and justified dismissal by resort to the unclean hands doctrine"). In contrast to *Keystone's* general unclean hands doctrine, however, the Court provided further guidance about what information should be considered for inequitable conduct, ruling that the patentee must disclose "all facts concerning fraud *or inequitableness* underlying the applications in issue" to the PTO, akin to what we now consider in the materiality analysis. *Id.* at 818. And the Court warned that if such disclosure is not made, the PTO and public would become helpless victims of "deception," similar to what we analyze today under intent. *Id.* Thus, the materiality and intent elements of the current materiality-intent-balancing framework mirror this *Precision* analysis.

2. Reversion To Fraud Or Unclean Hands Generally Is Contrary To Supreme Court Precedent And The Public Interest

Reverting to a fraud, or even a general unclean hands standard, contravenes Supreme Court precedent. The Supreme Court made clear that inequitable conduct was a form of unclean hands specific to patents and separate from fraud. *Id.* at

816-18. It explained that there is an uncompromising duty to report to the PTO "all facts concerning possible fraud *or inequitableness*" because the public has a strong interest in "seeing that patent monopolies spring from backgrounds free from fraud *or other inequitable conduct*." *Id.* Several courts, including this one, have recognized this distinction in patent cases.[9]

"A patent by its very nature is affected with a public interest." *Id.* at 816. A fraud standard would harm that interest by allowing enforcement of patents procured by "other inequitable conduct" short of fraud. *Id.* Swinging the pendulum too far in the other direction to go back to *Keystone's* general unclean hands standard for all deceptive acts is equally harmful. That standard is not bound to any formula for analyzing patentability cases, and thus provides less guidance to courts and litigants than the materiality-intent-balancing test. It will

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[9] *Norton v. Curtiss*, 433 F.2d 779, 792-94 & n.12 (C.C.P.A. 1970) (explaining that "inequitable" conduct that does not meet the technical requirements of common law fraud can still result in a patent being found unenforceable); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069-71 (Fed. Cir. 1998) (inequitable conduct is a "broader, more inclusive concept" than fraud); *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 807 (Fed. Cir. 2000) (explaining that "inequitable conduct is not by itself common law fraud"); *Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 710 (1st Cir. 1981); *Carter-Wallace, Inc. v. Davis-Edwards Pharmacal Corp.*, 443 F.2d 867, 881 (2d Cir. 1971); *Eudy v. Motor-Guide, Herschede Hall Clock Co.*, 651 F.2d 299, 305 (5th Cir. 1981); *Kolene Corp. v. Motor City Metal Treating, Inc.*, 440 F.2d 77, 83 (6th Cir. 1971); *E.I. du Pont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247, 1274 (8th Cir. 1980); *Monolith Portland Midwest Co. v. Kaiser Aluminum & Chem. Co.*, 407 F.2d 288, 294 (9th Cir. 1969).

only increase the frequency of the defense by injecting uncertainty in both prosecution and litigation.

C. This Court Should Not Revert To The "But/For" Standard

Abbott proposes a materiality requirement that "but for" the alleged misconduct, one or more claims would not have issued. The Court should reject that proposal. (Order for *En Banc* rehearing, Q3). The materiality standard has evolved over time, going through four different iterations. The "but/for" standard was one of several materiality standards the courts applied from the time of *Precision* until the 1970s. Current Rule 1.56 was adopted by the PTO to overcome the weaknesses of previous standards. (Gov't 12). Reversion to the "but/for" test turns back the clock of progress.

The "but/for" test suffers from several shortcomings. The first problem is that the "but/for" standard fails to capture situations where the patent issued due to misconduct, but the prosecution record is unclear about the reason for allowance. Because Examiners may not testify in litigation, the court will not know critical facts that may prove inequitable conduct. Thus, patentees may withhold or misrepresent information that *significantly* impacts the examiner's decision to issue the patent, without creating any record that such information was *necessary* for issuance. It is the public who suffers when competition is stifled by a patent procured in violation of the PTO's Rules and left unchecked by the courts.

Moreover, the "but/for" standard is much narrower than Rule 1.56. If this Court adopts it, *dishonest* patentees could ignore the PTO's disclosure requirements knowing that the courts will apply a narrower materiality standard, without any effective sanction for violating the PTO's Rule. This would leave it to the PTO alone to enforce its rules. But, as the PTO itself states, it lacks the capability to do so. (Gov't 15-16); M.P.E.P. § 2010. An *honest* applicant, on the other hand, would be left with less guidance about what to disclose because the "but/for" test is applied in hindsight. Because he cannot know in advance what will be the "but/for" reason for allowance, he will be forced to overdisclose to the PTO out of an abundance of caution. The end result would be to undermine the duty of disclosure that is critical to the *ex parte* nature of U.S. patent prosecution.

Some *amici* state the "but/for" test requires showing that invalid claims would not have issued absent the misconduct. This concurrent requirement of an invalidity adjudication further rewards dishonest applicants. Rarely will a case meet a "but/for" test without also showing that the claims are invalid. Because the challenger bears the burden of proof in the face of a presumption of validity, the patentee will have this additional evidentiary advantage on validity to help evade a finding of misconduct.

A judicial standard of materiality that is inconsistent with Rule 1.56 will create more uncertainty and further burden not only the courts, but the PTO.

Clarifying that the standard of materiality should be whatever PTO Rule 1.56 required at the time of the conduct, as *Therasense* did, will limit the number of inequitable conduct charges, and will prevent any disconnect in the event the PTO amends Rule 1.56 again.

D. Neither Case Law Nor Statute Supports Abbott's "But/for" Proposal

Abbott mischaracterizes a litany of cases to suggest that the "but/for" test is common. Abbott's cases show no such thing.

Abbott misreads *Keystone, Hazel-Atlas*, and *Precision* to argue that they support a "but/for" fraud standard of materiality. Abbott does so by first claiming inequitable conduct originated in fraud, (Abbott 8-10), but then claiming that the "but/for" standard is required by unclean hands. (Abbott 35). Abbott's arguments are inconsistent and incorrect. Reverting to "but/for" fraud violates Supreme Court precedent that created inequitable conduct as a separate and distinct defense. (*Supra*, p. 16). Nor does the doctrine's unclean hands roots justify Abbott's test. No such standard was mentioned or applied in *Keystone*, which held that perjury during litigation constitutes unclean hands, not a misrepresentation "but/for" which claims would not have issued.[10] Abbott argues that Congress adopted the

[10] Abbott cites other unclean hands cases that allow for standards far less stringent than "but/for" causation. *See W. L.A. Inst. for Cancer Research v. Mayer*, 366 F.2d 220 (9th Cir. 1966)''(no mention of but/for fraud); *S&R Corp. v. Jiffy*

unenforceability defense in 35 U.S.C. § 282 against the backdrop of the "fraudulent procurement" standard in the trilogy of Supreme Court cases. (Abbott 12-13). If so, the statute must reflect *Precision's* unambiguous reference to inequitable conduct as an alternative to fraud.

Abbott's reliance on Supreme Court fraud cases that predate *Precision's* creation of the doctrine is misplaced, as is its reliance on early 1970's cases that have since been superseded by the PTO's Rule for materiality.[11] Neither compels application of a "but/for" test to present day inequitable conduct.

Abbott's reliance on cases outside the patent arena, beginning with copyright and trademarks, (Abbott 11-12), also fails. Copyright and trademark standards are ill-suited to patents because the impact of misconduct in patent prosecution is more deleterious to the public. An inequitably procured patent is an improper monopoly that, if allowed to survive, excludes infringing goods from the market and stifles competition. Errors in copyright and trademarks, on the other hand, do not prevent articles from entering the market provided they were not copied from another or use a different mark. Accordingly, a different materiality standard than that which is designed to check patent prosecution may be tolerable in those cases. In any

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Lube Int'l, Inc., 968 F.2d 371, 377 n.7 (3d Cir. 1992) (defendant must show "fraud, unconscionability, or bad faith on the part of the plaintiff").

[11] *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358 (1928); *Mowry v. Whitney*, 81 U.S. (14 Wall.) 434 (1871); *Norton v. Curtiss*, 433 F.2d 779 (C.C.P.A. 1971).

event, Abbott's copyright and trademark cases typically rely on something less than "but/for" causation.[12]

Abbott's reliance on contract law to support "but/for" causation is inapposite. (Abbott 35-36). The victim of fraud in a contract, unlike the Examiner, can testify in court about his reliance on the misrepresentation to meet this higher burden of proof. Failing that standard affects only the parties to the contract. The consequence of allowing an inequitably procured patent monopoly to survive because its prosecution history does not reveal the reason for allowance, in contrast, adversely affects the public at large.

Other areas of law do not consistently use "but/for" causation. There is no compelling reason to apply such a standard in patent cases. The Supreme Court established the inequitable conduct defense as a more specific form of unclean

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[12] Abbott's two Supreme Court copyright cases have nothing to do with "but/for" causation. *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417 (1984) (comparing copyright and patent law on contributory infringement); *eBay Inc. v. MercExchange L.L.C.*, 547 U.S. 388 (2006) (applying same test for injunction in copyright as patents). Abbott's only Federal Circuit case espouses a trademark standard identical to the current materiality-intent-balancing framework in *Therasense*. *In re Bose Corp.*, 580 F.3d 1240, 1245 (Fed. Cir. 2009) (explaining that cancellation requires proof that the "applicant or registrant knowingly makes a false, material representation with the intent to deceive the PTO"). Several of Abbott's remaining cases likewise do not employ "but/for" in their analyses. *See Far Out Prods., Inc. v. Oskar*, 247 F.3d 986 (9th Cir. 2001); *Meineke Discount Muffler v. Jaynes*, 999 F.2d 120 (5th Cir. 1993); *Money Store v. Harriscorp Fin., Inc.*, 689 F.2d 666 (7th Cir. 1982); *Urantia Found. v. Maaherra*, 114 F.3d 955 (9th Cir. 1997); *Advisors, Inc. v. Wiesen-Hart, Inc.*, 238 F.2d 706 (6th Cir. 1956).

hands for patent cases separate from fraud. In patentability cases, this distinction should stand.

E. The Conclusion of Materiality Was Correct In *Therasense*

This Court reviews the District Court's findings of materiality and intent for clear error, and reviews its balancing of the equities and the ultimate conclusion of inequitable conduct for abuse of discretion. *Star Scientific*, 537 F.3d at 1365.

The District Court carefully applied the correct legal standard to the facts at hand to find the undisclosed information at issue here "highly material" under Rule 1.56 at the time of the misconduct because Pope and Sanghera told the PTO one thing in Sanghera's declaration to obtain the '551, but failed to disclose that the declarant, Sanghera, had previously told the EPO the exact opposite. Trial Op. at 1112; Panel Op. at 1301.

1. Sanghera's False And Misleading Declaration Was Material

Sanghera's declaration was highly material under Rule 1.56 because it was critical to patentability over Abbott's '382 prior art.

When Pope and Sanghera took over the '551 prosecution in 1997, they knew that Abbott's '382 prior art patent was the primary basis for the Examiner's repeated rejections over the previous thirteen years. Trial Op. at 1093, 1105; Panel

Op. at 1301; JA2976 at 618:16-619:3.[13] Pope first raised these new membraneless sensor claims at a November 1997 interview that he initiated with the Examiner. Trial Op. at 1105-06; Panel Op. at 1301; JA2976 at 619:4-25. But the Examiner noted that the '382 patent already disclosed membraneless sensors by explaining that membranes were only optional:

> ***Optionally, but preferably when being used on live blood***, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.

Trial Op. at 1105-06; Panel Op. at 1295; JA7639.[14]

In order to overcome this teaching, Pope convinced the Examiner to allow him to submit extrinsic evidence in a scientist's declaration. Pope did not approach a disinterested scientist or a '382 patent inventor to submit the declaration. Instead, he chose Sanghera, Abbott's technical liaison to its patent lawyers. Trial Op. at 1106; Panel Op. at 1301-02; JA2980 at 632:23-634:13. Pope then drafted a declaration that Sanghera signed under penalty of perjury. Trial Op.

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[13] The '551 patent application was initially filed by a company named Medisense. Abbott purchased Medisense in 1996. Trial Op. at 1093; JA2976 at 618:18-20. For convenience, the Majority uses the single designation "Abbott" to refer to any and all of the foregoing, as shall we. Panel Op. at 1302.

[14] Abbott's technical expert, Dr. Jay Johnson, explained that this sentence describes two scenarios: a preferable scenario for a membrane in "live blood" and an optional scenario for other fluids, including whole blood. Live blood is blood that is tested *in vivo* while still in the patient's body. Blood that is removed from the patient and tested by an *in vitro* glucose sensor is referred to as "whole blood." Abbott's expert further conceded that the '382 patent does not state a membrane is required in any case. JA2748 at 533:12-JA2749 at 537-5.

at 1106. In it, Sanghera swore that a skilled person would not read the '382 patent to mean what its plain language actually says but, instead, would believe otherwise, *i.e.*, a membrane was neither optional nor preferable, but *required*:

> [O]ne skilled in the art would have felt that an active electrode comprising an enzyme and a mediator ***would require a protective membrane*** if it were to be used with a whole blood sample. Therefore, he is sure that one skilled in the art ***would not read*** [the "optionally, but preferably" language at] lines 63 to 65 of column 4 of U.S. Patent No. 4,545,382 ***to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred***.

Trial Op. at 1094; Panel Op. at 1301; JA7636-38. Sanghera's declaration failed to mention the EPO arguments saying otherwise: that the '382/'636 prior art "does not require a membrane." (*Infra*, p. 26-27). Nor did he mention that Abbott had marked the '382 patent on its prior art Exactech sensor that measured glucose in whole blood without a membrane.[15] Either fact would have revealed Sanghera's declaration as false.

Recognizing the '382 patent as "the key reference," Pope relied on Sanghera's declaration to argue that a skilled person would read that patent to require a membrane. Trial Op. at 1107; Panel Op. at 1301-1302; JA7640-46.

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[15] Independent claim 1 of the '382 patent covered membraneless sensors; the addition of the membrane option does not appear until dependant claim 12. Consequently, '382 patent claim 1 covers the membraneless Exactech sensor. Trial Op. at 1124; Panel Op. at 1299; JA6511. The '636 claims were similar. Trial Op. at 1108.

The District Court correctly found that Sanghera's declaration, coupled with Pope's arguments, was a deliberate, "materially false and misleading" affirmative misrepresentation that was instrumental in securing the '551 patent. Trial Op. at 1094, 1107, 1110.

2. Abbott's Prior Inconsistent Admissions Before The EPO Were "Highly" Material

Abbott's withheld prior inconsistent EPO statements were material under Rule 1.56. Pope and Sanghera argued to the PTO that the '382 patent "required" a membrane while intentionally concealing Abbott's prior inconsistent statements to the EPO, which Sanghera himself helped prepare. Trial Op. at 1107-10; Panel Op. at 1301-05.

In an EPO opposition, Abbott and Sanghera saved the '636 counterpart by arguing that it "not only *does not require* a membrane but must not have a membrane." Trial Op. at 1109; JA6533. They emphasized the fact that "the *protective* membrane *optionally* utilized with the glucose sensor" in that art was a distinguishing feature. Trial Op. at 1108; JA6530-31 (emphasis in original). Abbott and Sanghera told the EPO that the "optionally, but preferably" language meant exactly what it said:

> It is submitted that this disclosure is unequivocally clear. The protective membrane ***is optional***, however, it is preferred when used on live blood… .

Trial Op. at 1109; Panel Op. at 1303; JA6585.

Abbott now tries to deflect the significance of these submissions by arguing that it simply characterized the '636 counterpart based on the type of membrane it used, rather than whether a membrane was optional. (Abbott 53). That argument fails. The EPO statements "plainly went beyond this point of distinction and submitted that it was 'unequivocally clear' that the '382/'636 needed no membrane at all for use with blood." Trial Op. at 1116. There is no doubt that Abbott argued to the EPO that the membrane was optional. Panel Op. at 1304.

The District Court properly concluded that the EPO submissions were "highly material" within the meaning of Rule 1.56 because they were flatly inconsistent with the main point being made to the PTO. Trial Op. at 1112. The Majority held this finding was not only "clearly correct," but "strongly supported by the uncontradicted record." Panel Op. at 1301, 1305. Indeed, but for Sanghera's declaration, the claims would not have issued.

3. *Therasense* Is Not A Case Of Mere Attorney Argument

Abbott's claim that the EPO papers were mere attorney argument, attributable solely to German counsel, (Abbott 58-59), is misleading because it ignores the fact that Sanghera helped draft those papers. Abbott is also wrong when it argues that Sanghera's false declaration is somehow irrelevant. (Abbott 58). This Court correctly ruled otherwise. Panel Op. at 1305 ("[T]he

representations to the PTO *were not merely lawyer argument*; they were factual assertions as to the views of those skilled in the art, provided in affidavit form.").

The District Court and the Majority properly found that Abbott's cases regarding attorney argument on art before the PTO are inapposite. (Abbott 58). Trial Op. at 1112; Panel Op. at 1305. In those cases, the relevant information was in the *intrinsic* record before the Examiner, who could draw his own conclusions as to what the art taught and was "free to accept or reject" legal arguments directed solely to the four corners of that art. *Innogenetics N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008). None of those cases authorize a patent prosecutor to knowingly mislead the Examiner about the art, and none involve a situation where contradictory arguments made in another forum were withheld from the PTO. *See id.*; *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1344 (Fed. Cir. 2007); *Azko N.V. v. U.S. Int'l Trade Comm'n*, 808 F. 2d 1471, 1485 (Fed. Cir. 1986).[16]

As the District Court found, *Therasense* is not a case of lawyer argument where the Examiner can draw his own conclusions about the art. Trial Op. at 1112. The claims were allowed because Pope convinced the PTO to look beyond

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[16] Abbott further relies on *Akzo* to contend that attorney argument characterizing prior art is immaterial even in affidavit form. (Abbott 58). But *Akzo* has long been superseded by the *Ferring* line of cases, which state that an affidavit prepared for the PTO must be construed as being intended to be relied upon. *Ferring B.V . v. Barr Labs., Inc.*, 437 F.3d 1181, 1188 n.9 (Fed. Cir. 2006); *Refac Int'l Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1583 (1996). Here, the PTO relied on Sanghera's declaration to allow invalid claims.

the art to extrinsic evidence in the form of Sanghera's sworn declaration. The PTO had no way to test the veracity of Sanghera's statements that a skilled artisan would have understood that art differently than the plain meaning of its language, and no way of knowing that Sanghera himself had argued to the EPO that the same skilled person would have a contrary interpretation of the same art. The District Court correctly found that Pope and Sanghera were "duty-bound to present any inconsistent extrinsic information" known to them because "[i]n the arena of *extrinsic* evidence, the examiner was unable to fend for himself." Trial Op. at 1112. The Majority agreed that this was "not merely lawyer argument." Panel Op. at 1305.

Pharmacia Corp. v. Par Pharm., Inc., 417 F.3d 1369 (Fed. Cir. 2005), is instructive. There, a finding of inequitable conduct was affirmed on similar facts. To overcome prior art, a Pharmacia scientist had submitted a misleading declaration containing statements that were directly contradicted by the declarant's withheld prior publication. Materiality was established because the declaration went to the very point of novelty. Intent was, in part, based on the declarant's failure to submit his prior conflicting statement. *Id.* at 1373.

Abbott's claim that *Therasense* imposes an enormous new burden of disclosing every statement about prior art in every tribunal is wrong. The District Court and Majority followed Rule 1.56, which since 1992 has required those with a

duty of candor to disclose prior inconsistent statements of which they are aware. As always, there is no obligation to disclose consistent statements made to other tribunals. They continue to fall outside the scope of the Rule.

4. Sanghera's False Declaration And The Withheld EPO Admissions Are Material Under Any Standard

As discussed, the proper standard of materiality is Rule 1.56 at the time of the conduct in question. Even if this Court modifies that law, the outcome in this case would not change. The facts establish inequitable conduct under any standard. Thus, the judgment should be affirmed on the record, without resort to remand, even if a different standard applies. *See Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 830-31 (Fed. Cir. 2010) (remand would produce same equitable result).

Therasense is the rare case that meets Abbott's proposed "but/for" fraud standard. In addition to materiality and intent, the District Court's findings meet the remaining reliance and harm elements of fraud, but for which the patent would not have issued. Trial Op. at 1105-1110. The Examiner's reliance appears in the findings that the "optionally, but preferably" sentence was "the single roadblock to allowance" and that the Examiner finally approved the '551 patent relying on Sanghera's declaration and Pope's parallel remarks. Trial Op. at 1094, 1102, 1106-07, 1110. The finding that absent that declaration, the Examiner said no allowance would be made shows that "but/for" Pope and Sanghera's misconduct,

the Examiner would not have issued the ’551 patent. Trial Op. at 1107. The resulting harm being that the ‘551 patent was wrongfully enforced against competitors, the asserted claims of which were affirmed invalid in light of the ‘382 prior art. Panel Op. at 1293-1300.

One *amicus* suggests that information in sources the PTO routinely searches should be immaterial. That has no bearing on this case because the withheld EPO papers are not something the Examiner would have found on his own. The PTO was therefore forced to rely on, and to reasonably expect, Pope and Sanghera’s candor during prosecution.

The inequitable conduct here would undoubtedly meet *Keystone’s* general maxim of unclean hands that some *amici* propose, requiring an unconscionable act related to the equity sought. Misleading the Examiner on the key reference in prosecution while hiding information that directly contradicted arguments for patentability is an unconscionable abuse of the patent system. Moreover, Pope and Sanghera’s misconduct had immediate and necessary relation to the equity that Abbott sought because it was directly responsible for issuance of the ’551 patent. The suggestion by one *amicus* that there must also be litigation misconduct to raise unclean hands is incorrect. Unclean hands bars anyone who has committed misconduct in the past from seeking equity; there is no need for continued misconduct in litigation for the defense to apply.

II. INTENT MUST BE THE SINGLE MOST REASONABLE INFERENCE BASED ON THE TOTALITY OF THE EVIDENCE AS EXEMPLIFIED BY *THERASENSE*

The law on intent already weighs heavily against finding inequitable conduct. Gross negligence cannot amount to inequitable conduct. *Kingsdown, Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 876 (Fed. Cir. 1988). Instead, the challenger bears the burden of proving intent to deceive the PTO by clear and convincing evidence. *Star Scientific*, 537 F.3d at 1366; *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1296 (Fed. Cir. 2008); *Young*, 492 F.3d at 1344. Because admissions of deceptive intent are rare, intent can be, and often is, inferred from circumstantial evidence. *Star Scientific*, 537 F.3d at 1366; *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1189 (Fed. Cir. 1995) ("smoking-gun" evidence not required to establish deception). If this were not the rule, a dishonest patentee could deceive the PTO and then further perpetuate the wrong by simply refusing to admit intent in court.

In the past decade, *Star Scientific* and its progeny have followed *Kingsdown*, holding that the totality of evidence on intent must be considered – including evidence of good faith – such that deceptive intent is the single most reasonable inference in order for inequitable conduct to apply. *Star Scientific*, 537 F.3d at 1366. This is the most stringent possible standard for intent short of requiring an

outright admission. It is the principle applied in *Therasense*, (*supra*, p. 38-50), and the standard Abbott advocates. (Abbott 21).

As to what circumstances make it proper to infer intent from materiality (Order for *En Banc* rehearing, Q4), facts regarding materiality can be used to prove intent but materiality *alone* cannot establish intent. *Star Scientific*, 537 F.3d at 1366 (finding that "the fact that information later found material was not disclosed cannot, by itself, satisfy the deceptive intent element"). Materiality and intent are separate elements. But certain *facts* that bear on materiality can also be circumstantial evidence of intent. *See Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1325 (Fed. Cir. 2010) (Prost, J. concurring).

Abbott's criticism that *Therasense* inferred intent from materiality is misplaced. The notion that *facts* may be relevant to both these elements should not be misunderstood as conflating the *elements* themselves. This Court has correctly rejected the notion that "intent requires facts wholly distinct from those establishing materiality." *Taltech*, 604 F.3d at 1334.

There is no justification for excluding a fact from the intent analysis simply because it also sheds light on materiality. To do so ignores the "totality of evidence," as well as reality. "If a reference is of very high materiality, and it is shown that the patentee knew of the reference, then it is more probable that the reference was withheld from the examiner with deceptive intent, as compared to a

reference of low materiality." *Optium Corp.*, 603 F.3d at 1323 (Prost, J. concurring). Indeed, it is unlikely that a patentee would risk deceiving the PTO about information that is clearly immaterial. That is why patentees sometimes claim they did not appreciate materiality as an excuse for withholding material information, as Abbott has here. In response, challengers often point to facts that demonstrate high materiality to show why such excuses are incredible. As such, facts often span both materiality and intent. "[I]t is not that a high level of materiality lowers the threshold evidentiary burden for an inference of intent, but rather, that a high level of materiality is circumstantial evidence of intent that brings the challenger closer to satisfying his burden." *Id.* at 1325.

A. Facts That Bear On Intent

Facts common to materiality and intent include the prominence of a withheld reference in prosecution, concealing prior inconsistent statements, and submitting false declarations. Prominence of a reference, even in related litigation, underscores its materiality and the patentee's awareness of its relevance to show he deceptively withheld it.[17] Hiding information that is inconsistent with an applicant's arguments for patentability is material under Rule 1.56, and shows that he intentionally misled the PTO by burying the inconsistency.[18] A false

[17] *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995).

[18] *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005) (intent found based on "the highly material nature" of misleading statements and

declaration to overcome a rejection is material given its significance to the prosecution, and shows intent because the Examiner has to rely on the declarant when he cannot investigate the facts himself.[19]

Analysis of facts common to materiality and intent does not end the inquiry. Additional facts that evidence intent include the applicant's awareness of withheld art,[20] his years of prosecution experience and/or awareness of the duty to disclose,[21] his control over content of declarations,[22] his refusal to investigate potentially material information,[23] his inability to describe what is presumably his

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"*failure to submit a directly conflicting article co-authored by the declarant himself*"); *Molins*, 48 F.3d at 1181 (withheld EPO statements were highly material under Rule 1.56 and showed intent); *Bruno Indep. Living Aids v. Acorn Mobility Servs.*, 394 F.3d 1348, 1352, 1354 (Fed.Cir. 2005) (prior inconsistent statements to FDA showed materiality and intent); *Agfa Corp. v. Creo Prods., Inc.*, 451 F.3d 1366, 1378-79 (Fed.Cir. 2006) (statements to PTO showed materiality and intent because they were inconsistent with knowingly withheld prior art).

[19] *Refac*, 81 F.3d at 1580 (intent inferred "not simply from the materiality of [submitted] affidavits, but from the affirmative acts of submitting them, their misleading character, and *the inability of the examiner to investigate the facts*") (citation omitted).

[20] *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239 (Fed. Cir. 2003).

[21] *Digital Control*, 437 F.3d at 1319-20; *Leviton Mfg. v. Universal Sec. Insts., Inc.*, 606 F.3d 1353, 1356 (Fed. Cir. 2010); *Ferring*, 437 F.3d at 1192; *Molins*, 48 F.3d at 1181.

[22] *Id.*; *Ferring*, 487 F.3d at 1193-94.

[23] *Brasseler, U.S.A.I., LP, v. Stryker Sales Corp.*, 267 F.3d 1370, 1384 (Fed. Cir. 2001).

own work,[24] whether there was heightened pressure to acquire a patent,[25] and whether his excuses for his conduct were a moving target.[26]

Evidence of good faith may also be considered. A patentee need not offer any explanation for his conduct until and unless the challenger makes a threshold showing on intent. *Star Scientific*, 537 F.3d at 1368. But patentees often elect to explain their conduct because a "reasonable explanation" of good faith defeats a finding of deceptive intent. *Id.* at 1366-67. Contrary to Abbott's suggestion, however, courts are not obligated to accept any excuse a patentee may offer in this regard, however incredible. *Star Scientific* does not allow an *unreasonable* excuse to defeat a finding of intent. Otherwise, a patentee could deceive the court into enforcing an ill-gotten patent by fabricating an incredible excuse at trial.

Courts must therefore separate legitimate, good faith explanations from incredible ones. Some explanations can be rejected based on the record itself,[27] as the Majority did here. Others may require a court to assess the credibility of the

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[24] *Advanced Magnetic Closures*, 607 F.3d at, 830.

[25] *Digital Control*, 437 F.3d at 1319-20 (Fed. Cir. 2006).

[26] *Id*.

[27] *Ferring*, 437 F.3d at 1192-93; *Bristol-Myers Squibb*, 326 F.3d at 1239-40; *Bruno*, 394 F.3d at 1352-55 (innocent parties do not present "disingenuous excuses" for their actions).

witness offering the explanation,[28] as Judge Alsup did. (*Supra*, p. 44-45). This puts the trial court, having actually observed the witnesses, in a unique position to assess intent. *Anderson v. City of Bessemer City,* 470 U.S. 564 (1985) (giving great deference to trial court's assessment of witness demeanor, which bears heavily on believing what is said); *Molins*, 48 F.3d at 1181 (drawing inferences in the "intent-implicating question … is peculiarly within the province of the fact finder that observed the witnesses") (citation omitted); *Agfa*, 451 F.3d at 1379 ("T[he Federal Circuit] must defer heavily to the trial court's credibility determinations."); *JVW Enters., Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1334 (Fed. Cir. 2005) ("[C]redibility determinations by the trial judge 'can virtually never be clear' error.") (citations omitted).

The "single most reasonable inference" based on the totality of the evidence provides a high standard of intent, just short of an outright admission. That totality includes all the facts, including those that may also bear on materiality. It also limits the inequitable conduct doctrine by giving the patentee every opportunity to provide exculpatory evidence of good faith for his conduct and maintains "a high bar" for proving intent. *Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1360 (Fed. Cir. 2008).

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[28] *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1241 (Fed. Cir. 2008); *Advanced Magnetic Closures*, 607 F.3d at 830; *Refac*, 81 F.3d at 1582.

B. Deceptive Intent Was The "Single Most Reasonable Inference" in *Therasense*

The evidence in this case of Pope and Sanghera's specific intent to deceive the Examiner is exceptionally strong; deceptive intent is the only reasonable conclusion. Trial Op. at 1113; Panel Op. at 1308. The District Court's finding of intent was not inferred solely from high materiality, but instead was based on abundant of evidence that falls in five general categories:

(i) Pope and Sanghera were highly motivated to get the '551 patent issued

After thirteen years of rejections, Pope and Sanghera's, "primary goal was to eke out some claim and save the fight over enforceability for [another] day." Trial Op. at 1114; JA3015 at 775:7-15. Sanghera was hardly a disinterested scientist; supervising Abbott's patent portfolio was one of his management duties as Director of R&D. Trial Op. at 1093; JA3011 at 759:14-25. To accomplish their goal, Pope and Sanghera held high-level brainstorming sessions to devise a plan to get around the Examiner's rejections. Trial Op. at 1093, 1105. As Sanghera testified, he and Pope worked as a "team" to get the '551 patent issued. JA3015 at 774:19-25; JA3016 at 776:8-12, 777:23-778:5.

Further, Abbott's Exactech strip was facing increasing competitive pressure. JA3012 at 761:21-23, 763:11-20, 765:13-22. Aware that a competitive LifeScan product was coming onto the market, Pope and Sanghera were motivated by

marketplace developments to craft patent claims that would suppress such competition. Trial Op. at 1105, 1093; JA3012 at 761:25-763:16; *see also Digital Control*, 437 F.3d at (heightened pressure to procure patent can evidence intent). Not only were they the '551 patent procurers, but also the patent enforcers. The day the '551 patent issued, Abbott sued its first major competitor, LifeScan. Trial Op. at 1105; JA3014 at 770:16-21. Sanghera provided a technical declaration in support of a preliminary injunction, and Pope was counsel of record in that case.[29] Trial Op. at 1105; JA3014 at 770:16 – JA3015 at 772:11.

(ii) Both men were aware of their duty of candor to the PTO, and of the requirements of Rule 1.56

Both knew that they had a duty to disclose material information, including prior inconsistent statements, to the PTO. JA 2976 at 616:21-25; JA3015 at 774:9-13; JA3016 at 779:2-8. Pope even testified at the hearings at which the PTO adopted Rule 1.56. JA2976 at 616:21-25. Pope was an experienced patent prosecutor, and Sanghera supervised prosecution. JA2975 at 615:24 – JA2976 at 616:16; JA3012 at 760:1-11. Nonetheless, Pope prepared, and Sanghera signed under oath, the false declaration that they submitted to the PTO. Trial Op. at 1106-07; Panel Op. at 1307-08; JA2980 at 633:21 – 634:13; JA3016 at 778:11-13.

[29] LifeScan settled with Abbott, which then went on to sue other competitors, including Roche and Appellees Becton Dickinson, Nova Biomedical, and Bayer Healthcare here. Thus, Abbott enforced its inequitably-procured patent against competition for an entire decade: since its issuance in 1998 until the District Court in this case found it invalid and unenforceable in 2008.

(iii) Pope and Sanghera were well aware that Sanghera's declaration was highly material

Both knew Abbott's '382 patent was the "key" prior art reference. Trial Op. at 1107; JA7646. The '382/'636 disclosure was the basis of eleven rejections, and the single roadblock to patent issuance that Sanghera's declaration was specifically designed to overcome. Trial Op. at 1093-94, 1106.

With this in mind, Pope convinced the Examiner to accept Sanghera's declaration to overcome that key reference. Trial Op. at 1106, 1112; Panel Op. at 1301; JA7639. He admitted that their representations to the PTO that "optionally, but preferably" meant "required" were important to patentability and intended for the Examiner's reliance. Trial Op. at 1114; JA3297 at 18-22; JA3303 at 20 – JA3304 at 1. Sanghera admitted that he knew his declaration was critical to convince the Examiner "to allow the claims [they] were pushing for." Trial Op. at 1106; JA3015 at 775:16-24.

Nonetheless, they concealed material information. Sanghera admitted he told the EPO that one "may not need a membrane at all" according to the prior art and knew Abbott's membraneless Exactech sensor was marked with the '382 patent when filing his declaration.[30] Trial Op. at 1124; JA3005 at 735:13-16;

[30] The Exactech sensor was also marked with the '551 patent after it issued, further confirming that both the '382 and '551 patents are directed to membraneless sensors. Panel Op. at 1299. Abbott effectively extended patent

JA3008 at 746:23-25; JA3015 at 773:14-25. Pope also admitted that the EPO submissions said membranes were optional. JA2986 at 657:13-23. Yet, neither the EPO proceedings nor the Exactech patent marking was mentioned in Sanghera's declaration or otherwise revealed to the Examiner. JA7636-38; JA7640-46.

Relying entirely on Sanghera's declaration to inform him that a skilled person would read the '382 patent contrary to its plain language, the Examiner finally issued the '551 patent. Trial Op. at 1107; Panel Op. at 1302.

(iv) Pope and Sanghera's litany of implausible excuses for withholding betrayed their awareness that the EPO submissions were highly material

It is undisputed that Pope and Sanghera were aware of the EPO submissions. JA2980 at 634:19-635:14; JA3001 at 718:25-719:9. Sanghera helped prepare the EPO arguments, and attended the June 1995 hearing before the EPO. Trial Op. at 1093-94, 1110; JA3009 at 750:11-21; JA3010 at 755:5-7. He disclosed those submissions to Pope, who read and understood them. Trial Op. at 1093-94, 1110; JA3011 at 757:20-25; JA2980 at 634:19 – JA2981 at 637:3. It is also undisputed that they consciously and deliberately withheld the EPO submissions. Trial Op. at 1107-08, 1113-15; Panel Op. at 1306; JA2983 at 647:4-18; JA3016 at 776:16-20.

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protection for its Exactech product after the '382 patent expired by obtaining the '551 patent on the same subject matter.

At trial, Pope and Sanghera offered a litany of excuses as to why their withholding was not intended to deceive, each more implausible than the last. First, they tried to dismiss the EPO admission that the ’382/’636 patent membrane was optional, claiming Abbott’s EPO arguments had centered instead on the type of membrane. JA2983 at 647:4-18; JA3016 at 776:16-20. But, as they both knew, whether or not Abbott needed to argue to the EPO that the ’382/’636 required no membrane, that argument was made. Trial Op. at 1112-16; Panel Op. at 1304; JA2986 at 657:13-23; JA3009 at 750:16 – 751:15. Their attempt to excise that part of the EPO proceeding and pretend it never happened was disingenuous. Trial Op. at 1116; Panel Op. at 1306.

Second, Pope’s suggestion that the EPO statements were cumulative failed. JA2983 at 647:4-18. There is nothing of record before the PTO showing that a skilled person would read the ’382 patent as argued to the EPO. Trial Op. at 1112; Panel Op. at 1306-07.

Third, Pope and Sanghera’s argument that the critical “optionally, but preferably” teaching in the ’382 patent was “mere patent phraseology” that really meant “required” (JA2986 at 658:25-659:15; JA3010 at 754:10-755:1) failed because there is “no authority for this secret-code theory.” Trial Op. at 1114. Indeed, there are technical reasons why membranes are optional, and Sanghera had

relied on that same sentence as a technical teaching in the EPO. Trial Op. at 1102, 1107-09; JA3009 at 750:19-751:15.

Fourth, Pope's claim that he misunderstood the term "live blood" in the '382 patent to mean the same thing as "whole blood" and read the "optionally, but preferably" sentence as stating a preference for use of a membrane in all blood (JA2984 at 651:14 – JA2985 at 654:17; JA2988 at 665:25-667:16) does not excuse withholding. Trial Op. at 1113-14. Even in the unlikely event that he was so confused, the EPO admission that a filter was optional in blood remains a material inconsistent statement that should have been disclosed. *Id*.

Ultimately, both Pope and Sanghera admitted that their litigation-inspired reading of the EPO papers is contrary to plain English. When confronted with those papers, Pope testified that Abbott's description in the EPO of what was "unequivocally clear" applied only to the second half of the "optionally, but preferably" sentence so as to exclude the optional aspect of the membrane in that phrase. Trial Op. at 1113; JA2989 at 671:9 – JA2990 at 673:4. But he then conceded that the District Court's reading of the EPO submissions – as inconsistent with Sanghera's declaration – was correct "'as a matter of normal English construction.'" Panel Op. at 1304 n.10; JA2990 at 673:5-13. Likewise, Sanghera admitted that "'in general English usage, [he] would not use the terms "optional" or "preferable" to describe something that is required,' and he could not

recall 'any instance during the course of [his] scientific career in which [he] use[d] the terms "optional" or "preferable" to refer to something that was required.'" Panel Op. at 1307; JA3008 at 747:9 – JA3009 at 748:21.

(v) The District Court found Pope and Sanghera's trial demeanor to be not credible

Judge Alsup observed Pope and Sanghera testify and found both of them unconvincing and not credible. Trial Op. at 1112-16; Panel Op. at 1306. Sanghera was repeatedly impeached on substantive points by his own prior inconsistent statements. Trial Op. at 1115. The District Court found "[Pope's] trial explanation for his withholding was not plausible and he was not credible". *Id*. at 1113. The District Court took these credibility findings into account in arriving at its decision. *Id*. at 1112-16.

* * *

The District Court undertook an exhaustive analysis of the evidence, and correctly found that Pope and Sanghera had not just intent to withhold, but to deceive. *Id*. at 1113-15; Panel Op. at 1306. It was mindful that prosecutors must make judgment calls and that courts must take care to "penalize only clear cut violations of Rule 56." Trial Op. at 1114. The District Court gave Pope and Sanghera every benefit of doubt – even considering excuses they raised that Abbott did not clearly articulate. *Id.* at 1112-16. It searched for "any credible explanation" and took into account "all possible inferences of good faith," as

required by *Kingsdown* and *Star Scientific*, but found none. *Id*. Pope and Sanghera's reinterpretation of the EPO papers was so incredible that it "suggested intent to deceive." Panel Op. at 1306.

The Majority held that not only were the District Court's findings not clearly erroneous, but were "amply supported" and "manifestly correct." Panel Op. at 1304-08. Although witness credibility was a factor in the District Court's analysis, the Majority confirmed that Pope and Sanghera's excuses were implausible based on the record itself. *Id*.

The dissent raised various theories that are either (i) not a basis of the District Court's intent finding, or (ii) simply a repetition of Pope and Sanghera's implausible excuses. *Id*. at 1308. The Majority dismissed the former as irrelevant and the latter as unconvincing, especially considering Pope and Sanghera's attempts to read Abbott's EPO admissions contrary to plain English. *Id*. at 1304-08. The dissent repeatedly and mistakenly stated that Abbott never told the EPO a membrane was "not required" when dealing with blood. *Id*. at 1313-16. In fact, Abbott argued to the EPO that its '382/'636 patent "not only *does not require* a membrane but must not have a membrane." (*Supra*, p. 26). As the dissent acknowledges, such a statement is not only "clearly material," but "devastating to Abbott." Panel Op. at 1313.

1. Abbott's Argument That There Was No Deceptive Intent Is Belied By The Record

Abbott's claim that Pope and Sanghera's reinterpretation of the EPO statements went uncontradicted fails. (Abbott 55-56). Not only did they contradict themselves on cross, but no other trial witness read the EPO papers contrary to their plain meaning. Both parties' technical experts, and the lead inventor on the '382 patent agreed that it disclosed membraneless sensors as stated to the EPO.[31] Appellees presented a former PTO examiner to explain that those EPO submissions, inconsistent with what Pope and Sanghera argued to the PTO, were material under Rule 1.56. Abbott did not present a counter expert. Trial Op. at 1113.

Abbott's criticism of the Majority's summary of intent findings also fails. (Abbott 51-52). The first two findings (that Sanghera and Pope's statements to the PTO were critical to overcoming the '382 prior art and that the withheld EPO statements contradicted what they told the PTO) are not directed solely to

[31] Defendants' technical expert, Dr. Turner, testified at length on the '382 patent and the issues before the EPO to explain that in both those instances Abbott stated the '382 disclosure did not require a membrane. Trial Op. at 1102, 1120, 1122; JA2603 at 272:18-23; JA2618 at 335:7-24; JA3696 at 6-13. Dr. Higgins, the '382 patent's lead inventor, and Abbott's own expert Dr. Johnson, admitted that the '382 patent does not say a membrane is required and that the statements to the EPO were actually correct. Panel Op. at 1296 n.4, 1307; JA2746 at 526:23-25; JA2748 at 533:6-7. Abbott's Dr. Johnson, further confirmed that the '382 patent claims membraneless sensors and covers Abbott's membraneless Exactech Strip. Trial Op. at 1124; Panel Op. at 1299; JA2752 at 549:18 – JA2753 at 552:18; JA2755 at 559:11-14.

materiality. Rather, they demonstrate Pope and Sanghera's actual knowledge of that materiality, and prove that they intentionally misled the PTO by concealing that inconsistency.

The third finding (that Pope and Sanghera consciously hid the EPO statements) does not stand alone. It is just one piece of the totality of evidence establishing deceptive intent. This is not just a case of withholding information; Sanghera's declaration was an affirmative, material misrepresentation. Trial Op. at 1115. Pope and Sanghera certainly appreciated that withholding information which would otherwise defeat their argument for patentability would deceive the Examiner into issuing the '551 patent – that was their plan.

The fourth finding (that neither Pope nor Sanghera provided a credible excuse) does not change the burden of proof. Defendants made a compelling showing of intent in their case-in-chief based on Pope and Sanghera's deposition testimony. In rebuttal, these witnesses did not merely claim that they did not recall what happened or that their actions were somehow accidental. Instead, they raised various unconvincing theories in a failed attempt to justify their misconduct. (*Supra*, p. 41-44). Having elected to bring them to testify in its rebuttal case, Abbott cannot complain that it was prejudiced by the incredible excuses they then provided.

The fifth finding (that Pope and Sanghera's excuses were so incredible that they suggested deceptive intent) was not based on the District Court's disagreement with them, but informed by the record before the EPO and PTO, by Pope and Sanghera's own admissions, and by their lack of credibility. The Court also heard expert testimony about the '382 patent and the EPO statements and how the two were inconsistent with what Pope and Sanghera told the PTO. (*Supra*, p. 46). Indeed, what made their excuses so incredible was that they were fundamentally contradicted by all of the evidence.

2. Pope And Sanghera Had Actual Knowledge Of Materiality

Abbott does not dispute that Pope and Sanghera knowingly and purposefully withheld the EPO statements from the PTO. Given the clear evidence of materiality in this case, Abbott's only remaining argument is that they did not appreciate the materiality of their misrepresentations and omissions. But the record overwhelmingly proves otherwise.

The District Court did not find that Pope and Sanghera were negligent in their withholding, or that they only "should have known" of the materiality of Sanghera's declaration and the EPO submissions. Indeed, there is no doubt that Pope and Sanghera knew that their misrepresentations and omissions were material. As the District Court found, Pope and Sanghera (1) "knew" the "optionally, but preferably" sentence was the single roadblock to allowance, (2)

"knew" Sanghera's declaration would be submitted without the EPO submissions to the contrary, and 3) "knew" the EPO materials made affirmative statements inconsistent with Sanghera's declaration and Pope's remarks to overcome the '382 patent. Trial Op. at 1105, 1110. This awareness, proven by circumstantial but nonetheless clear and convincing evidence, leads inexorably to a conclusion of specific deceptive intent. Trial Op. at 1113-17; Panel Op. at 1306, 1308.

3. Abbott's Alternative Explanations are Implausible

Abbott claims it should prevail simply because Pope and Sanghera offered alternate interpretations of the EPO statements at trial. (Abbott 52-58). Abbott effectively suggests that the Court must accept *any* inference that could possibly be drawn in favor of the patentee as an excuse for misconduct, however implausible, and however contrary to the facts, the plain meaning of prior statements, and common sense. That is not the law, nor should it be. Otherwise, anyone could escape a finding of inequitable conduct by reciting a litigation-induced twist of language that nobody could have possibly intended when written. Here, Pope and Sanghera's reading of the EPO submissions at trial was, by their own admission, contrary to plain English. Thus, the single most reasonable inference here is of deceptive intent.

Abbott's reliance on *M. Eagles Tool Warehouse v. Fisher Tooling Co.*, (Abbott 22), to argue that the absence of a credible explanation cannot by itself

show deceptive intent is misplaced. In that case, there was no evidence to suggest that the applicant appreciated the materiality of the withheld information, and no explanation was given for its withholding. 439 F.3d 1335 (Fed. Cir. 2006). This case is the exact opposite. Pope and Sanghera had actual knowledge of materiality. And they did not simply decline to explain their actions. Instead, they offered several incredible explanations that, coupled with their unconvincing trial demeanor, further evidenced deceptive intent.

III. THE MATERIALITY-INTENT-BALANCING FRAMEWORK OF *THERASENSE* SHOULD REMAIN IN PLACE FOR CASES WHERE PATENTABILITY IS AT ISSUE

The materiality-intent-balancing test is the appropriate standard in cases such as *Therasense* where the information at issue bears on patentability of claims. This is because patent prosecutors look to Rule 1.56 in effect at the time of the conduct in question to determine what information must be disclosed as material, and that Rule is directed to patentability. The vast majority of inequitable conduct cases are of this nature (*e.g.*, disclosures regarding prior art) and, for them, the materiality-intent-balancing test should remain in place. (Order for *En Banc* rehearing, Q1 and Q5).

In a handful of cases (not *Therasense*), the conduct in question has no bearing on patentability (*e.g.*, disclosures regarding Inventorship,[32] Petitions to Make Special,[33] or Small Entity Status[34]) yet those cases are forced under the broad "reasonable examiner" standard. The issue of non-patentability cases is not before this Court on the facts here. If the Court nevertheless decides to address such cases, we submit that the materiality-intent-balancing test should not apply in those circumstances because, absent a patentability issue, there is nothing to invoke Rule 1.56's requirement of disclosure of material information. Courts should have the discretion to refer such cases to the PTO for disciplinary action or, in rare circumstances, find the patent unenforceable under the unclean hands doctrine. These alternate mechanisms are better suited to address such cases. They would prevent rendering patents unenforceable for minor missteps unrelated to patentability without overwhelming the PTO's enforcement abilities.

A. The Materiality-Intent-Balancing Framework is Designed To Limit Inequitable Conduct

In patentability cases, the frequency of the defense will be limited if the materiality standard consistently matches Rule 1.56 and deceptive intent remains the single most reasonable inference. (*Supra*, p. 5-7). Once these elements are

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32 *PerSeptive BioSystems Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315 (Fed. Cir. 2000).

33 *Gen. Electro Mus. Corp.*, 19 F.3d 1405.

34 *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223 (Fed. Cir. 2007).

met, the final balancing step can be used only to allow a court to avoid finding inequitable conduct when the equities so dictate.

Allowing courts to balance the equities before finding inequitable conduct is an important safeguard where the overall context of the case shows that the conduct was too insignificant to justify the severe penalty of unenforceability. *Star Scientific*, 537 F.3d at 1366 (cautioning against "strik[ing] down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith"). Once materiality and intent are independently established, the balance will typically favor finding inequitable conduct. *See*, *e.g.*, *Refac*, 81 F.3d at 1582-83; *Molins PLC*, 48 F.3d at 1178. But "even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the court may still decline to render the patent unenforceable" on balance. *Star Scientific*, 537 F.3d at 1365.

Thus, the final act of balancing can only reduce the number of inequitable conduct determinations by allowing the court discretion to avoid so finding where, although materiality and intent are independently shown, the circumstances as a whole prescribe a different outcome. *See e.g., Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods.*, No. CIV-03-4244, 2010 U.S. Dist. LEXIS 76917, at *12-13 (D.S.D. July 28, 2010) (finding on remand that although patentee "intentionally and materially deceived" the PTO, in view of diminished overall materiality, the

"conduct was not so egregious as to warrant holding [the] patent unenforceable"). Although such a case is rare, without this last chance to avoid an unfair application of the doctrine, any case in which threshold levels of materiality and intent are met would automatically – and sometimes unjustifiably – result in finding inequitable conduct.

Contrary to Abbott's assertion, (Abbott 41-48), balancing does not dilute the requirements of inequitable conduct because it is not a substitute for establishing materiality or intent. As exemplified by *Therasense*, those elements must first be proven by clear and convincing evidence before a court can proceed to "balancing." *Star Scientific*, 537 F.3d at, 1367 ("Only after adequate showings are made as to both materiality and deceptive intent may the district court look to the equities by weighing the facts underlying those showings."). If clear and convincing evidence of either element is missing, there is nothing to balance and no inequitable conduct. *Id*. There is therefore no risk that balancing will lead to unenforceability absent proof of both materiality and intent.

Accordingly, the materiality-intent-balancing framework should remain in place for patentability cases to ensure that patentees are not unjustifiably foreclosed from enforcing patents where the overall circumstances of the case dictate otherwise.

B. The Balance Of Equities in *Therasense* Was Not An Abuse Of Discretion

The determinations of materiality and deceptive intent in this case were not a close call, and did not result from applying a lower standard of proof on either element. The District Court found that the withheld extrinsic evidence was "richly material" and deceptive intent was clearly in their minds. Trial Op. at 1114-16. Only then did the District Court proceed to balance the equities, "tak[ing] into account all possible inferences of good faith (and [finding] none)." *Id*. Abbott's claim that the balancing step dilutes intent for materiality, (Abbott 41-48), has the process exactly backwards. Because the evidence on both elements was high, this case did not balance any lower showing on one against a higher showing of another. Trial Op. at 1112-17. The District Court was well within its discretion when it balanced the equities to conclude inequitable conduct.

1. Eliminating The Balancing Step Will Not Eliminate Inequitable Conduct Here

If this Court elects to eliminate the balancing step, it will not alter the finding of unenforceability in this case. Abbott points to no evidence that would change the outcome on balance. To the contrary, Abbott argues that this step should be eliminated. (Abbott 41-48). Because materiality and intent were already established, elimination of the balancing step would automatically lead to a finding of inequitable conduct.

IV. THE PTO'S STANDARD SHOULD TRUMP THAT OF OTHER AGENCIES IN PATENTS

The Court asks whether the laws of other agencies or at common law shed light on the appropriate standards for patents. (Order for *En Banc* rehearing, Q6). They do not.

There is no uniform standard of materiality or intent employed across agencies. Likewise, cases outside the patent context do not consistently apply a standard that could provide any guidance here. (*Supra*, p. 21-23). Instead, each agency has adopted standards specific to their needs and operation.

Standards in other agencies may be ill-suited for patents. Our patent system relies on the PTO's ability to issue valid patents in *ex parte* prosecution and the courts' ability to protect the public from patents that are inequitably procured. The PTO has stated what inequitable conduct standard it needs the courts to enforce for it to function properly. It urges this court to adopt its Rule 1.56 standard of materiality and follow *Star Scientific* on intent. (Gov't 8-12, 24-26). Ignoring the PTO's voice for another standard from some other context undermines the very agency responsible for our patent system.

V. THE REMEDY OF UNENFORCEABILITY WAS PROPER IN *THERASENSE*

Although the Court's Order for rehearing *en banc* raises no question concerning remedies, some *amici* have proposed changes along those lines. As discussed below, none of those proposals disturb the application of unenforceability to every '551 patent claim in *Therasense*.

Some *amici* suggest a range of remedies arising out of varying degrees of misconduct, including removing the presumption of validity for claims where the conduct does not rise to the "but/for" standard. That approach is impractical. A range of remedies will not bring any certainty to the defense. Challengers will still allege inequitable conduct in the hope that some remedy applies. Removing the validity presumption will further burden the courts and increase litigation costs. It would require a preliminary trial on inequitable conduct to first determine the level of misconduct and set the standard for invalidity. Only then could courts turn to a second trial on invalidity involving much of the same evidence about prosecution history and prior art. Moreover, a lesser standard of invalidity may be a hollow victory for alleged infringers in jury trials, as the patentee would retain the aesthetic benefit before jurors of having been issued a patent. In any event, this proposal is irrelevant here because both inequitable conduct and invalidity were found and affirmed by the clear and convincing standard.

One *amicus* claims that innocent purchasers of patents should not be liable for inequitable conduct that occurred prior to their involvement. That, however, rewards bad actors who benefit from the sale of their ill-gotten patents. It too is not a concern in this case because Pope and Sanghera took over the '551 prosecution *after* Abbott purchased Medisense. Abbott was not an innocent purchaser that inherited the misconduct in this case, but the perpetrator of that conduct after the Medisense purchase.

There are *amici* who suggest that the remedy of unenforceability should be limited to invalid claims that issued as a result of the misconduct. That will depend on the particular facts and circumstances at hand. Courts of equity should have the discretion to tailor unenforceability to specific claims on a case-by-case basis. In this case, every claim of the '551 patent included the membraneless limitation and were born of Pope and Sanghera's inequitable conduct. The remedy of unenforceability aligns with the patent as a whole on these facts and should not be disturbed.

VI. CONCLUSION

The purpose of patents is to promote innovation. Patents procured by inequitable conduct do the exact opposite; they stifle competition. It is difficult to envision a clearer example of misconduct than that which was perpetrated to

secure the '551 patent. Both the District Court and the Majority correctly applied the materiality-intent-balancing framework to conclude inequitable conduct.

There is no standard that excuses such behavior. This is "one of those rare cases in which a finding of inequitable conduct is appropriate." Panel Op. at 1300. Any contrary conclusion on the facts of this case would swallow Rule 1.56 and completely "eviscerate the duty of disclosure." *Id.* at 1305. Not only would that have a catastrophic effect on our patent system, it would undermine the ability of the courts to avoid enforcing patents procured by inequitable conduct.

For the foregoing reasons, we respectfully urge this Court to affirm.

Respectfully submitted,

Dated: October 8, 2010

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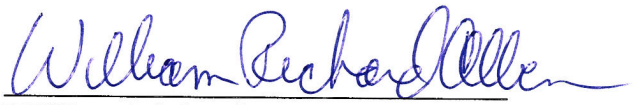

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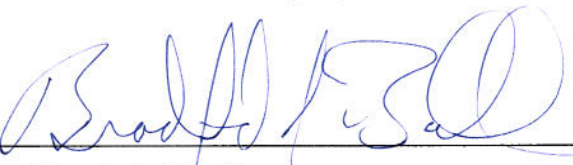
(s) 

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