

***Therasense* – Does It Make Sense?**

Has the Federal Circuit Finally Fixed Inequitable Conduct Law?

and Associated Matters of Ethics and Practice

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TABLE OF CONTENTS

| | | |
|-------|---|----|
| I. | First, A Primer On Canons And Disciplinary Rules Of Ethics For Lawyers When Practicing Law At The U.S. P.T.O. | 1 |
| II. | Before There Was Inequitable Conduct, There Was Unclean Hands | 7 |
| III. | Unclean Hands Begat Inequitable Conduct..... | 9 |
| IV. | The Supreme Court Case Law Of Unclean Hands As To Patents Was Codified In The 1952 Patent Act..... | 10 |
| V. | The CCPA And Federal Circuit Created The Materiality-Intent-Balancing Test For Inequitable Conduct..... | 11 |
| VI. | The Law Of Equity, Within Which Unclean Hands Was A Doctrine, Had Variability In Its Remedies | 15 |
| VII. | The Federal Circuit Created The Single Consequence Of Patent Unenforceability For Inequitable Conduct..... | 17 |
| VIII. | The Uniqueness Of Inequitable Conduct Led To Its Frequent Use As A Defense | 19 |
| IX. | Inequitable Conduct Escaped The Bounds Of Cases About Disclosing Or Withholding Prior Art And Test Results..... | 23 |
| X. | After Letting Inequitable Conduct Drift, The Federal Circuit Faced Up To The Injection Of The Supreme Court Into Patent Cases And The Drift Of Inequitable Conduct Law In <i>Therasense</i> | 24 |
| | A. The Supreme Court Got Into Patent Cases, Speaking To Flexibility And Rigidity | 24 |
| | B. The Federal Circuit Inequitable Conduct Standards Drifted | 28 |
| XI. | In <i>Therasense</i> , The Federal Circuit Faced Wide Ranging Choices | 29 |
| XII. | In Spite Of The Potential, Oral Argument Signaled Little Change Was Possible..... | 37 |
| XIII. | Then Came <i>Thereasense</i> | 41 |
| XIV. | Does <i>Theransense</i> Make Sense? Has The Federal Circuit Finally Fixed Inequitable Conduct Law?..... | 43 |

TABLE OF AUTHORITIES

Cases

| | |
|--|----------------|
| <i>A.C. Aukerman Co. v. R.L. Chaides Const. Co.</i> , 960 F.2d 1020 (Fed.Cir. 1992) | 7 |
| <i>Akzo N.V. v. United States Int'l Trade Comm'n</i> , 808 F.2d 1471 (Fed.Cir.1986) | 48 |
| <i>Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.</i> , 725 F.2d 1350 (Fed. Cir. 1984) | 54 |
| <i>Anderson v. Bessemer City</i> , 470 U.S. 564 (1985) | 57 |
| <i>Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.</i> , 525 F.3d 1334 (Fed.Cir. 2008) | 19 |
| <i>Bilski v. Kappos</i> , 129 S.Ct. at 2735 (2010)..... | 26, 29, 32 |
| <i>Bose Corp. v. Consumers Union of United States</i> , 466 U.S. 485 (1984) | 57 |
| <i>Burlington Industries, Inc. v. Dayco Corp.</i> , 849 F.2d 1418 (Fed.Cir. 1988) | 20 |
| <i>Conard v. Nicoll</i> , 29 U.S. (4 Pet.) 291 (1830) | 8, 35 |
| <i>Corona Cord Tire Co. v. Dovan Chemical Corp.</i> , 276 U.S. 358 (1928) | 32, 36, 37 |
| <i>Diamond v. Diehr</i> , 450 U.S. 175 (1981) | 32 |
| <i>Digital Control Inc. v. Charles Machine Works</i> , 437 F.3d 1309 (Fed.Cir. 2006) | 15 |
| <i>eBay Inc. v. Mercexchange, L.L.C.</i> , 547 U.S. 388 (2006) | 25, 26, 27, 31 |
| <i>Exergen Corp. v. Wal Mart Stores, Inc.</i> , 575 F.3d 1312 (2009) | 22 |
| <i>FMC Corp. v. Manitowoc Co., Inc.</i> , 835 F.2d 1411 (Fed.Cir. 1987) | 20 |
| <i>Gen. Electro Music Corp. v. Samick Music Corp.</i> , 19 F.3d 1405 (Fed.Cir. 1994) | 23 |

| | |
|--|--------------------|
| <i>Hazel-Atlas Glass Co. v. Hartford-Empire Co.</i> , 322 U.S. 238 (1044) | 27 |
| <i>Holland v. Florida</i> , 2010 WL 2346549 (June 14, 2010)..... | 27 |
| <i>Holmberg v. Armbrecht</i> , 327 U.S. 392 (1946) | 27 |
| <i>In re Bilski</i> , 545 F.3d 943 (Fed.Cir. 2008) | 29 |
| <i>In re Seagate Technology</i> , 497 F.3d 1360 (Fed. Cir. 2007) (<i>en banc</i>)..... | 32, 35, 36 |
| <i>J.P.Stevens & Co. v. Lex Tex Ltd., Inc.</i> , 747 F.2d 1553 (Fed.Cir. 1984) (<i>en banc</i> , in part)..... | 19 |
| <i>Kearney & Trecker Corp. v. Giddings & Lewis, Inc.</i> , 425 F.2d 579 (7 th Cir. 1971) | 18 |
| <i>Keystone Driller Co. v. General Excavator Co.</i> , 290 U.S. 240 (1933) | 8, 9, 10 |
| <i>Kingsdown Medical Consultants, Ltd. v. Hollister Inc.</i> , 863 F. 2d 867 (Fed.Cir. 1988) | 24, 41, 42, 55, 58 |
| <i>Kothmann Enters. Inc. v. Trinity Indus., Inc.</i> , 455 F.Supp.2d 608 (S.D. Tex. 2006)..... | 20 |
| <i>KSR International Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007) | 25, 26 |
| <i>Larson Mfg. v. Aluminart Products</i> , 559 F.3d 1317 (Fed.Cir. 2009) | 14 |
| <i>Leinoff v. Louis Milona & Sons, Inc.</i> , 726 F.2d 734 (Fed.Cir. 1984) | 15 |
| <i>Life Technologies v. Clontech Laboratories</i> , 224 F. 3d 1320 (Fed.Cir. 2000) | 48 |
| <i>Loughran v. Loughran</i> , 292 U.S. 216 (1934) | 7, 8 |
| <i>Markman v. Westview Instruments, Inc.</i> , 517 U.S. 370 (1996) | 52, 53 |
| <i>Martin v. Franklin Capital Corp.</i> , 546 U. S. 132 (2005) | 27 |
| <i>McKennon v. Nashville Banner Publishing Co.</i> , 513 U.S. 352 (1995) | 15 |

| | |
|--|----------------|
| <i>New York Trust Co. v. Eisner</i> , 256 U. S. 345 (1921) | 27 |
| <i>Nilssen v. Osram Sylvania, Inc.</i> , 504 F.3d 1223 (Fed.Cir. 2007) | 23, 45 |
| <i>Norton v. Curtiss</i> , 433 F.2d 779 (C.C.P.A. 1973)..... | 11, 12, 36 |
| <i>Pfaff v. Wells Electronics</i> , 525 U.S. 55 (1998) | 25 |
| <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed.Cir. 2005) (en banc)..... | 53 |
| <i>Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.</i> , 324 U.S. 806 (1945) | 9, 11 |
| <i>Pullman-Standard v. Swint</i> , 456 U.S. 273 (1982) | 57 |
| <i>Refac Int'l, Ltd. v. Lotus Dev. Corp.</i> , 81 F.3d 1576 (Fed. Cir. 1996)..... | 45, 49 |
| <i>Rohm & Haas Co. v. Crystal Chem. Co.</i> , 722 F.2d 1556 (Fed.Cir. 1983) | 18, 36, 44 |
| <i>Safeco Ins. Co. of Am. v. Burr</i> , 127 S.Ct. 2201 (2007) | 36 |
| <i>Scanner Technologies Corp. v. ICOS Vision Systems</i> , 528 F.3d 1365 (2008) | 42 |
| <i>Skilling v. United States</i> , 130 S.Ct. 2896 (2010) | 33, 34, 36 |
| <i>Sperry v. Florida</i> , 373 U.S. 379 (1963) | 1 |
| <i>Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.</i> , 537 F.3d 1357 (Fed. Cir. 2008) | 13, 35, 42, 55 |
| <i>Taltech Ltd. v. Esquel Enterprises Ltd.</i> , 604 F.3d 1324 (Fed.Cir. 2010) | 20, 21 |
| <i>The Pension Committee of the University of Montreal Pension Plan v. Banc of America Securities, LLC</i> , 685 F.Supp.2d 456 (S.D.N.Y. 2010)..... | 16, 19, 37 |
| <i>The Telephone Cases</i> , 126 U.S. 1 (1888) | 25 |

| | |
|--|--|
| <i>Therasense, Inc. v. Becton, Dickinson & Co.</i> , 649 F.3d 1276 (Fed. Cir. 2011)(en banc)..... | 6, 28, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56 |
| <i>TSC Industries, Inc. v. Northway, Inc.</i> , 426 U.S. 438 (1976) | 30 |
| <i>Ulead Systems v. Lex Computer & Management Corp.</i> , 351 F.3d 1139 (Fed.Cir. 2003) | 45 |
| <i>United States v. American Bell Tel. Co.</i> , 128 U.S. 315 (1888) | 19 |
| <i>United States v. United States Gypsum Co.</i> , 333 U.S. 364 (1948) | 57 |
| <i>Zubulake v. UBS Warburg LLC</i> , 229 F.R.D. 422 (S.D.N.Y.2004)..... | 16 |

Rules

| | |
|--|---------------------|
| 37 CFR 1.27 | 6, 45 |
| 37 CFR 1.4 | 45 |
| 37 CFR 1.56 | 2, 3, 6, 38, 39, 43 |
| 37 CFR 1.68 | 50 |
| 37 CFR 10.20 et seq..... | 1 |
| 37 CFR 11.18 | 45, 46 |
| Federal Rule of Civil Procedure 52 | 57 |
| Illinois Rules of Professional Conduct | 1, 3 |

Statutes

| | |
|--|--------|
| 18 U.S.C. § 1001 | 46 |
| 28 U.S.C. § 1746 | 50 |
| 28 U.S.C. § 398 | 7 |
| 35 U.S.C. § 257 | 11 |
| 35 U.S.C. § 282 | 10 |
| Leahy-Smith American Invents Act | 10, 11 |

Other Authorities

3 M. Nimmer, Copyright § 13.09(b)(1978).....31

6 D. Chisum, *Chisum on Patents*, §19.03[6] (Matthew Bender).....21

American Bar Association as Amicus Curiae,
Therasense, Inc. v. Becton, Dickinson & Co.,
Nos. 2008-1511 et seq. (June 17, 2010)..... 6, 14, 24, 28, 29, 32, 35, 38, 46, 47

American Bar Association Report 24, 35

E. Peters, Note, *Are We Living in a Material World?: An Analysis of the Federal Circuit's Materiality Standard Under the Patent Doctrine of Inequitable Conduct*, 93 Iowa L. Rev. 1519 (2008).....36

L. Dolak, *As If You Didn't Have Enough To Worry About: Current Ethics Issues for Intellectual Property Practitioners*, 82 J. Pat. & Trademark Off. Soc'y 235, (2000).....24

N. Murphy, Note, *Inequitable Conduct Doctrine Reform: Is the Death Penalty for Patents Still Appropriate?*, 93 Minn. L. Rev. 2274 (2009).....37

Northern District of Illinois LPR Appendix A23

P. J. Federico, *Commentary on the New Patent Act*, 75 J. Pat. & Trademark Off. Soc'y 161 10, 11

R. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 Harv. J.L. & Tech. 37 (1993) 9, 28

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I. FIRST, A PRIMER ON CANONS AND DISCIPLINARY RULES OF ETHICS FOR LAWYERS WHEN PRACTICING LAW AT THE U.S. P.T.O.

Lawyers, of course, are subject to multiple codes of professional responsibility (“ethics”) when representing clients before the Patent and Trademark Office.¹ They are subject to the codes of ethics of the states of their state licenses, and the Patent and Trademark Office Code of Professional Responsibility, 37 CFR 10.20 et seq.² The “PTO Code of Ethics” includes canons and disciplinary rules much like state codes. *Id.* “Canons” in this PTO Code of Ethics are “axiomatic norms,” “standards of ... expected ... professional conduct.” *Id.*³ Disciplinary rules are “mandatory ... and minimum below which no practitioner can fall without being subjected to disciplinary action.” *Id.*⁴

As related to “equitable conduct,” meaning the proper execution of those ethical duties that might otherwise subject lawyers and their clients to conclusions of inequitable conduct, there are not any specifically relevant canons of the PTO

¹ There can be no doubt that lawyers are practicing law when they represent clients before the Patent Office. *Sperry v. Florida*, 373 U.S. 379, 383 (1963) (“[T]he preparation and prosecution of patent applications for others constitutes the practice of law.”).

² They are said to be potentially subject to four codes and additional legal standards. See D. Hricik, *Patent Ethics: Prosecution at 11 et seq.* (Oxford University Press 2009)

³ Comparable to canons, in Illinois, is the Preamble to the Illinois Rules of Professional Conduct, states values and goals. It replaced canons. See http://www.state.il.us/court/supremecourt/rules/art_viii/ArtVIII.htm.

⁴ In Illinois, the same is true. “Violation of [the disciplinary rules] is grounds for discipline.” *Id.*

Code of Ethics. *Id.* A canon 7 on zealous representation limits zealotry to being “within the bounds of the law,” and a canon 9 restricts against the appearance of professional impropriety. *Id.*

The disciplinary rules of the PTO, however, speak both generally and directly to equitable conduct:

10.23(b) A practitioner shall not: ...

- (4) Engage in conduct involving dishonesty, fraud, deceit, or misrepresentation.

10.23(c) Conduct which constitutes a violation of paragraphs (a) and (b) of this section includes, but is not limited to: ...

- (2) Knowingly giving false or misleading information or knowingly participating in a material way in giving false or misleading information, to: ... (ii) The Office or any employee of the Office.
- (10) Knowingly violating or causing to be violated the requirements of 1.56 or 1.555 of this subchapter.
- (18) In the absence of information sufficient to establish a reasonable belief that fraud or inequitable conduct has occurred, alleging before a tribunal that anyone has committed a fraud on the Office or engaged in inequitable conduct in a proceeding before the Office.

10.23(d) A practitioner who acts with reckless indifference to whether a representation is true or false is chargeable with knowledge of its falsity. Deceitful statements of half-truths or

concealment of material facts shall be deemed actual fraud within the meaning of this part.

10.85(a) (a) In representation of a client, a practitioner shall not:

...

- (2) Knowingly advance a claim or defense that is unwarranted under existing law, except that a practitioner may advance such claim or defense if it can be supported by good faith argument for an extension, modification, or reversal of existing law.
- (3) Conceal or knowingly fail to disclose that which the practitioner is required by law to reveal.
- (4) Knowingly use perjured testimony or false evidence.
- (5) Knowingly make a false statement of law or fact.
- (6) Participate in the creation or preservation of evidence when the practitioner knows or it is obvious that the evidence is false.⁵

The familiar 37 CFR 1.56 as of the recent past⁶ is as follows:

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all

⁵ Comparable rules exist in the Illinois Rules, as for example, in Rule 3.3 on conduct before a tribunal, prohibiting for example statements of material fact and law known to be false or that should reasonably be known to be false. See http://www.state.il.us/court/supremecourt/rules/art_viii/ArtVIII.htm#3.3.

⁶ The PTO has proposed to change 37 CFR 1.56. See Federal Register Vol. 76, No. 140/Thursday, July 21, 2011/Proposed Rules 43631.

information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) Prior art cited in search reports of a foreign patent office in a counterpart application, and

- (2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) 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 applicant takes in:

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

(ii) Asserting an argument of patentability.

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

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Note especially for purposes of consideration of *Therasense* that 37 CFR 1.56 has its provisions (b)(1) and (2) on materiality. The standard of materiality of provision (b)(1) is characterized here as a “*prima facie*” standard – information is material if it renders a claim unpatentable, on a *prima facie* basis (alone or with other information of record or otherwise, and if not cumulative). The materiality standard of provision (b)(2) is much different. It is characterized here as a “consistency” standard – information is material if it is inconsistent with a position taken to argue for patenting a claim, or against an Office argument to refuse the patenting of a claim (again, alone or with other information of record or otherwise, and if not cumulative).

Surprising to some is this further reference to potential fraud in 37 CFR 1.27

(h):

Fraud attempted or practiced on the Office.

(1) Any attempt to fraudulently establish status as a small entity, or pay fees as a small entity, shall be considered as a fraud practiced or attempted on the Office.

(2) Improperly, and with intent to deceive, establishing status as a small entity, or paying fees as a small entity, shall be considered as a fraud practiced or attempted on the Office.

An associated requirement of “determination” and a “recommendation” of inquiry into small entity status exists in the same section 1.27:

(f) Assertion requires a determination of entitlement to pay small entity fees. Prior to submitting an assertion of entitlement to small

entity status in an application, including a related, continuing, or reissue application, a determination of such entitlement should be made pursuant to the requirements of paragraph (a) of this section. It should be determined that all parties holding rights in the invention qualify for small entity status. The Office will generally not question any assertion of small entity status that is made in accordance with the requirements of this section, but note paragraph (h) of this section.

II. BEFORE THERE WAS INEQUITABLE CONDUCT, THERE WAS UNCLEAN HANDS

Before there was inequitable conduct, there were suits for equity,⁷ and in such suits, there was the maxim of clean hands, also known as the doctrine of unclean hands. *E.g.*, *Loughran v. Loughran*, 292 U.S. 216, 229 (1934). The “hands” of the “suitor” – the plaintiff – were sometimes considered “unclean” such that the plaintiff was deemed to be undeserving of the aid of the equity court. *Id.*

⁷This was a time before about 1915. As *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1031 (Fed. Cir. 1992) stated:

For many decades, parties have generally been allowed to plead equitable defenses at law without having to resort to a separate bill in equity. In 1915, Congress enacted 38 Stat. 956, codified as 28 U.S.C. § 398, which authorized such pleadings. ... Section 398 was then superseded in 1937 by Fed.R.Civ.P. 2 which merged legal and equitable claims into a single civil action. See Fed.R.Civ.P. 2 Advisory Committee note 1; 2 J.W. Moore, *Moore's Federal Practice* ¶ 2.05[2], at 2-33 n. 49 (2d ed. 1991). Section 398 was later repealed as being obsolete in light of Fed.R.Civ.P. 2. *Id.* FN10

FN10. Even before these provisions, an equitable defense could be interjected into a claim at law by way of a bill in equity to enjoin the prosecution of an adversary's suit at law until the equitable defense was decided. *See Liberty Oil Co. v. Condon Nat'l Bank*, 260 U.S. 235, 243, 43 S.Ct. 118, 121, 67 L.Ed. 232 (1922).

See also an adequate Wikipedia treatment of the subject at [http://en.wikipedia.org/wiki/Equity_\(law\)](http://en.wikipedia.org/wiki/Equity_(law)).

This sometimes was a matter of refusing divorced women relief against former spouses – matters of marriage, alleged adultery, divorce, and suits for payment of unpaid alimony. *Id.*

To gain an equity court’s attention, unclean hands had to have an immediate and necessary relationship to the equity for which suit was brought. *Id.*, see Story’s Equity Jurisprudence, 14th ed., §§98, 99, relied on by *Keystone Driller, infra*. Unclean hands did not require that suitors lead blameless lives. *Loughran* at 229. In early jurisprudence, unclean hands also had the limit that it barred the aid of equity, but did not bar the aid of the law court. Story, *id.*

Further, early jurisprudence also stated that when assessing “motive and design,” if motive and design could be ascribed to honesty and legitimacy, as equally as they were ascribed to corruption, there was no unclean hands. *Conard v. Nicoll*, 29 U.S. (4 Pet.) 291, 297 (1830). In other words, doubt about intent was resolved against intention to do wrong.

All of this occurred, of course, in a time of the division of the courts into law courts and equity courts.⁸ Because the equity courts were in the business of

⁸ The referenced “time of the division” is not a reference to Delaware, Illinois, New Jersey, or Virginia, which retain some distinctions between law and equity. See [http://en.wikipedia.org/wiki/Equity_\(law\)](http://en.wikipedia.org/wiki/Equity_(law)). Illinois, for example, still has the division of state courts into Law Division and Chancery Division. Other states do not retain this distinction, having abandoned it beginning in the mid-19th century, and the U.S. federal courts merged law and equity upon adoption of the Federal Rules of Civil Procedure in 1938. *Id.*

providing relief in the presence of rules of law against providing such relief, based on the principal thought of providing mercy where mercy was deserved, refusing mercy to the undeserving was simply a corollary statement of the purpose of the equity courts.

III. UNCLEAN HANDS BEGAT INEQUITABLE CONDUCT

The doctrine of unclean hands led to the doctrine of inequitable conduct. See R. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 *Harv. J.L. & Tech.* 37 (1993). The United States Supreme Court started the courts toward the doctrine of inequitable conduct in a series of cases in the first half of the 20th century that refused to enforce patents for unclean hands. *Id.* An example is *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933).⁹ The Court refused to enforce five patents. It refused because, in relation to one of the patents, the inventor had bought off the potential adverse testimony of a possible prior user of the invention. *See, e.g., Keystone Drill* at 240.

The Supreme Court thus opened the door to the defense of “inequitable conduct” in factual circumstances related to fraud. *Id.*¹⁰ The words of the Supreme Court precedents, though, were words of equity, words of unclean hands. That is,

⁹ See also *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), discussed *infra*.

¹⁰ See also R. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 *Harv. J.L. & Tech.* 37 (1993), both as to this point and the history of inequitable conduct.

Supreme Court patent jurisprudence supported determination of inequitable conduct “not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion.” *Keystone Driller*, 290 U.S. at 245, 246. “Any willful act concerning the [patent infringement] cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim [that “he who comes into equity must come with clean hands”] by the chancellor.” *Id.* Thus, as in all cases seeking equity, in a patent case, the plaintiff had to be free of the taint of “[a]ny willful act” that “transgress[ed] equitable standards of conduct,” including acts taken in procurement of the patent.¹¹

IV. THE SUPREME COURT CASE LAW OF UNCLEAN HANDS AS TO PATENTS WAS CODIFIED IN THE 1952 PATENT ACT

The current patent law is stated, in the main, in the 1952 Patent Act.¹² The Act was in major part a codification of the law in existence at the time. P. J. Federico, *Commentary on the New Patent Act*, 75 J. Pat. & Trademark Off. Soc’y 161, 166-170. As to patents being unenforceable, the Act stated at 35 U.S.C. § 282

¹¹ The Federal Circuit first Chief Judge, Howard Markey, explicitly identified the Supreme Court inequitable conduct cases to be unclean hands cases in *Consolidated Aluminum Corp. v. Foseco Intern. Ltd.*, 910 F.2d 804 (Fed.Cir. 1990).

¹² Congress passed and the President signed the Leahy-Smith American Invents Act in 2011, which modifies portions of the law of the 1952 Act. See http://en.wikipedia.org/wiki/Leahy-Smith_America_Invents_Act. Most provisions are effective in the future, although some few took effect on the day of signing, September 16, 2011.

that a defense to patent infringement was unenforceability. Federico at 215 stated that the defense of unenforceability was to include “equitable defenses such as laches, estoppel and unclean hands.”¹³

V. THE CCPA AND FEDERAL CIRCUIT CREATED THE MATERIALITY-INTENT-BALANCING TEST FOR INEQUITABLE CONDUCT

The Court of Customs and Patent Appeals and its successor, the Federal Circuit, created the materiality-intent-balancing test (hereafter sometimes “the M-I-B” test) for inequitable conduct. For example, *Norton v. Curtiss*, 433 F.2d 779, 792-6 (C.C.P.A. 1971) stated that patent applicants owed a duty of “the highest standards of honesty and candor” to the Patent Office.

The frequent continuing statement that patent applicants owe an uncompromising duty of candor and good faith appears to be a conflation of two statements by the Supreme Court in *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945). The Supreme Court stated that unclean hands concerned “the requirements of conscience and good faith,” and

¹³ The Leahy-Smith America Invents Act leaves inequitable conduct untouched as an available defense to patent infringement litigation, except to the extent of the consequence of new supplemental examination under 35 U.S.C. § 257. Under this provision, within limits beyond this publication, patent owners may seek supplemental examination of issued patents as to previously uncited prior art information. In appropriate circumstances, the involved patent cannot be held unenforceable as to such information. See e.g., http://www.martindale.com/intellectual-property-law/article_Sterne-Kessler-Goldstein-Fox-PLLC_1347604.htm.

separately that patent applicants had an “uncompromising duty to report to [the PTO] *all facts concerning possible fraud or inequitableness underlying the applications in issue.*” *Precision* at 814, 818 (emphasis added). An uncompromising duty to report possible fraud and inequitableness is a different duty than “the highest standards of honesty and candor.” Patent applicants are not PTO fiduciaries.

Nevertheless, *Norton v. Curtiss*, 433 F.2d at 793, subscribed to a relationship of trust between the Patent Office and applicants. The Court stated that *ex parte* prosecution and examination of a patent application “must not be considered as an adversary proceeding” and “should not be limited to the standards required in *inter partes* proceedings.” *Id.* It said the Patent Office had a “tremendous burden” of work, and “no testing facilities,” such that it needed to rely on applicants for many of the facts upon which its decisions were based. *Id.* at 794. These reasons gave rise to its language of the “highest standards of honesty and candor.”

The Court reviewed the elements of fraud, (1) a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation. *Id.* at 792-3.

The Court then reviewed the actions of other courts, which, it said, looked at the equities of the particular cases and determined whether the conduct before them — which might have been admittedly less than fraudulent in the technical sense — was still so reprehensible as to justify the court's refusing to enforce the rights of the party guilty of such conduct. It endorsed the expansion of holdings of unenforceability beyond fraud. *Id.* It stated a standard of materiality beyond “but for” materiality. “Findings of materiality should not be limited only to those situations where there can be no dispute that the true facts, or the complete facts, if they had been known, would most likely have prevented the allowance of the particular claims at issue or alternatively, would provide a basis for holding those claims invalid.” *Id.* It also endorsed a gross negligence standard of intent, and diminished the technical fraud elements of reliance and injury. *Id.*

A recent articulation of the resulting “M-I-B” test is stated, for example, in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). The test had these stated limits:

- The burden of proving inequitable conduct was with the accused infringer.
- To successfully prove inequitable conduct, the accused infringer needed to present evidence that the applicant made an affirmative

- misrepresentation of material fact, failed to disclose material information, or submitted false material information.
- To successfully prove inequitable conduct, the accused infringer needed to also present evidence that the applicant intended to deceive the PTO.
 - At least a threshold level of each element, both materiality and intent to deceive, had to be proven by clear and convincing evidence.
 - Even if this elevated evidentiary burden was met as to both elements, the equities still needed to be balanced to determine whether the applicant's conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable.
 - Where intent to deceive was inferred, the inference of deceptive intent needed to be the single most reasonable inference to be drawn from the evidence.

The Federal Circuit inequitable conduct jurisprudence that stated the “M-I-B” test was often criticized as being vague in its variability, as for example in sanctioning five standards for materiality. See Judge Linn's concurrence in *Larson Mfg. v. Aluminart Products*, 559 F.3d 1317 (Fed. Cir. 2009), see also Brief of *Amicus Curiae* – American Bar Association, in *Therasense*, at 5.

The Federal Circuit asserted that these five these standards were subsumed within and are part of the single overarching test, whatever that meant. *See Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006).

VI. THE LAW OF EQUITY, WITHIN WHICH UNCLEAN HANDS WAS A DOCTRINE, HAD VARIABILITY IN ITS REMEDIES

As above, the Supreme Court case law that gave rise to the presence of the defense of unenforceability in the Patent Act and inequitable conduct in patent cases was unclean hands case law. Unclean hands is a doctrine that refuses the aid of courts to suitors. Still, the law of equity has variability in its remedies. Patent unenforceability is a “terminating sanction,” an ultimate sanction for unjust conduct. Such an ultimate sanction is not always the consequence in equity for unjust conduct.

That is, not all equitable defenses, even considering only patent defenses, provided or now provide complete bars to relief. Laches is an equitable defense, yet it does not bar all relief, only pre-filing damages. *See e.g., Leinoff v. Louis Milona & Sons, Inc.*, 726 F.2d 734, 741 (Fed. Cir. 1984). Further, there are areas of law where an objective of the law is to force infringers of rights (other than patent rights) to consider and examine their actions, and where a duality exists between legitimate interests of infringers and important claims of those who invoke the laws’ policies against infringers. *E.g., McKennon v. Nashville Banner Publishing Co.*, 513 U.S. 352, 360-1 (1995)(age discrimination case). In those areas, courts

may grant relief according to the equities in spite of unclean hands. *Id.* (Patent law is certainly an area such as this, in objective and duality of interests and claims.) It is not inherent in equitable defenses that they must be complete bars to relief.

A case from another area of law is instructive. In *The Pension Committee of the University of Montreal Pension Plan v. Banc of America Securities, LLC*, 685 F.Supp.2d 456 (S.D.N.Y. 2010), District Judge Scheindlin of *Zubulake*¹⁴ fame has written an opinion that is a *tour de force* on the spoliation of evidence, a concern for courts as they consider whether those who “petition” the government (courts) have been fair in their petitioning. The concern arises from the need of the courts to preserve the integrity of the judicial process, to assure it works to uncover the truth. *Id.* at 465. The courts have the power to impose sanctions to protect integrity, but the power is limited to that necessary to redress abusive conduct. *Id.*

The case addresses not egregious examples of wrongful litigants, but careless and indifferent efforts that resulted in adverse consequences for litigation opponents, deprived of something they should have had, *i.e.*, in this area of law, evidence. *Id.* at 463. The question was whether the plaintiff’s conduct deserved sanctions. *Id.*

The law provides a range of sanctions. *Id.* at 467. Less severe ones are fines and cost-shifting. *Id.* More severe ones are dismissal, preclusion and the imposition

¹⁴ See, e.g., *Zubulake v. UBS Warburg LLC* (“*Zubulake V*”), 229 F.R.D. 422 (S.D. N.Y. 2004).

of adverse inferences. *Id.* The court has broad discretion to determine the appropriate sanction. *Id.* at 469. The purposes of sanctions are to: (1) deter the parties from engaging in the wrongful conduct; (2) place the risk of erroneous judgment on the party who wrongfully created the risk to the integrity of the system; and (3) restore the prejudiced party to the same position it would have been in absent the wrongful conduct. The full range of potential sanctions include further discovery, cost-shifting, fines, special jury instructions, preclusion, and the entry of default judgment or dismissal (also known as terminating sanctions). *Id.*

It is well accepted in this area of law that the courts should always impose the least harsh sanction that can provide an adequate remedy. *Id.* A terminating sanction is justified only in the most egregious cases, such as where a party has engaged in perjury, tampering with evidence, or intentionally destroying evidence. *Id.* Further, awards of sanctions risk increased frequency in the filing of sanctions motions. *Id.*

VII. THE FEDERAL CIRCUIT CREATED THE SINGLE CONSEQUENCE OF PATENT UNENFORCEABILITY FOR INEQUITABLE CONDUCT

As demonstrated to this point, uniform, complete and permanent unenforceability of patents to sanction inequitable conduct was not mandated by the law of unclean hands, or equity in general. The Supreme Court precedents on inequitable conduct were hard cases, fraud cases. Thus, consistency with the law

and the Supreme Court inequitable conduct precedents would have permitted that the terminating sanction of patent unenforceability would be justified only in cases of the most egregious conduct, such as the conduct of the Supreme Court precedents. Unenforceability was permitted as a defense to a patent infringement civil action in the 1952 Patent Act, but the Act was permissive that unenforceability is a defense, and only a codification of the common law, such that complete and utter patent unenforceability was not mandated as the minimum consequence of inequitable conduct by the 1952 Act any more than the Supreme Court precedents.

Indeed, not all inequitable conduct is incurable. In the current state of the law, inequitable conduct is not without possibility of cure, albeit in the limited circumstances of correcting it at the PTO before patents issue, with a full disclosure. *See, e.g., Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556 (Fed. Cir. 1983)(“Taking into account human frailty and all of the objectives of the patent system, ... misdeeds [may] be overcome under certain limited circumstances.”).

Further, at least one court in the past considered the possibility of cure of inequitable conduct after prosecution, although it rejected the curative efforts in the specific case. *See Kearney & Trecker Corp. v. Giddings & Lewis, Inc.*, 425 F.2d 579, 597 (7th Cir. 1971).

It is not inherent in inequitable conduct as an equitable defense that taint is permanent and without cure. The analysis in *The Pension Committee*, 685 F.Supp.2d 456, and the resolution there, as to spoliation, are not without their instructive aspect for consideration as to the law of the limits and consequences of inequitable conduct. For inequitable conduct, as for spoliation of evidence, the concern is whether those who “petition” government -- the courts or the PTO -- have been fair in their petitioning. The concern in both areas of law arises from the need of the courts to preserve the integrity of the judicial process, to assure it works to uncover the truth.¹⁵

Nevertheless, it has been the Federal Circuit’s case law, as in *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553 (Fed. Cir. 1984)(*en banc*, in part), that has stated that the minimum consequence of inequitable conduct is always complete, permanent unenforceability of the patents involved. *J.P. Stevens* at 1560.

VIII. THE UNIQUENESS OF INEQUITABLE CONDUCT LED TO ITS FREQUENT USE AS A DEFENSE

Panels and members of the Federal Court, among others, decried inequitable conduct as a plague in at least two periods. *See, e.g., Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008)(Rader, J., dissenting)(inequitable conduct, once “a plague,” “has taken on a new life as a

¹⁵ Patents issue from quasi judicial processes. *See, e.g., United States v. American Bell Tel. Co.*, 128 U.S. 315, 363 (1888).

litigation tactic.”); *see also* the dissent in *Taltech Ltd. v. Esquel Enterprises Ltd.*, 604 F.3d 1324 (Fed. Cir. 2010) (Gajarsa) (“This case exemplifies the ongoing pandemic of baseless inequitable conduct charges that pervade our patent system.”); *see also Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (“[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”); *see also* Randall R. Rader, *Always at the Margin: Inequitable Conduct in Flux*, 59 Am.U.L.Rev. 777, 779 (2010) (The number of inequitable conduct appeals doubled from 2004 to 2008).

In fact, in these same two periods, inequitable conduct cases were pursued in the presence of cautions by the Court against inequitable conduct allegations. *See, e.g., Kothmann Enters. Inc. v. Trinity Indus., Inc.*, 455 F.Supp.2d 608, 647 (S.D. Tex. 2006) (“The Federal Circuit is concerned about the virtually routine assertion of inequitable conduct in patent cases.”); *see also Burlington Indus.*, 849 F.2d at 1422 (Fed. Cir. 1988) (“A patent litigant should be made to feel . . . that an unsupported charge of ‘inequitable conduct in the Patent Office’ is a negative contribution to the rightful administration of justice.”); *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987) (“‘Inequitable conduct’ is not, or should not be, a magic incantation to be asserted against every patentee.”).

The Court may have seen more inequitable conduct cases in these periods despite its warnings for many reasons. Among these reasons, conclusions of inequitable conduct had unique consequences relative to other aspects of patent cases. Inequitable conduct was unique in potential and result for sometimes rendering a group of patents unenforceable. Proof of inequitable conduct could terminate the patent owner's case on the patent in suit and its potential cases on other patents within and beyond its family. *See, e.g., Keystone Driller* (five patents unenforceable).

Inequitable conduct was also unique in potential and consequences in its potentially direct path to compensation from a patent owner for the bringing and expenses of suit. As an example, the Federal Circuit's decision in *Taltech*, 604 F.3d at 1324, affirmed the award of attorneys' fees and costs for reasons including two grounds of inequitable conduct. *See also* 6 D. Chisum, *Chisum on Patents*, §19.03[6] (Matthew Bender), as to nine possible consequences of inequitable conduct.

Inequitable conduct was also unique in patent infringement defenses in the three aspects of (1) diverting attention from the activities of the accused infringer, (2) requiring much less proof of correspondence between prior art and the claimed invention than such patent defenses as anticipation and obviousness, and (3)

focusing on aspects of “who knew what and when they knew it” -- matters that federal district courts were most accustomed to in handling their criminal dockets.

Perhaps only willfulness had a nearly equal focus on intent. However, because the situation addressed in inequitable conduct was interaction with the government in requesting a grant from the government, inequitable conduct had had a uniquely fascinating angle in patent law.

Last, inequitable conduct allegations were made and proofs were attempted because they could be. The Federal Court raised the standards for pleading inequitable conduct in *Exergen Corp. v. Wal Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009). This did not change the substantive aspects of the law.

Raising the pleading standards, as well, was not a panacea for controlling the blight of inequitable conduct allegations. As an example, the Federal Circuit required only that the allegations of facts support a reasonable inference of intent. *Id.* at 1328-29. The Court did not impose that the inference to be drawn from the facts at the pleadings stage had to meet the tests of a case on the merits, as for example, that the inference be the single most reasonable inference able to be drawn from the facts. *Id.* at n. 5.

Moreover, in at least in one district court, pleading barriers did not preclude the pursuit of inequitable conduct charges. That is, the Local Patent Rules enacted by the United States District Court for the Northern District of Illinois included a

form order for patent cases. See N.D.II. LPR Appendix A. According to that order, the accused infringer could pursue inequitable conduct as a defense whether inequitable conduct was pleaded or not. *Id.* at 4.(e) (“Discovery is permitted with respect to ... defenses of patent ... unenforceability not pleaded by a party.”)

IX. INEQUITABLE CONDUCT ESCAPED THE BOUNDS OF CASES ABOUT DISCLOSING OR WITHHOLDING PRIOR ART AND TEST RESULTS

Given the state of the law and the benefits of the consequences of proving inequitable conduct, inequitable conduct came to be asserted against litigants who were not necessarily egregious about highly material prior art and testing matters, but instead who exhibited careless and indifferent efforts as to tangential matters. As an example, in *Gen. Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411-12 (Fed. Cir. 1994), the issue was that a patent owner asserted that its search of the prior art had been careful and thorough, although it was not. The purpose was to gain expedited prosecution. The adverse consequence to the accused infringer was only that it faced a patent that enjoyed expedited examination.

As another example, in *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223 (Fed.Cir. 2007), the issue was the payment of maintenance fees. The adverse consequence to the accused infringer was only that it was sued on a patent as to which the patent owner saved some PTO fees.

“These cases hardly involve the gross misconduct and deceit that characterized the original Supreme Court cases.” Rader, 59 Am.U.L.Rev at 782. Further, in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F. 2d 867 (Fed. Cir. 1988), the Federal Circuit characterized the situation it addressed as to which a District Court found inequitable conduct as a matter of “a ministerial act.” *Id.* at 873. Moreover, “[a]llegations of inequitable conduct often are based on speculation or harmless mistake.” American Bar Association Report with Recommendation #s 107B and 107D at (Policy adopted Aug. 2009).¹⁶ See also L. Dolak, *As If You Didn't Have Enough To Worry About: Current Ethics Issues for Intellectual Property Practitioners*, 82 J. Pat. & Trademark Off. Soc'y 235, 237 and 244-45 (2000)(as to other unique allegations of inequitable conduct).

X. AFTER LETTING INEQUITABLE CONDUCT DRIFT, THE FEDERAL CIRCUIT FACED UP TO THE INJECTION OF THE SUPREME COURT INTO PATENT CASES AND THE DRIFT OF INEQUITABLE CONDUCT LAW IN *THERASENSE*

A. THE SUPREME COURT GOT INTO PATENT CASES, SPEAKING TO FLEXIBILITY AND RIGIDITY

Clearly, the Supreme Court in recent years injected itself into patent cases and patent law. It implicitly and sometimes explicitly stated lessons about which

¹⁶ Attached to the Brief and Appendix of the American Bar Association as *Amicus Curiae*, *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511 et seq. (June 17, 2010). See http://www.americanbar.org/content/dam/aba/migrated/media/nosearch/therasense_v_becton_amicus.authcheckdam.pdf

patent law rules of law should be flexible, and which should be more structured. For example, in *Pfaff v. Wells Electronics*, 525 U.S. 55 (1998), concerning the on-sale bar as to patent validity, the Supreme Court did not accept the Federal Court's flexible, multifactor, totality-of-the-circumstances test to determine the trigger for the on-sale bar, although the test was developed through many cases over years of analysis. 525 U.S. at n.11. As the Supreme Court noted, the totality of the circumstances cases was criticized as unnecessarily vague. *Id.* The Supreme Court resolved that a single more rigid test, in two parts, was appropriate. In reaching this resolution, the Supreme Court used its own precedents, such as *The Telephone Cases*, 126 U.S. 1 (1888), as its primary sources of relevant authority. 525 U.S. at 62-3.

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 728, 737 (2002), the Supreme Court overturned the Federal Circuit's rigid rule that prosecution history estoppel completely barred relief by equivalents. Flexibility of relief as a matter of equity was permitted. As said in *KSR* at 550 U.S. 398 (2007), "[r]igid preventative rules that deny [decisionmakers] recourse to common sense .. are neither necessary ... nor consistent with [Supreme Court case law]."

In *eBay Inc. v. Mercexchange, L.L.C.*, 547 U.S. 388 (2006), the Supreme Court rejected the perceived rigid rule of the Federal Circuit "that a permanent injunction will issue once infringement and validity have been adjudged." *Id.* at

393-34. The Supreme Court again determined that a single rule was not appropriate.

In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court called for flexibility for determining obviousness. The Supreme Court stated that when the CCPA established the “TSM” test, it “captured a helpful insight.” *Id.* at 401. The issue for the Supreme Court was not the value of the test, because it was a helpful insight, but that “[h]elpful insights ... need not become rigid and mandatory formulas.” *Id.* at 401-2. Further, helpful insights applied as rigid and mandatory formulae, can be “incompatible with [Supreme Court] precedents.”

In *Bilski v. Kappos*, 129 S.Ct. at 2735 (2010), the Supreme Court resolved that the Federal Circuit “machine or transformation” test for eligible subject matter for patenting was not appropriate as a rigid single test, and a single test itself was inappropriate. The Supreme Court stated that the “machine or transformation” test remained, as “a useful and important clue, an investigative tool, for determining” the matter to be decided. *See Bilski*, 129 S.Ct. at 2385.

Where it had reason to speak on the scope of the exercise of discretion, an exercise that is inherent in equitable matters such as injunction and unclean hands, the Supreme Court also stated that familiar principles of equity apply with equal force to disputes arising under the Patent Act as elsewhere. *eBay*, 547 U.S. at 391. These principles include, inherently, flexibility, so as to permit providing relief in

the presence of rules of the law courts against such relief.¹⁷ For example, in a distant and unrelated area of law, the Supreme Court stated that it had “made clear that often the ‘exercise of a court’s equity powers ... must be made on a case-by-case basis”:

....In emphasizing the need for ‘flexibility,’ for avoiding ‘mechanical rules,’ *Holmberg v. Armbrecht*, 327 U.S. 392, 396 (1946), we have followed a tradition in which courts of equity sought to ‘relieve hardships which, from time to time, arise from a hard and fast adherence ‘ to more absolute legal rules, which, if strictly applied, threaten the ‘evils of archaic rigidity.’ *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 248 (1944).

Holland v. Florida, 2010 WL 2346549 (June 14, 2010). There, a first degree murderer was subject to strict time limits of the Antiterrorism and Effective Death

¹⁷ The Supreme Court also explained that discretion is not to be free of legal standards. For example, in speaking on the grant of injunctions in *eBay*, the Supreme Court stated:

Discretion is not whim, and limiting discretion according to legal standards helps promote the basic principle of justice that like cases should be decided alike." *Martin v. Franklin Capital Corp.*, 546 U. S. 132, 139 (2005). When it comes to discerning and applying those standards, in this area as others, "a page of history is worth a volume of logic." *New York Trust Co. v. Eisner*, 256 U. S. 345, 349 (1921) (opinion for the Court by Holmes, J.).

Id. at 395.

Quoting another of its cases, the Supreme Court also stated that “in a system of laws discretion is rarely without limits. ... we have found limits in ‘the large objectives’ of the relevant Act, which embrace certain ‘equitable considerations.’”
Id.

Penalty Act of 1996, specifically intended to expedite executions. Nevertheless the Supreme Court gave equitable relief, and more time.

B. THE FEDERAL CIRCUIT INEQUITABLE CONDUCT STANDARDS DRIFTED

Perhaps the greatest knock on Federal Circuit inequitable conduct law before *Therasense*¹⁸ was its five different standards of materiality for determining inequitable conduct. As well, as the Brief of the American Bar Association as *Amicus Curiae*, *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511 et seq. (June 17, 2010) advocated at 11-15, one could readily assert that the test of inequitable conduct was at substantial variance with Supreme Court precedents. Notable is that the Supreme Court had not considered inequitable conduct in the terms of the test of the Federal Circuit. *Id.* As advocated by the ABA, the Supreme Court had only considered inequitable conduct in factual circumstances related to fraud. *Id.*²⁰

Consistent with the swirl of Supreme Court patent law and other cases in which it was caught, the Federal Circuit used *Therasense* to state numerous questions for decision (the court's references to specific cases are omitted):

¹⁸ The en banc decision is *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011)(en banc). Unless indicated otherwise, the term “*Therasense*” refers to this decision.

²⁰ See also R. Goldman, Evolution of the Inequitable Conduct Defense in Patent Litigation, 7 Harv. J.L. & Tech. 37 (1993), both as to this point and the history of inequitable conduct.

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? If so, what is the appropriate standard for fraud or unclean hands?
3. What is the proper standard for materiality? What role should the US PTO'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?
4. Under what circumstances is it proper to infer intent from materiality?
5. Should the balancing inquiry (balancing materiality and intent) be abandoned?

Order, *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511 et seq. (April 26, 2010). See http://scholar.google.com/scholar_case?case=168078651441767028&q=therasense+becton&hl=en&as_sdt=4,131.

XI. IN *THERASENSE*, THE FEDERAL CIRCUIT FACED WIDE RANGING CHOICES

In considering inequitable conduct in *Therasense*, the Federal Circuit faced wide ranging choices among matters that might affect its decision making. For example, it needed to consider whether its test for inequitable conduct was at variance with Supreme Court precedents, as to both their holdings and pronouncements, but before that, whether the Supreme Court pronouncements were *dicta* or the *ratio decidendi*.

As an example, the Federal Circuit dissent correctly observed in *In re Bilski*, 545 F.3d 943, 984 (Fed. Cir. 2008), *rev'd*, *Bilski v. Kappos*, 129 S.Ct. at 2735

(2010), that a Supreme Court description seeming to endorse “transformation” as a test for patent-eligible subject matter was *dictum* and not to be followed.

As a second example, in the context of stockholder proxy solicitation disclosures, the Supreme Court itself observed that a formulation of materiality found in its own words was not the correct formulation of materiality. *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 446-47 (1976). The formulation in its own words was a “might” formulation. The Supreme Court instead applied the formulation found in the Restatement of Torts, an objective “would” formulation. It said the “might” formulation would have led to an inappropriate “avalanche” of disclosure, not unlike the problem caused by inequitable conduct in patent law. *Id.* at 448-49.

After considering the problem of *dicta*, the Federal Circuit also had to consider whether courts should apply a rigid sole test for decision, or on the other hand, apply discretion that is not bound by formula but has limits in large objectives of the Patent Act that embrace equitable considerations. The Court could decide that discretion should be permitted. If so, then the Federal Circuit single test was to be changed, at a minimum from being the sole test for decision.

Perhaps the Federal Circuit single test was to be changed to being a useful and important clue, an investigative tool, for determining whether some patents are unenforceable for unclean hands. The Federal Circuit could then have accepted

that determination of inequitable conduct is not to be restrained by any limitation that tends to trammel the free and just exercise of discretion, in that any willful act in patent prosecution that concerns the patent infringement cause of action at bar and which rightfully can be said to transgress equitable standards of conduct, as exemplified in the early Supreme Court cases on inequitable conduct, is sufficient cause for the invocation by a district court of the maxim that "he who comes into equity must come with clean hands."

On the other hand, given that the cases in which the Supreme Court concluded that inequitable conduct was present were cases of egregious conduct, the Federal Circuit could have considered whether its test should conform to the narrow actual holdings of the Supreme Court cases. "A page of history is worth a volume of logic." *eBay* at 395. In copyright law, also, unclean hands is "recognized only rarely ...when the ... transgression is of serious proportions [as by] falsifying a court order, ... evidence, or misrepresented ... or obtained information ... through unfair means." 3 M. Nimmer, Copyright § 13.09(b)(1978).

If fraud was to be the standard of inequitable conduct, developing the application of the standard of fraud could have been a concern to the Court. "Fraud" is not self-defining. Of course, in *Seagate*, the Federal Circuit adjusted the standard of intent for willfulness to comport with Supreme Court law. It became a standard requiring objective recklessness, see *In re Seagate Technology*, 497 F.3d

1360, 1371 (Fed. Cir. 2007) (*en banc*). The Court also trusted future cases to further develop the application of the standard, *Seagate* at 1371.

The Court could also have considered the parallels of the *Therasense* case to the *Bilski* case. There, Supreme Court precedents were several in number, with some on one side of a divide and one, *Diamond v. Diehr*, 450 U.S. 175 (1981), on the other. So too in *Therasense*, there were several Supreme Court precedents, with some on one side of a divide and one, *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358 (1928), apparently on the other.

In *Corona*, the Supreme Court was sitting as a court of equity, as the subject case was a bill to enjoin infringement, a subject of equity. *Corona* at 364. A contention analyzed in the case was whether the patent was procured by false evidence. The contention was also stated to be in the interest of depriving the patent of its presumption of validity. The Court rejected the contention. The Court stated that affidavits filed at the PTO “though perhaps reckless, were not the basis for [the granting of the patent] or essentially material to its issue.” Without saying a word as to whether a court could, within the bounds of equity, strip a patent of its validity presumption, the Court resolved that in the case before it, the presumption was not destroyed.

The Federal Circuit could have considered whether *Corona* represented the analog to *Diehr* in the *Bilski* situation, and whether *Corona* demanded that conduct

that can be characterized as “perhaps reckless” but not more, and not a basis for the granting of a patent or essentially material to the grant, should not be inequitable conduct.

The Court could have also considered whether the analysis within and the resolution of *Skilling v. United States*, 130 S.Ct. 2896 (2010) could have been useful for consideration of the scope of the law of inequitable conduct. In *Skilling*, the Supreme Court addressed challenges to the federal criminal “honest services” law. Like inequitable conduct law, *see infra*, the honest services law had drifted in its application. Like inequitable conduct law, the honest services law was in a statute, but one that codified common law. As with the Federal Circuit’s inequitable conduct law, the honest services law was subject to assertions of vagueness and overbreadth. The Supreme Court resolved that the honest services law had a scope consistent with the common law it codified. It had a scope limited to fraud and bribery. The Supreme Court returned the honest services law to its common law roots of fraud and bribery.

Surely the Federal Circuit intended its inequitable conduct law to articulate as its test of inequitable conduct the very factors for analysis that spring from and harmonized the precedents of the common law of unclean hands in patent cases. As with the common law roots of the honest services law, the Federal Circuit’s inequitable conduct law sprang from the Supreme Court’s common law precedents,

some of which immediately preceded the 1952 Patent Act and which are narrow in terms of their facts and holdings. Thus, just as the *Skilling* Court returned the honest services law to its common law roots of fraud and bribery, the Federal Circuit could have found it appropriate to return the scope of inequitable conduct law to its common law roots of fraud. And as with *Skilling*, the Court would have thereby overcome challenges to inequitable conduct law as to vagueness and overbreadth, while preserving the law.

In considering whether to change its test for inequitable conduct, the Federal Circuit could have concomitantly considered whether to adjust its law as to the limits and consequences of inequitable conduct. If the Court returned to the origin of the equitable maxims and seminal precedents involved, it could have also returned to the limits and consequences of the maxims.

For example, if the Court found that there was variance from maxims and seminal precedents, it could have then considered whether the law of inequitable conduct should permit court relief to a patent owner who has distanced itself from inequitable conduct, before seeking the aid of the court -- based on the lack of an immediate and necessary relationship between the unclean hands and the equity sought.

The Federal Circuit could also have considered whether it should reinforce the limit that its case law has recently strongly embodied, and that exists in the

origin of unclean hands doctrine, that if motive and design can be ascribed to honesty and legitimacy, as the single most reasonable inference, then there has not been inequitable conduct. *See, e.g., Star Scientific*, 537 F.3d at 366-67 and *Conard*, 29 U.S. (4 Pet.) at 291, 297.

But for existing Federal Circuit law, as courts of equity, the district courts would have the range of power of equity to impose sanctions to protect system integrity, for inequitable conduct, a power properly limited to that necessary to redress conduct which abuses the process. In both equitable conduct law and spoliation law, the question for the court is whether conduct deserves sanctions. The purposes of sanctions would seem to be the same. It is also known that awards of sanctions risk increased frequency in the filings of both types of charges.

As in willfulness and the *Seagate* decision, the Court could have considered that times change and call for different legal tests. Just as *Seagate* at 1368 *et seq.* recognized that the widespread disrespect of patents that existed in 1982 no longer existed as of the time of *Seagate* (2007), *Therasense* could have recognized that the issue of the day was not widespread, egregious inequitable conduct. It was in fact the opposite, a time of almost universally obsessive overdisclosure of information to the PTO. ABA Report #s 107b, 107d, *supra*. It was also a time of allegations that are a plague and pandemic.

Also, just as in *Seagate*, the Court could have recognized that its test of inequitable conduct had created practical concerns that called for change. This is not to say that the necessary relationship of trust in *ex parte* prosecution, see *Norton v. Curtiss*, 433 F.2d at 794, was to be undone. It is that reasoning was required beyond the reasoning that honesty and candor are needed to unburden the PTO. Reasoning was needed about the new, then-present set of facts – that by reason of the current test of inequitable conduct, honesty and candor *themselves* were burdening the PTO. Compare *Norton* at 794. See also *Rohm & Haas Co.*, 722 F.2d 1556, 1571, and E. Peters, Note, *Are We Living in a Material World?: An Analysis of the Federal Circuit's Materiality Standard Under the Patent Doctrine of Inequitable Conduct*, 93 Iowa L. Rev. 1519 (2008), as to policy considerations to be balanced, and how to balance them. (*Skilling* might also have provided the parallel for *Safeco Ins. Co. of Am. v. Burr*, 127 S.Ct. 2201 (2007), cited in *Seagate*. See *Seagate* at 1370-1.)

Likewise, perhaps the law could have provided a range of sanctions, just as in the area of spoliation. *Corona* at 373 considered whether to strip a patent of its presumption of validity because of “false evidence,” and simply by addressing the matter as such implied that stripping the presumption was a potentially appropriate sanction for the inequitable conduct aspect of the situation as well as the validity aspect.

Perhaps the same less severe sanctions as in spoliation could have been caused to exist. Perhaps the same more severe sanctions could have been caused to exist. Perhaps as in *Corona*, stripping the presumption of patent validity could lie somewhere along the spectrum of sanctions. Further, perhaps consistent with their powers and capabilities as courts of equity, as admirably represented by the analysis and resolution of *Pension*, the district courts could have been given broad discretion to determine the appropriate sanction for the inequitable conduct before them. Perhaps as in spoliation, it could have been accepted in inequitable conduct law that courts should impose the least harsh sanction that can provide an adequate remedy, after selection of an appropriate remedy as a delicate matter, after the investment of a great deal of time and attention.

Perhaps it was time for not only the limits but also the consequences of inequitable conduct law to change, such that on a case-by-case basis, lesser offenses as in wrongly expediting patent prosecution and wrongly paying small entity fees could be addressed by appropriate and less severe sanctions than a complete loss of the right to a remedy.²¹

XII. IN SPITE OF THE POTENTIAL, ORAL ARGUMENT SIGNALLED LITTLE CHANGE WAS POSSIBLE

²¹ For additional ideas, see N. Murphy, Note, *Inequitable Conduct Doctrine Reform: Is the Death Penalty for Patents Still Appropriate?*, 93 Minn. L. Rev. 2274 (2009).

The Federal Circuit heard the oral arguments in *Therasense* in November 2010.²² In spite of the potential for significant change to the law from the Federal Circuit’s initial listing of the questions for which it wanted argument, and the wide range of choices for analysis available to it, the oral argument signaled that the change to the law could range from big change to some change to little change at all.

Striking during argument – the only striking aspect of argument - was the freely made admission by the advocate for the PTO that under current standards, including the current Rule 56 standard for which he advocated, the Patent Office was experiencing the disclosure of so many prior art references by so many applicants that it had labeled the practice as “reference flooding.” Transcript at 23, *Id.* The advocate also volunteered that the USPTO knew applicants were acting in fear and did not know what to disclose. *Id.*

In spite of this admission, however, and in spite of setting the case up as if the whole of the framework of law for inequitable conduct was in question, the Federal Circuit at oral argument revealed it might only change inequitable conduct law in nuanced and minor ways. In spite of reference flooding as a compelling reason to narrow the law, some judges were focused solely on the potential for

²² A transcript of the argument is available at <http://www.patentlyo.com/files/therasense-v-becton---transcription.pdf>

applicants to commit inequitable conduct under a significantly narrowed rule of law. Other judges were focused solely on a companion issue, the lack of precedents for a narrow “but for” standard of a narrowed rule.

Questioning by the judges of all advocates speaking on materiality at the oral argument revealed that, perhaps to get to a unifying decision of the Court, the judges might have invented a new, “midrange” standard of materiality for the law, a standard having a scope somewhere between both of “but for” materiality and the section (b)(1) materiality of the current Rule 56 of the Patent Office,²³ on the one hand – the narrow side of materiality - and section (b)(2) of the current Rule 56, on the other hand – the broad side of materiality.

The judges were accepting of the part (b)(1) of the rule, which states that information is material if it “establishes, by itself or in combination with other information, a *prima facie* case of invalidity of a claim.” This is somewhat broader than the narrow “but for” materiality,” but not truly broad.

²³ (b) 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 applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

The judges were not accepting of part (b)(2) of the rule, that information is material if it “refutes, or is inconsistent with, a position an applicant takes in opposing an argument of unpatentability relied on by the Office,” or a position the applicant takes in “asserting an argument of unpatentability.” This standard *is* truly broad. More than one judge spoke out against the (b)(2) standard, the most notable assertion being that it was broad and amorphous, and would swallow up any other definitional aspect of “materiality.” An example given was that if an applicant argued for non-obviousness, inequitable conduct under the (b)(2) standard could be asserted in any failure to disclose any known information tending toward obviousness.

The potential change of the case became not as predictable as possible, in part, because the oral argument lacked for responses to obvious questions of the Court. In a golden opportunity, an advocate was invited to suggest the articulation of a standard that would lie between the (b)(1) standard and the (b)(2) standard, and overcome the problem of the stated example. The advocate involved failed to respond meaningfully.

The potential of the case for drama was also reduced because on the intent aspect of inequitable conduct, there was an apparent consensus among the advocates, rather than a vigorous dispute that could lead to significant analysis and change. The apparent consensus was that the Court should state that intent could

not be inferred from materiality alone, and that wrongful intent had to be the single most reasonable inference from the evidence. This, however, was essentially no change from recent Federal Circuit case law. Uniformity of suggestion to reinforce the intent standard of the *Kingsdown* case would also cause no change in the law, as that case articulated only a language variation that wrongful intent must be the single most reasonable inference from the evidence.

It was the author's opinion, that with no change to the (b)(1) standard of materiality, and no change to the standard of intent, patent prosecutors would not enjoy inequitable conduct law gaining the sense it lacked. There would be no fix of the law. Prosecutors would continue to be concerned that they could not know what they could refrain from disclosing, and could not assure that their good intentions would be assessed so as to prevent conclusions of inequitable conduct. They would worry that the one or two references they did not disclose would be considered to make out a *prima facie* case of invalidity of one or more claims, and that inability to remember later why references were not disclosed, would subject them to decisions against them and their licenses to practice. And with no change to prosecutor worries, the PTO would continue to get flooded.

XIII. THEN CAME THEREASENSE

After some delay, the *en banc* decision in *Therasense* issued, as a split decision, authored by the Federal Circuit Chief Judge, with five other judges in

support in full, one judge joining in only one part of the opinion, and four judges in dissent. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011)(*en banc*). In a surprise decision, given the oral argument, the Court majority did act to narrow the materiality test for inequitable conduct to “but-for materiality” -- as a general matter. Explaining the application of the new rule to the important situation of undisclosed prior art, the Court stated, “When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” 649 F.3d at 1292. Patent applicants thus have a different assurance in this standard than in the past as they go about considering whether to disclose what they judge to be marginal prior art.

The Court also narrowed the intent test, as well, tightening it down to a tight recitation of the *Kingsdown*, *Star Scientific* and *Scanner Techs.* standards. 649 F.3d at 1291. “[T]o meet the clear and convincing evidence standard, the specific intent to deceive must be the ‘single most reasonable inference above to be drawn from the evidence.’” *Id.* Adding emphasis, the Court stated, “the evidence ‘must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances.’” *Id.* “Hence,” it said, “when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.” *Id.*

Moreover, the Court stated there is not to be a “sliding scale” balancing materiality and intent, and that intent may not be inferred solely from materiality.

Id.

Thus, the Court’s decision represents the Court’s abandonment of the “reasonable examiner” standard of materiality, the gross negligence standard of intent, and the balancing of materiality and intent. It also represents the Court’s rejection of “Rule 56” (37 CFR 1.56) of the recent past. On Rule 56, the Court found that even its standards of materiality and intent were too broad.

Somewhat unusually, however, the majority opinion stated that “but for” materiality and the rest of its test for inequitable conduct were subject to an exception – one for a patentee who “has engaged in affirmative acts of egregious conduct.” 649 F.3d at 1293. The opinion stated that “[w]hen the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.” *Id.* Little else was said about the exception, leaving it largely unbounded in its structure and standards.

XIV. DOES *THERANSENSE* MAKE SENSE? HAS THE FEDERAL CIRCUIT FINALLY FIXED INEQUITABLE CONDUCT LAW?

Whether *Therasense* has fixed inequitable conduct law, unfortunately, like beauty, is in the eye of the beholder. The US PTO, on the one hand, having argued against change, and for respect for its then-current Rule 56, reversed field and announced plans to adopt the *Therasense* standard of materiality shortly after

issuance of the *Therasense* decision. But others are not so pleased with the decision.

A first priority for debate is the exception the Court created to its new rule of materiality. That exception is for “affirmative acts of egregious misconduct.” The exception, the Court stated, “incorporates elements of the early unclean hands cases before the Supreme Court.” 649 F.3d at 1293. The exception is that “where the patentee has engaged in affirmative acts of misconduct, ... the misconduct is material.” *Id.* Arguably, the exception rephrased is that “affirmative acts of egregious misconduct [are *per se*] material.”

This exception will not swallow the rule, the Court said, in that the exception would not “penaliz[e] the failure to disclose information that would not have changed the issuance decision.” *Id.* The Court was striking “a necessary balance,” it said, “between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct.” *Id.* “After all,” it reasoned, “a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent.” *Id.* The example it gave of an affirmative act of egregious misconduct was “the filing of an unmistakably false affidavit,” and it cited two of its own cases to support its point, *Rohm & Haas Co.*, 722 F.2d 1556, 1571 (“there is no room to argue that submission of false affidavits is not material”) and *Refac Int'l, Ltd. v. Lotus Dev.*

Corp., 81 F.3d 1576, 1583 (Fed. Cir. 1996) (finding the intentional omission of a declarant's employment with the inventor's company rendered the affidavit false and that "[a]ffidavits are inherently material"). *Id.*

A first concern of critics is that unfortunately, the laws and PTO regulations are written such that small entity status is established by “inherent” affidavit. As a result, the *Therasense* decision arguably elevates the filing of at least an “unmistakably false” small entity assertion to *per se* materiality. This elevation apparently occurs even though no less than the Chief Judge specifically criticized the *Nilssen* case, 504 F.3d 1223, for finding inequitable conduct in the filing of a small entity affidavit, see Rader, 59 Am.U.L.Rev. at 782. It also apparently occurs even as to maintenance fee payments even though the opinion in *Ulead Systems v. Lex Computer & Management Corp.*, 351 F.3d 1139, 1146 (Fed. Cir. 2003) described as correct an argument that after patent issuance, a small entity filing has “no bearing on patentability” and “[could not have] induce[d] issuance of the patent.”

That is, according to PTO rules, small entity status is established by either a signed assertion of status or payment of a small entity fee. See 37 CFR 1.27(c)(1) and (c)(3). According to MPEP 509.03, “[u]nder 37 CFR 1.4(d)(4), an assertion ... including the mere payment of an exact small entity basic filing fee, inherently contains a certification under 37 CFR 11.18(b).” Indeed, 37 CFR 1.4(d)(4) does

state that “the presentation to the Office (whether by signing, filing, submitting, or later advocating) of any paper by a party ... constitutes a certification under § 11.18(b) ...” Thirty-seven CFR 11.18(b) in turn states that [b]y presenting to the Office ... (whether by signing, filing, submitting, or later advocating) any paper, the party presenting such paper ... is certifying that – (1) All statements made therein ... are made with the knowledge [that they are] subject to the penalties set forth under 18 U.S.C. 1001 [for perjury for perjurious statements].” Indeed, 18 U.S.C. 1001 generally states that in communications with the United States Government, those who submit false statements of fact are punishable by fine, time in prison, or both. Thus, by reason of law and regulation, small entity status, critics of *Therasense* argue, is established by an assertion or fee payment either of which takes the form of a declaration under penalty of perjury, equivalent to an affidavit.

Thus, critics argue, in elevating the filing of unmistakably false affidavits to the status of *per se* materiality, the *Therasense* decision elevates the filing of at least an unmistakably false small entity assertion to the status of *per se* materiality. But arguably, in apparently making small entity status remain a potential subject of inequitable conduct, rather than clearing it out as a potential subject, *Therasense* did not hold true to its goal of clearing the system of penalties for “the failure to disclose information that would not have changed the issuance decision.” 649 F.3d at 1293. Arguably, it did not strike “a necessary balance between encouraging

honesty before the PTO and preventing unfounded accusations of inequitable conduct.” *Id.* And arguably, the filers of false small entity assertions and fees are not those who have gone “to great lengths to deceive the PTO with a falsehood” such that they deserve their filings to be subject to *per se* materiality. *Id.*

But on the other hand, consider again 18 U.S.C. 1000. It *generally* states that in *all* communications with the United States Government, those who submit false statements of fact are punishable by fine, time in prison, or both. Thus, if the logic of critics is followed, *Therasense* established that *any and every* communication to the PTO that states facts takes the form of a declaration under penalty of perjury, equivalent to an affidavit. If that is what *Therasense* meant, it chose poor language in stating that the primary example of its affirmative egregious misconduct subject was *affidavits*, as opposed to *all communications with the PTO that state facts*.

If then, as would seem logical, the *Therasense per se* materiality is directed to a subset of communications with the PTO, but, it also states, “not just the filing of false affidavits,” 649 F.3d at 1293-4, the question is, what subset? One approach to defining the subset would be to limit the rule to only those communications that expressly, actually include the language of an affidavit or declaration. There certainly are instances where the PTO requires the express language or applicants expressly use it. And the Federal Circuit itself holds that some communications that would seem to include statements of fact do not include such statements. *See,*

e.g., Life Technologies v. Clontech Laboratories, 224 F. 3d 1320, (Fed.Cir. 2000)(“the inventors merely advocated a particular interpretation of the teachings of the Johnson article and the level of skill in the art ...This argument did not contain any factual assertions that could give rise to a finding of misrepresentation.”); *Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1482 (Fed.Cir.1986) (holding that an argument for distinguishing prior art, even though favorable to the applicant's position, was not a material misrepresentation because the Examiner could reach his/her own conclusions regarding the prior art). Another approach would be to direct the rule to all communications, as opposed to express affidavits or declarations, but only the communications within the limit of the Court’s thought that “inequitable conduct ... should only be applied in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.” 649 F.3d at 1293. A third approach would be to limit *per se* materiality to only express affidavits and declarations and only those express affidavits and declarations that resulted in an unwarranted claim. The last approach would certainly exclude small entity “affidavits” (assertions of small entity status, whether by express affidavit or inherent affidavit).

Still within the bounds of the “affirmative act” exception establishing, paraphrased, *per se* materiality, critics further consider the facts of one of the cited

cases *Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576. There, a patent was rejected for lack of adequate disclosure. Affidavits were submitted to overcome the rejection. One, a Pardo affidavit, was from an inventor, and the examiner rejected it as self-serving. After that, three other affidavits were filed, Bullen, Cikra and Jones. No inequitable conduct was found as to the Bullen or Cikra affidavits, and each asserted an opinion of enablement. Ultimately, however, a judgment of inequitable conduct was affirmed. It was affirmed because the Jones affidavit omitted that Jones had worked at the inventor's company within the six months before he signed the affidavit, even though he did not work there at the time of the affidavit, that he had worked with and reviewed documents for the commercial embodiment of the invention, and the invention had been explained to him. This was considered material information, *i.e.*, pre-existing knowledge of the invention.

Critics find in this cited case little to have deserved *per se* materiality treatment because of any *affirmative* acts of misconduct. The asserted matter of inequitable conduct was not an affirmative misstatement or falsehood. It was instead, omission. Thus, the *Refac* case citation seems to reveal to critics that *Therasense* states that courts are to treat the absence of available statements from affidavits as *per se* material, where the only affirmative acts were the acts of filing the affidavits, with no inquiry into whether there was active effort to exclude the missing statements. The otherwise apparent dichotomy of the case between its

exception for “affirmative acts” versus its rule for non-disclosure thus appears illogical in including in the exception the non-affirmative acts of omissions of available statements.

Of course, thus understood, *Therasense* does not state a dichotomy between affirmative acts and omissions. It states a dichotomy between affirmative acts that include omissions on the one hand, and omissions in disclosures of prior art on the other.

A panel decision of the Federal Circuit following *Therasense* offers some early hope for good sense in application of the *per se* rule. In *Powell v. The Home Depot U.S.A., Inc.*, slip op., No. 2010-1409 (Fed.Cir. November 14, 2011), the court affirmed a decision against inequitable conduct. The patent applicant had filed a Petition to Make Special. Before it was granted, circumstances changed, and the patent applicant did not update the petition. Indeed, the circumstances had so changed that the petition should no longer have been granted. The petition was granted, however, and the application received the benefit of the petition, expedited review.

The district court found intent to deceive and materiality but refused, on balance, to find inequitable conduct. The Federal Circuit stated that failing to update a petition to make special was not inequitable conduct. It stated that the conduct failed the but-for materiality test of *Therasense* and was “not the type of

unequivocal act, ‘such as the filing of an unmistakably false affidavit,’ that would rise to the level of ‘affirmative egregious misconduct.’” Slip op. at 18.

Note that *Powell* categorizes the subset of communications with the PTO that deserve *per se* materiality treatment as those that represent the same “type of unequivocal act” as the filing of unmistakably false affidavits. While the “unequivocal act” standard of *Powell* does provide guidance, it begs the question, “what is the measure of unequivocal-ity?” It only excludes from these acts the act of failing to update a record on a petition to inform the PTO that the petition should no longer be granted. Its reasoning that this failure “is not the type of unequivocal act ... that would rise to the level of ‘affirmative egregious misconduct’” is also arguably conclusory and not explanatory.

Critics also turn to the remand to the District Court as a subject of confusion. *Therasense* concerned a declaration, of a Sanghera. 649 F.3d at 1285. The declaration did not disclose briefs to the EPO in a corresponding patent application where the briefs were directed to the European equivalent of U.S. cited prior art as to which the declaration was directed. *Id.* at 1286. A declaration, of course, is the equivalent of an affidavit. See, *e.g.*, 28 U.S.C. § 1746 and 37 CFR 1.68. Unmistakably false affidavits are *per se* material. Nevertheless, the *Therasense* decision sent the case back to the District Court to “determine whether the PTO would not have granted the patent but for [the] failure to disclose the EPO briefs.

In particular, the district court must determine whether the PTO would have found Sanghera's declaration ... unpersuasive in overcoming ... rejection ... if Abbott had disclosed the PTO briefs."649 F.3d at 1296.

The confusion of the critics is as to the interplay of the Court's statement about the *per se* materiality of unmistakably false affidavits and its simultaneous lack of direction on remand that the District Court should apply a *per se* rule of materiality. Was the Court not even careful enough in its decision to implement its own new rule as to affidavits? Did it mean to draw a distinction between an affidavit and a declaration? (Surely not.) Was there something unique about the Sanghera declaration such that it was outside the *per se* rule about affidavits? Or something unique such that it enjoyed an unstated exception to the *per se* rule? Was it not unmistakably false? To critics, the interplay of instructions on remand with the rules of the case leave something to be desired.

Critics also direct attention to an early statement in the case concerning unclean hands. The Court states: "The unclean hands doctrine remains available to supply a remedy for egregious misconduct like that in the Supreme Court cases." 649 F.3d at 1289. The Court makes this statement in the context of stating that the Court's own development of a materiality requirement for inequitable conduct "does not (and cannot) supplant Supreme Court precedent." *Id.* It notes that the Supreme Court cases did not state a standard of materiality.

What does this mean? Does the Court mean to say that as to court review of conduct before the PTO, there is not only a governing doctrine of inequitable conduct with standards of materiality and intent, and an exception for affirmative acts of egregious misconduct, but there is also a governing doctrine of unclean hands, as to egregious misconduct, with no stated standard of materiality? It might seem so. If so, how is the doctrine of unclean hands as to egregious misconduct different from the Court's own doctrine about affirmative acts of egregious misconduct? Does the doctrine of unclean hands extend only to egregious misconduct "like that in the Supreme Court cases ("perjury, the manufacture of false evidence, and the suppression of evidence," 649 F.3d at 1289)," while the Court's own doctrine extends beyond such misconduct? Perhaps. The Court noted that the doctrine of inequitable conduct "adopted a different and more potent remedy – unenforceability of the entire patent rather than dismissal of the entire suit" – than did the unclean hands doctrine. *Id* at 1288. Is the difference then in the remedy, such that the same acts could be judged under the Court's standards as to patent unenforceability and yet also under the Supreme Court's case law as to dismissal of the suit? Also perhaps.

After airing these concerns, critics then turn to the assessment to be made of materiality for undisclosed prior art. Most patent cases now have *Markman* hearings. See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). The

rules for interpreting patent claims in *Markman* proceedings are now fairly well known. Patent claim limitations are not to simply be given their broadest reasonable construction. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed.Cir. 2005) (en banc). In the assessment of materiality for undisclosed prior art, however, the rules of *Markman* do not apply. Instead, patent claims *are* to be given their broadest reasonable construction. 649 F.3d at 1292. Hence, nothing done by *Markman* interpretation will typically have relevance to what is coined here as “*Therasense* interpretation.” Where inequitable conduct for undisclosed prior art is an issue in a case, is the court then to conduct a *Markman* proceeding to arrive at a *Markman* interpretation, but also to conduct a *Therasense* proceeding to arrive at a *Therasense* interpretation? So it would seem. Why should interpretation for purposes other than inequitable conduct be any less carefully handled than interpretation for inequitable conduct purposes, where “the remedy for inequitable conduct is [admittedly] the ‘atomic bomb’ of patent law.” 649 F.3d at 1290. There will no doubt be at least as much dispute over *Therasense* interpretations of claim terms as there are over *Markman* interpretations. Should the proceedings then be simultaneous, with each party proposing, briefing and orally arguing for two interpretations of the claim terms in dispute, one for *Markman*, one for *Therasense*? That would seem confusing. When and how, then, is *Therasense* interpretation to occur?

Critics further turn to the issue of balancing between materiality and intent. The *Therasense* majority opinion does not even use the term “balancing” or any variation of the word in relation to the issue of balancing materiality and intent. Instead, in the closest language used, the Court stated that a “district court should not use a ‘sliding scale’ where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa.” 649 F.3d at 1291. Critics consider the Court to have not abolished balancing through use of this language. The Court spoke of its past case law, however, as having “placed intent and materiality together on a ‘sliding scale,’” and cited *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984) to that effect. *Am. Hoist* does not use the language “sliding scale,” though, and instead uses the term “balancing,” such that the Court was obviously using the terms “sliding scale” and “balancing” as synonyms, probably using the term “sliding scale” as a pejorative to denigrate its own test of balancing. On this point, consequently, the cries of critics are much misplaced.

Counter-critics, however, have a more significant, related point to make. The Court eliminated balancing of materiality and intent, but did not eliminate the largely equivalent use of materiality to prove intent. Speaking of the use of materiality to prove intent, the Court stated that “[i]ntent and materiality are separate requirements. ... A district court should not use a ‘sliding scale’ ...

Moreover, a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality.” 649 F.3d at 1291. Still, the Court continued that “[b]ecause direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence.” *Id.* In another part of the decision, the Court stated that proof of intent to deceive, where the allegation of inequitable conduct is based on lack of citation of a reference, includes proof “that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” 649 F.3d at 1291. This combination of statements, counter-critics note, does not state that materiality is not relevant to intent, and in any event, proof of knowledge of materiality by circumstantial evidence should reasonably include consideration of materiality. If materiality is high, then the inference is that knowledge of materiality was present. Thus, they criticize, the “sliding scale” of balancing materiality and intent is gone in name, but not gone in practice.

Another portion of the statements of the opinion relative to practice in relation to the statements of the opinion also comes into criticism. Quoting *Kingsdown*, the opinion states that “the evidence [of intent] ‘must be sufficient to require a finding of deceitful intent ...’” 649 F.3d at 1291. Moreover, quoting *Star Scientific*, the opinion states “the ‘patentee need not offer any good faith explanation’ ... The absence of a good faith explanation for withholding a material

reference does not, by itself, prove intent to deceive.” *Id.* at 1292. Critics ask, however, if the reference was known, materiality was high, could not a court infer intent from the combination of knowledge, lack of citation, high materiality, and lack of good faith explanation? The opinion would seem to permit this inference, as it only prohibits inferring intent from the lack of good faith explanation in and of itself, and also materiality in and of itself, but it does not prohibit use of the combination of materiality and lack of good faith explanation together to infer intent. Critics consider the three assurances (1) that materiality alone cannot be used to infer intent, (2) that a good faith explanation need not be offered, and (3) that lack of good faith explanation alone cannot be used to infer intent, to provide cold comfort for patent applicants when the probability exists under *Therasense* that materiality and lack of good faith explanation may be used in combination to the same effect.

A related issue contributes to the view of cold comfort. Those who offer good faith explanations for lack of citation of references are subject to credibility assessments by the judges (and possibly juries²⁴) before whom they testify. *Therasense* does nothing to prevent district courts from assessing credibility of such witnesses as deficient. Thus, if they testify, the witnesses permit the courts to

²⁴ Inequitable conduct is a matter of equity to be heard by judges, but the testimony is also sometimes heard by juries, when judges try all case issues together, by order or consent.

assess them as not credible, potentially permitting the elimination of the explanation they assert for their lack of citation as a reasonable explanation.²⁵ If eliminated as a reasonable explanation, their explanation is also eliminated as a reasonable inference. In the presence of that elimination, the most reasonable inference from the evidence is highly likely to be an adverse inference, an inference of intent to deceive. Potential witnesses are thus damned if they do not testify, and also potentially damned if they do testify. Credibility assessments, of course, are uniquely the province of the district courts, as Federal Rule of Civil Procedure 52(a) states that "[f]indings of fact ... shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of witnesses," and the cases are legion to the effect that appellate review should not tread on credibility assessments. *E.g.*, *Bose Corp. v. Consumers Union of United States*, 466 U.S. 485, 498 & 501 (1984); *Anderson v. Bessemer City*, 470 U.S. 564, 575 (1985), *Pullman-Standard v. Swint*, 456 U.S. 273, 287 (1982), *United States v. United States Gypsum Co.*, 333 U.S. 364, 394 (1948). Thus, those who testify about nondisclosure of references can potentially be found to be not credible, their testimony ignored, and inference made against them, as the most reasonable of the available inferences after the finding of lack of credibility.

²⁵This also potentially permits a damage to reputation of the kind *Therasense* was making an effort to eliminate. 649 F.3d at 1290.

This conceivably exhausts the criticisms of the new rules of *Therasense*.

All this said, of course, never has a court decision been written that satisfied everyone. *Therasense* has clarified the standards for inequitable conduct in relation to the non-disclosure of prior art. It has narrowed the standard for materiality as to such non-disclosure. It has reinforced the *Kingsdown* standard for intent for all assessments of inequitable conduct. It has eliminated a sliding scale analysis between materiality and intent. To non-critics, it has made sense, and finally fixed the law of inequitable conduct, at least as to non-disclosure of prior art, arguably the most common and most problematic issue of inequitable conduct. To critics, it has the lack of sense of the stated deficiencies, and is little help fixing the problematic area of the fair rules of deciding upon the existence or non-existence of inequitable conduct.