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2010 4 26

Therasense, Inc. v. Becton, Dickinson & Co.

23

inequitable conduct duty of disclosure duty of candor and
good faith misconduct patent unenforceable

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e-mail: chaing0925@gmail.com



2010 4 26

en banc

*Therasense, Inc. v. Becton, Dickinson & Co.*¹

*Therasense*² inequitable conduct

amicus curiae

Kingsdown Med.

*Consultants, Ltd. v. Hollister Inc.*³

Kingsdown

23

2011 5 25

1988

⁴ plague

non-infringement

invalidity

¹ *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289 (Fed. Cir. 2010).

² *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553 (Fed. Cir. 1984). inequitable conduct

improper conduct, misconduct inequitable conduct

³ *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.* 863 F.2d 867 (Fed. Cir. 1988) (*en banc*).

⁴ *Burlington Industries, Incorporated. v. Dayco corporation*, 849 F.2d 1418, 1422 (“The habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”).



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1999 2009

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⁵ United States Patent and Trademark Office, PTMT SPECIAL REPORT. ALL PATENTS, ALL TYPES, available at <<http://www.uspto.gov/web/offices/ac/ido/oeip/taf/apat.pdf>> (last visited on Nov. 3rd 2010).

⁶ *Id.*

⁷ Philip Elmer DeWitt, *HTC counter-sues Apple*, CNN MONEY.COM, May 12th 2010, available at <http://tech.fortune.cnn.com/2010/05/12/htc-counter-sues-apple/?source=yahoo_quote> (last visited on Nov. 4th 2010).

⁸ See 2 Martin J. Adelman & Randall R. Rader & John R. Thomas & Harold C. Wenger, *Cases and Material on Patent Law*, 647 (2nd ed. 2003).



2011 5 25

Therasense

1945

Precision Instrument

*Manufacturing. v. Automotive Maintenance Machinery Co.*⁹

Precision

unclean hands doctrine

1952

enforceability

¹⁰

35 U.S.C.

United States Code § 282 2 1

¹¹

37 C.F.R.

⁹ Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806 (1945).

¹⁰ DAVID HRICIK, *Wrong About Everything: The Application by the District Courts of Rule 9(b) to Inequitable Conduct*, 86 MARQ. L. REV. 895, 896 (2003).

¹¹ 35. U.S.C. §282 para.2 (1): The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded: (1) Noninfringement, absence of liability for infringement or unenforceability,



Code of Federal Regulations § 1.56 ¹²

common law

affirmative defense ¹³

ex parte

candor

good faith ¹⁴

patentability

material

¹⁵

¹² Agfa v. Creo 73-74

2006

¹³ ALICIA GRIFFIN MILLS, *Protecting Yourself from Your Assertions: Navigating Multiple Regulatory Schemes and Disclosure*. 2, J. HEALTH & LIFE SCI. L. 109, 114 (2009).

¹⁴ duty of candor and good faith

74 2004

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45 2009

BLACK'S LAW DICTIONARY 9th ed. (2009), **Duty of**

Candor and Good Faith (A patent applicant's responsibility to disclose to the U.S. Patent and Trademark Office **all known** information relevant to the invention's patentability, esp. prior art, novelty, and embodiment. If an applicant **fails to be candid** in disclosing all relevant information, the PTO may reject the application. If the patent is issued and undisclosed but relevant information is discovered later, the patent may be invalidated, and the applicant charged with fraud on the PTO, even if the undisclosed information might not have barred the patent's issuance.) 1

candid

Candor ²

Good Faith

Duty of Candor and Good Faith

¹⁵ 37 C.F.R. § 1.56 (2010).



2 3 16 1 3 17
 18 19
 20 unenforceable family patent
 21 22 exceptional case

37 C.F.R. 1.56 c

¹⁶ Dean L. Fanelli & Victor N. Balancia & Robert J. Smyth & Carl P. Bretscher & Arthur M. Antonelli & Mark J. Sullivan & Kent E. Basson, *A Review of Recent Decisions of The United States Court of Appeals For The Federal Circuit: Area Summaries: 2007 Patent Law Decisions of The Federal Circuit*, 57 Am. U.L. Rev. 821, 998 (2008).

¹⁷ 14 27-40

¹⁸ See 35 U.S.C. § 102.

¹⁹ See 35 U.S.C. § 103.

²⁰ *Kingsdown*, 863 F.2d at 877.

²¹ *A.B. Chance Co. v. RTE Corp.*, 854 F.2d 1307, 1312 (Fed. Cir. 1988). (“inequitable conduct is a separate defense to patent infringement and, either alone or in conjunction with trial conduct, may constitute the basis for an award of attorney fee under 35 U.S.C. § 285 ”)

²² See 35 USC § 285. (“The court in exceptional case may award reasonable attorney fees to the prevailing party”); *Epcon Gas System, Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1034 (Fed. Cir. 2002) (“The prevailing party may prove the existence of an exceptional case by showing inequitable conduct before PTO”).



²⁴ malpractice suit

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²³ 37 C.F.R. § 1.56 (c) (2011).(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.

²⁴ CHRISTOPHER A. COTROPIA, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 766 (2009).

²⁵ *Id.*

²⁶ *Id.*

²⁷ *See* Nisus Corp. v. Perma-Chink Systems, Inc., 497 F.3d 1316, 1320-22 (Fed. Cir. 2007).

²⁸ JOHN F. LYNCH, *An Argument for Eliminating the Defense of Patent Unenforceability Based on Inequitable Conduct*, 16 AIPLA Q.J. 7, 8 (1988); CHRISTOPHER E. MAMMEN, *Controlling the "Plague": Reforming the Doctrine of Inequitable Conduct*, 24 BERKELEY TECH. L.J. 1329, 1343 (2009).



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materiality

intent to deceive

inequitable

conduct balancing

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37 C.F.R. 1.56 (c)

²⁹ See *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329-31 (Fed. Cir. 2009). (attempting to increase the pleading requirements for inequitable conduct).

³⁰ *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008) (“The district court must still balance the equities to determine whether the applicant’s conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable.”); *MAMMEN*, *Supra* note 28, at 1342-44.



1945

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1. *Hazel-Atlas Glass Co. v. Hartford - Empire Co.*

wrongdoing

unenforceable

32

improper conduct

Hazel-Atlas Glass

Co. v. Hartford-Empire Co. ³³

Hazel-Atlas

34

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³¹ *Hazel-Atlas Glass Co. v. Hartford-Empire Co.* 322 U.S. 238 (1944); *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945).

³² GERALD SOBEL, *Reconsidering the Scope of the Inequitable Conduct Doctrine in View of Supreme Court Precedent and Patent Policy*, 18 FED. CIR. B.J. 169, 170 (2008).

³³ *Id.* at 170-71.

³⁴ *Hazel-Atlas*, 322 U.S. at 240.



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dismiss

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2. *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*

Precision

⁴¹ interference procedure

³⁵ Hartford-Empire Co. v. Hazel-Atlas Glass Co., 137 F.2d 764 (3d Cir. 1943).

³⁶ *Hazel-Atlas*, 322 U.S. at 243.

³⁷ *Id.* at 245-46.

³⁸ *Id.* at 248.

³⁹ *Id.* at 250.

⁴⁰ *Id.* (had the District Court learned of the fraud on the Patent Office at the original infringement trial, it would have been warranted in dismissing the patentee's case.)

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1

two pending applications

2

(between a pending application and an issued, un-expired patent)



settlement Precision Instrument Manufacturing
 Co. Precision Automotive Maintenance Machinery
 Co. Automotive 42
 Automotive Precision
 Larson affidavit
 Automotive Larson
 Larson Larson
 Larson 1 Automotive Larson
 concession 2 Larson
 assign Automotive 3
 Larson Precision
 43
 Automotive 2 Larson
 Precision Automotive
 44
 Automotive
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⁴² *Precision*, 324 U.S. at 816. 809.

⁴³ *Id.* at 813-14.

⁴⁴ *Automotive Maintenance Machinery Co. v. Precision Instrument Manufacturing Co.*, 143 F.2d 332, 333 (7th Cir. 1944), *rev'd* 324 U.S. 806 (1945).

⁴⁵ *Precision*, 324 U.S. at 816.

⁴⁶ *Id.* (applicant's duty to report facts related to fraud or inequitable conduct is uncompromising).



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public representative

⁴⁹ equitable nature

unclean hands doctrine

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Automotive

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Norton v. Curtiss ⁵²

Norton

⁵³ United States Court of Customs and Patent Appeals,

⁴⁷ *Id.* at 818. (safeguards the public in the first instance against fraudulent patent monopolies).

⁴⁸ *Id.* at 816. (The far-reaching social and economic consequences of a patent ... give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope) 14 10-11

⁴⁹ *Precision*, 324 U.S. at 819.

⁵⁰ *Id.*

⁵¹ *Id.* at 816.

⁵² *Norton v. Curtiss*, 433 F.2d 779 (C.C.P.A.1970).

⁵³ United States Court of Customs and Patent Appeals

1982

Federal Court

Improvement Act 1982 10 1

United States Court of Customs and Patent Appeals

United States

Court of Claims

of the United States Court

of Appeals for the Federal Circuit



C.C.P.A.

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Norton

Curtiss

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Norton

Patent Office Rule 56⁵⁶

Curtiss

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materiality

intent

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⁵⁴ SOBEL, *Supra* note 32, at 173.

⁵⁵ *Norton*, 433 F.2d at 782.

⁵⁶ Patents, Trademarks, and Copyrights, 13 Fed. Reg. at 9579 (1948) §56: Improper applications. Any application signed or sworn to in blank, or without actual inspection by the applicant, and any application altered or partly filled in after being signed or sworn to, and also any application fraudulently filed or in connection with which any fraud is practiced or attempted on the Patent Office, may be stricken from the files.

⁵⁷ *Norton*, 433 F.2d at 782.

⁵⁸ *Id.* at 789.

⁵⁹ *Id.* at 795-96.



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the objective patentability of the
claims at issue

subjective considerations of the examiner and the applicant

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actual intent ⁶²

Norton

*American Hoist & Derrick Co. v. Sowa
& Sons, Inc.* ⁶³ *American Hoist & Derrick*

American Hoist & Derrick 4 ⁶⁴ 1

objective “but-for” test 2

subjective “but-for” test 3 but

it may have test 4

⁶⁰ *Id.* at 794.

⁶¹ *Id.* at 795.

⁶² *Id.* at 796.

⁶³ *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984).

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Norton

American Hoist & Derrick

Norton

J.P. Stevens

1.

J.P. Stevens & Co. v. Lex Tex Ltd.

J.P. Stevens

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Stevens

inequitable conduct
fraud

J.P.

⁶⁵ *J.P. Stevens*, 747 F.2d at 1559.

⁶⁶ *Precision*, 324 U.S. at 818.



ex parte application proceedings
priority proceedings

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2.

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Materiality

⁶⁷ GINA ELDER, *A Review of Recent Decisions of The United States Court of Appeals For The Federal Circuit: Casenote: A Practical Guide For Proving Fraud On The Patent And Trademark Office: J.P. Stevens & Co. V. Lex Tex Ltd.*, 34 AM. U.L. REV. 729, 734 (1985).

⁶⁸ *J.P. Stevens*, 747 F.2d at 1559.



⁶⁹

American Hoist & Derrick

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1992 37 C.F.R. § 1.56 (a)

2 intent

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wrongfulness

willfulness

bad faith

gross negligence

good faith

simple negligence

oversight

erroneous judgment

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⁶⁹ *Id.*

⁷⁰ *Digital*, 653 F.2d at 709

Norton, 433 F.2d at 793

⁷¹ *Id.*

⁷² *See Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1540 (Fed. Cir. 1984)

simple negligence

oversight

erroneous judgment



Argus Chemical Corp. v. Fibre Glass-Evercoat Co. ⁷³

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J.P. Stevens

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Therasense

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⁷³ *Argus Chemical Corp. v. Fibre Glass-Evercoat Co.*, 759 F.2d 10 (Fed. Cir. 1985).

⁷⁴ *Id.* at 14.

⁷⁵ KAREN G. BENDER & SUSAN HABERMAN GRIFFEN & CHARLES E. LIPSEY, *Area summaries: A Review of Recent Decisions of The United States Court of Appeals For The Federal Circuit: Patent Decisions of the United States Court of Appeals for the Federal Circuit: The Year 1985 in Review*, 35 AM. U. L. REV. 995, 1022 (1986).

⁷⁶ *Therasense, Inc. v. Becton, Dickinson & Co.*



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objective “but-for” test

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antitrust

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Walker Process Equipment v. Food Machinery & Chemical

⁷⁷ DONALD S. CHISUM, *Best Mode Concealment and Inequitable Conduct in Patent Procurement: A Nutshell, a Review of Recent Federal Circuit Cases and a Plea for Modest Reform*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 277, 293-94 (1997).

⁷⁸ *Corning Glass Works v. Anchor Hocking Glass Corp.*, 253 F. Supp. 461, 469 (D. Del. 1966) (Citing *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358 (1928)). (that the patent would not have issued but-for the fraud.); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.* 322 U.S. 238 (1944); *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945).

⁷⁹ *In re Multidistrict Litig. Involving Frost Patent*, 398 F.Supp. 1353, 1368 (D. Del. 1975).

⁸⁰ *Norton*, 433 F.2d at 795.

⁸¹ JAMES CRONIN, *Inequitable Conduct And The Standard of Materiality: Why The Federal Circuit Should Use The Reasonable Patent Examiner Standard*, 50 ST. LOUIS L.J. 1327, 1339 (2006).



Corp. ⁸²

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subjective “but-for” test

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⁸² Walker Process Equipment v. Food Machinery & Chemical Corp., 382 U.S. 172 (1965).

⁸³ *Id.* at 174; *See also* 35 U.S.C. 102(b) (2000).

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Waterman-Bic Pen Corp. v. W.A. Sheaffter Pen Co., 267 F. Supp. 849, 856 (D. Del. 1967).

⁸⁷ KAYTON, LYNCH & STERN, *Fraud in Patent Procurement: Genuine and Sham Charges*, 43 GEO WASH. L. REV. 1, 32-33 (1975); *See* WILLIAM COCHRAN, *Historical Review of Fraud in Patent Procurement: The Standards and Procedures for Doing Business Before the Patent Office*, 52 J. PAT. OFF. SOC’Y 71, 79 (1970).



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*American Cyanamid Co. v. F.T.C.*⁸⁸ American Cyanamid

Price fixing

Federal Trade Commission Act

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⁸⁸ *Skil Corp. v. Lucerne Prods., Inc.*, 684 F.2d 346, 350 (6th Cir. 1982); *Pfizer, Inc. v. Int'l Rectifier Corp.*, 685 F.2d 357, 359 (9th Cir. 1982); *Plastic Container Corp. v. Cont'l Plastics of Okla., Inc.*, 607 F.2d 889, 899 (10th Cir. 1979), *aff'd in part, rev'd in part*, 708 F.2d 1554 (10th Cir. 1983).

⁸⁹ *American Cyanamid Co. v. F.T.C.*, 363 F.2d 757 (6th Cir. 1966).

⁹⁰ *Id.* at 772.

⁹¹ *Id.* at 779.



but it may have test

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93

SCM Corp. v. Radio Corp. of America ⁹⁴

SCM
initial

application

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⁹² *Genveto Jewelry Co. v. Lambert Bros.*, 542 F. Supp. 933, 940 (S.D.N.Y. 1982); *See Plastic Container Corp. v. Continental Plastics of Okla., Inc.*, 607 F.2d 885, 900 (10th Cir. 1979).

⁹³ *CMI Corp. v. Barber-Greene Co.*, 683 F.2d 1061, 1066 (7th Cir. 1982); *Timely Prods. Corp. v. Arron*, 523 F.2d 288, 297-98 (2d Cir. 1975); *Trio Process Corp. v. L. Goldstein's Sons, Inc.*, 461 F.2d 66, 73 (3d Cir. 1972); *Monsanto Co. v. Rohm & Haas Co.*, 456 F.2d 592, 600 (3d Cir. 1972).

⁹⁴ *SCM Corp. v. Radio Corp. of America*, 318 F. Supp. 433 (S.D.N.Y. 1970).

⁹⁵ *Id.* at 444.



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SCM

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1977 37 C.F.R. § 1.56

99 37 C.F.R. § 1.56 (a)

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⁹⁶ *Id.* at 450.

⁹⁷ *Id.* at 449-50.

⁹⁸ *In re Multidistrict*, 398 F.Supp. at 1368.

⁹⁹ LISA A. DOLAK, *The Inequitable Conduct Gyre Widens*, 50 IDEA 215, 216 (2010).



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reasonable examiner standard

101

102

*A.B. Dick Co. v. Burroughs Corp*¹⁰³

104

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¹⁰⁰ 37 C.F.R. § 1.56 (a):

(a)...Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

¹⁰¹ ELDER, *Supra* note 67, at 738-40.

¹⁰² American Hoist & Derrick Co. v. Sowa & Sons, 725 F.2d 1350 (Fed. Cir. 1984).

¹⁰³ A.B. Dick Co. v. Burroughs Corp., 798 F.2d 1392, 1392 (Fed. Cir. 1986).

¹⁰⁴ CRONIN, *Supra* note 81, at 1342.

¹⁰⁵ *A.B.*, 798 F.2d at 1369-97.

¹⁰⁶ *Id.* at 1398.



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Patent Bar Association

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1992

37 C.F.R.

§§ 1.97-98

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1992 37 C.F.R. § 1.56

37 C.F.R. § 1.56 (b)

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ Jerome G. Lee *et al.*, *Equitable Defenses in Patent Cases*, 320 Practising Law Institute, *Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series 571*, 591 (1991).

¹¹⁰ *See* 37 C.F.R. §§ 1.97-98 (2005).



b
_____ ¹¹¹

1991
culpability component

112

1991
Halliburton Co. v. Schlumberger Technology Corp. ¹¹³

cumulative
114

115

¹¹¹ 37 C.F.R §1.56 (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...

¹¹² DONALD S. CHISUM, *United States Court of Appeals For The Federal Circuit Tenth Anniversary Commemorative Issue: 1991 Area Summary: Patent Law Developments In The United States Court of Appeals For The Federal Circuit During 1991*, 41 AM. U.L. REV. 869, 894 (1992).

¹¹³ *Halliburton Co. v. Schlumberger Technology Corp*, 925 F.2d 1435 (Fed. Cir. 1991).

¹¹⁴ *Id.* at 1440 (citing 37 C.F.R. § 1.56 (1991) (defining material information as that which would be "important in deciding whether to allow the application to issue as a patent").

¹¹⁵ *Id.* (The PTO recently proposed rule changes that would abandon the "important to a reasonable examiner" standard of materiality. *See* Notice of Proposed Rule Making, 56 Fed. Reg. 37,321 (1991) (to be codified at 37 C.F.R. § 1.56) (proposed Aug. 6, 1991).



1992

37 C.F.R. § 1.56

A B C D

X A B

X

C D

Y

A B C

Y

A B

Y

A B C

Y

X

X

116

37 C.F.R. § 1.56 b

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14 20-21

cumulative



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prima facie / inconsistent standard 1992

37 C.F.R. §

1.56 b

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¹¹⁷ 37 C.F.R §1.56

(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.

¹¹⁸ 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.

¹¹⁹ ELIZABETH PETERS, *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, 1535 (2008).



Bruno Independent Living Aids, Inc. v. Acorn Mobility Services.
*Ltd.*¹²⁰ *Bruno*

1992 37 C.F.R. § 1.56 121

1982 2005
1995 *Molins PLC v. Tetro*¹²²

retroactive

¹²³ 2000 *Semiconductor Energy Laboratory Co., Ltd. v.*
*Samsung Electronics Co.*¹²⁴ 1992
¹²⁵ 2005

Bruno *Purdue Pharma L.P. v. Endo Pharmaceuticals.*
*Inc.*¹²⁶ 1992 3 16

¹²⁰ *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services. Ltd.*, 394 F.3d 1348 (Fed. Cir. 2005).

¹²¹ *Id.* at 1352-53.

¹²² *Molins PLC v. Tetro*, 48 F.3d 1172 (Fed. Cir. 1995).

¹²³ *Id.* at 1179.

¹²⁴ *Semiconductor Energy Laboratory Co., Ltd. v. Samsung Elecs Co.*, 204 F.3d 1368 (Fed. Cir. 2000).

¹²⁵ *Id.* at 1374.

¹²⁶ *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, 410 F.3d 690 (Fed. Cir. 2005).



Control, Inc. v. Charles Machine ¹²⁷ 2006 *Digital*
Digital

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128

Digital 5

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Digital

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Therasense

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¹²⁷ *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (noting that "there is no reason to be bound by any single standard").

¹²⁸ *Id.* at 1315-16 (The PTO's recent adoption of an arguably narrower standard of materiality does not supplant or replace our case law. Rather, it merely provides an additional test of materiality. That is, if a misstatement or omission is material under the new Rule 56 standard, it is material. Similarly, if a misstatement or omission is material under the "reasonable examiner" standard or under the older three tests, it is also material).

¹²⁹ NICOLE M. MURPHY, *Inequitable-Conduct Doctrine Reform: Is the Death Penalty for Patents Still Appropriate?*, 93 MINN. L. REV. 2274, 2280 (2009).

¹³⁰ CRONIN, *Supra* note 81, at 1338.

¹³¹ *Therasense, Inc. v. Becton, Dickinson & Co.*



132

intent to deceive

¹³³ attorney-client privilege

134

direct evidence

circumstantial evidence

135

136

¹³⁷ The Seventh Amendment of

¹³² 6 Donald S. Chisum, *Chisum on Patents*, §19.03, 263 (1992).

¹³³ ALEXIS N. SIMPSON, *The Monster In The Closet: Declawing The Inequitable Conduct Beast In The Attorney-Client Privilege Arena*, 25 GA. ST. U.L. REV. 735, 736 (2009).

¹³⁴ *Id.* at 736-37.

¹³⁵ *Molins*, 48 F.3d at 1181.

¹³⁶ 2 PETER D. ROSENBERG, *PATENT LAW FUNDAMENT*, §15.08[1][b][96] 226, (1999).

¹³⁷ U.S CONST. amend. VII: In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.



the United States Constitution

Paragon

Podiatry Laboratory, Inc. v. KLM Laboratories, Inc. 138

139

140

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scienter

143

gross negligence

144

1984

J.P. Stevens

145

deliberate scheming

¹³⁸ *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182 (Fed. Cir. 1993).

¹³⁹ THOMAS L. IRVING & MICHAEL D. KAMINSKI & LINDA S. EVANS & DONALD R. MCPHAIL, *A Review of Recent Decisions of The United States Court of Appeals For The Federal Circuit: Area Summary: A Year in Review: The Federal Circuit's Patent Decisions of 1993*, 43 AM. U.L. REV. 1259, 1285 (1994).

¹⁴⁰ *Paragon*, 984 F.2d at 1190; *see also* *United States v. Louisiana*, 339 U.S. 699, 706 (1950) (stating that Seventh Amendment is not applicable to equity actions and only applies to actions at law).

¹⁴¹ *Paragon*, 984 F.2d at 1190.

¹⁴² SOBEL, *Supra* note 32, at 177-78.

¹⁴³ *Scott Paper Co. v. Fort Howard Paper Co.*, 432 F.2d 1198, 1204 (7th Cir. 1970) ("Unclean hands can be asserted only if there has been a deliberate misrepresentation in the Patent Office.").

¹⁴⁴ *DeLong Corp. v. Raymond Int'l Inc.*, 622 F.2d 1135, 1146 (3rd Cir. 1980) (stating that inequitable conduct requires at least a finding of "gross negligence").

¹⁴⁵ *J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553 (Fed. Cir. 1984).



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known

should have known

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1988

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Burlington Industrial Inc. v. Dayco Corp.

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¹⁴⁶ *Id.* at 1560.

¹⁴⁷ *Id.*

¹⁴⁸ JIM CARMICHAEL & CAMERON WEIFFENBACH, *Inequitable Conduct, Gross Negligence And The Kingsdown Decision*, 8 J. MARSHALL REV. INTELL. PROP. L. 18, 28 (2009).

¹⁴⁹ CHISUM, *Supra* note 132, at §19.03, 272.

¹⁵⁰ *Burlington Industrial Inc. v. Dayco Corp.*, 849 F.2d 1418 (Fed. Cir. 1988).

¹⁵¹ *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1998) (en banc).

¹⁵² PATENTLY-O BLOG, *Top Ten Most Cited Patent Cases 2007-2010*, available at <<http://www.patentlyo.com/patent/2010/05/top-ten-most-cited-patent-cases-2007-2010.html>> (last visited on May. 13th 2011).

Top Ten Most Cited Patent Cases 2007-2010

1. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed.Cir. 2005).

2. *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed.Cir. 1998).

3. *KSR Intern. Co. v. Teleflex Inc.*, 127 U.S. 1727 (2007).

4. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed.Cir. 1995).



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Summary Judgment

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5. *Graham v. John Deere Co. of Kansas City*, 86 U.S. 684 (1966).
 6. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed.Cir. 1996).
 7. *In re Calmar, Inc.*, 854 F.2d 461 (Fed.Cir. 1988).
 8. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 117 U.S. 1040 (1997).
 9. *MedImmune, Inc. v. Genentech, Inc.*, 127 U.S. 764 (2007).
 10. *Christianson v. Colt Industries Operating Corp.*, 108 U.S. 2166 (1988).
11. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed.Cir. 1988).
 12. *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538 (Fed.Cir. 1995).
 13. *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed.Cir. 2007).
¹⁵³ *Therasense, Inc. v. Becton, Dickinson & Co.*
¹⁵⁴ *Kingsdown*, 863 F.2d at 1419. ("**impregnat[ion of] individual fibers in the yarn bundle," and "impregnat[ion of] the fiber bundles and encapsulat[ion of] the individual fibers.**")
¹⁵⁵ *Burlington*, 849 F.2d at 1421. (The nondisclosure of facts of which the applicant should have known the materiality may justify an inference of intent to mislead in appropriate cases.)



¹⁵⁶ Newman

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J.P. Stevens

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***Kingsdown* 案**

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¹⁵⁶ *Id.* (it was error to reject the attorney's explanation out of hand in favor of "a less plausible sinister interpretation.)

¹⁵⁷ *Id.* at 1422. ("The habit of charging inequitable conduct in almost every major patent case has become an absolute plague.")

¹⁵⁸ *Kingsdown* 14 88-93

¹⁵⁹ *Kingsdown*, 863 F.2d at 874-75.

¹⁶⁰ *Id.* at 867.

¹⁶¹ *Id.* at 869-71.



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¹⁶² *Id.* at 872.

¹⁶³ *Id.* at 876 ("a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.")



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clear and

convincing evidence

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Kingsdown

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Newman

Critikon

bad law

Kingsdown

Driscoll v. Cebalo ¹⁷³ Linn

Critikon

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Critikon

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Kingsdown

¹⁷⁰ *Id.* at 1256.

¹⁷¹ *Id.* at 1256-57.

¹⁷² LYNN TYLER, *Kingsdown Twenty Years Later: What It Takes To Prove Inequitable Conduct Is No Clearer*, 10 WAKE FOREST INTELL. PROP. L.J. 30, 31 (2009).

¹⁷³ *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1202 (Fed. Cir. 2006) (this aspect of Critikon, Inc. has been correctly identified by practitioners as "**bad law**," both because it relies on the overruled Driscoll decision and because it is representative of a recent resurgence of the plague that Kingsdown had intended to cure) (Newman, J., dissenting).

¹⁷⁴ LYNN TYLER, *Kingsdown Fifteen Years Later: What Does It Take To Prove Inequitable Conduct?*, 13 FED. CIR. B.J. 267, 277-78 (2003).



Critikon

Therasense

Kingsdown

Critikon

Kingsdown

Critikon

panel

Kingsdown

Kingsdown ¹⁷⁵ *Critikon*

¹⁷⁵ *Kingsdown* : *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123 (Fed. Cir. 2006); *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335 (Fed. Cir. 2006); *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991 (Fed. Cir. 2006); *Old Town Co. v. Confluence Holdings Corp.*, 448 F.3d 1309 (Fed. Cir. 2006); *In re Metroprolol Succinate*, 494 F.3d 1011, 1013-14 (Fed. Cir. 2007); *Scanner Tech. Corp. v. Icos Vision Sys. Corp. N.V.*, 528 F.3d 1365 (Fed. Cir. 2008); *Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008); *Larson Mfg. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317 (Fed. Cir. 2009)



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Therasense

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Scott Paper

¹⁷⁶ Critikon : Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1350 (Fed. Cir. 2005); Pharmacia Corp. v. Parr Pharm., Inc., 417 F.3d 1369 (Fed. Cir. 2005); Warner-Lambert Co. v. Teva Pharm. U.S., Inc., 418 F.3d 1326 (Fed. Cir. 2005); Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347 (Fed. Cir. 2005); Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181 (Fed. Cir. 2006); Agfa Corp. v. Creo Prods., Inc., 451 F.3d 1366 (Fed. Cir. 2006); Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337 (Fed. Cir. 2007); Cargill, Inc. v. Canbra Foods Ltd., 476 F.3d 1359 (Fed. Cir. 2007); McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897 (Fed. Cir. 2007); Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223 (Fed. Cir. 2007); Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229 (Fed. Cir. 2008); Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334 (Fed. Cir. 2008); Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306 (Fed. Cir. 2008)

¹⁷⁷ Therasense, Inc. v. Becton, Dickinson & Co.

¹⁷⁸ *Digital*, 437 F.3d at 1313; Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1366 (Fed. Cir. 2001).



Co. v. Fort Howard Paper Co. ¹⁷⁹ 2 1

Digital Equipment Corp. v. Diamond, ¹⁸⁰

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Star Scientific, Inc. v. R.J. Reynolds Tobacco Co. ¹⁸⁶ *Star*

¹⁷⁹ *Scott Paper Co. v. Fort Howard Paper Co.*, 432 F.2d 1198 (7th Cir.1970).

¹⁸⁰ *Digital Equipment Corp. v. Diamond*, 653 F.2d 701 (1st Cir. 1981).

¹⁸¹ *Id.* at 716. (a lower showing of intent if coupled with a greater showing of materiality, and *vice-versa.*)

¹⁸² *Star*, 537 F.3d at 1367 .

¹⁸³ MAMMEN, *Supra* note 28, at 1333.

¹⁸⁴ *Id.*

¹⁸⁵ SOBEL, *Supra* note 32, at 181-82.

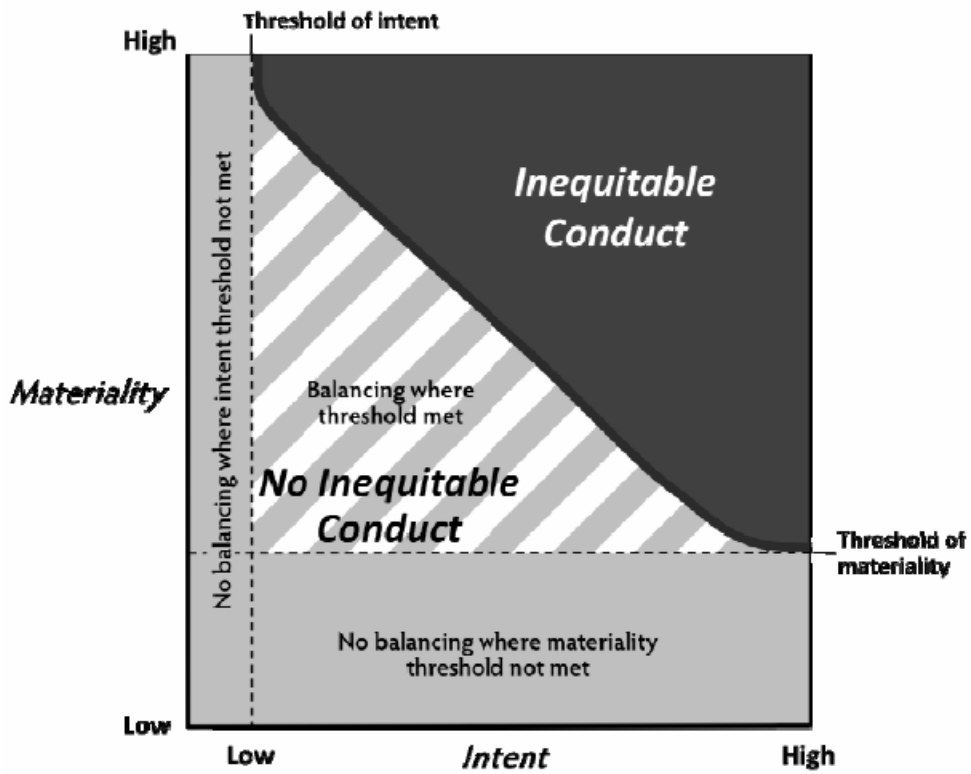
¹⁸⁶ *Star*, 537 F.3d at 1366.



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¹⁸⁷ *Id.* at 1367.

¹⁸⁸ *Id.*

¹⁸⁹ MAMMEN, *Supra* note 28, at 1344.



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¹⁹⁰ *Id.*

¹⁹¹ *Star*, 537 F.3d at 1367 (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997)).



Therasense, Inc. v. Becton, Dickinson & Co.

whole blood

¹⁹² KATHERINE NOLAN-STEVAUX, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147, 154 (2005).



live blood

Abbott Diabetes Care, Inc.		Abbott	
Therasense, Inc.		Abbott Laboratories,	2004
3	Becton Dickinson and Co.	BD	
		6143164	164
6592745	745	declaratory judgment	
of noninfringement		BD	1. BD
Latitude Diabetes. Management System		2. BD Logic Blood Glucose	
Monitor		BD	
Abbott			BD
164	745	5820551	551
BD		Abbott	
2008	4 3	BD	
164	745	745	1-5 5 21-23 28 31
	anticipated	¹⁹³	2008 6 27 551
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¹⁹³ Therasense, Inc. v. Becton, Dickinson & Co., 560 F. Supp. 2d 835, 880 (N.D. Cal. 2008).

¹⁹⁴ *Id.* at 1127 .



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Materiality-Intent-Balancing Framework

unclean hands

¹⁹⁵ TheraSense, Inc. v. Becton, Dickinson & Co., 374 Fed. Appx. 35.

¹⁹⁶ *Id.*

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 United States Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?
4. Under what circumstances is it proper to infer intent from materiality?
5. Should the balancing inquiry (balancing materiality and intent) be abandoned?
6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.



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551	1984	Abbott	13
		continuation application	
4545382		382	382
	¹⁹⁷ 1997	Abbott	
			Abbott
	Sanghera	Sanghera	551
			382
4	63-65		
	¹⁹⁸	Abbott	Lawrence Pope

¹⁹⁷ U.S. Patent No. 4,545,382, column 4, lines 63- 65. (“Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.”)

¹⁹⁸ *Therasense*, 593 F.3d at 1330-31 (“one skilled in the art would have felt that an active electrode comprising an enzyme and a mediator would require a protective membrane if it were to be used with a whole blood sample. Therefore, he is sure that one skilled in the art



optionally, but preferably...
 patent phraseology
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¹⁹⁹ Sanghera
 declaration
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 Abbott
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 1995 5 3 Abbott
 European Patent Office
 optionally, but
 preferably...

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would not read lines 63 to 65 of column 4 of U.S. Patent No. 4,545,382 to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred.”)

¹⁹⁹ *Id.* at 1329. (“the new claims with the argument that the claims of the application were not anticipated or obvious because the claims taught a new glucose sensor that did not require a protective membrane when testing whole blood.”)

²⁰⁰ *Id.* at 1334 (“It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent



	5	Abbott	Lawrence
Pope		Sanghera	
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		2 Abbott	
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		3 Abbott	
Lawrence Pope		Sanghera	Abbott
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Lawrence Pope		Sanghera	
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	5	Lawrence Pope	Sanghera
		Abbott	

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the large constituents of the blood, in particular erythrocytes from interfering with the electrode sensor. Furthermore it is said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is permeable to glucose molecules.”)

²⁰¹ *Therasense*, 565 F. Supp. at 1113-16 (N.D. Cal. 2008). (“(1) that the statements made to the PTO concerning the prior art '382 patent were absolutely critical in overcoming the examiner's earlier rejections of the claims of the '551 patent; (2) that the EPO statements would have been very important to an examiner because they contradicted the representations made to the PTO; (3) that Pope and Dr. Sanghera both knew of the EPO statements and consciously withheld them from the PTO; (4) that neither Pope nor Dr. Sanghera provided a credible explanation for failing to submit the EPO documents to the PTO; and (5) that Pope's and Dr. Sanghera's explanations for withholding the EPO documents were so incredible that they suggested intent to deceive.”)



551
/
Sanghera

Abbott EP636
37 C.F.R. 1.56(b) (2)
Lawrence Pope

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Linn *Scanner*
Technologies Corp. v. ICOS Vision Systems Corp. ²⁰²

Lawrence Pope Sanghera
EPO

²⁰² *Scanner Technologies Corp. v. ICOS Vision Systems Corp.*, 528 F.3d 1365 (Fed.Cir. 2008).



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but-for materiality standard

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²⁰³ Therasense, Inc v. Becton Dickinson and Co., No. 2008-1511, -1512, -1513, -1514, -1595, Slip Op. (May 25, 2011) (en banc), available at <
<http://www.patentlyo.com/therasensefrompatentlyo.pdf>> (last visited on May 25th 2011).

²⁰⁴ *Id.* at 18-35.

²⁰⁵ *Id.* at 26-28.

²⁰⁶ *Id.* at 36-37.

²⁰⁷ *Id.* at 25; Hazel-Atlas Glass Co. v. Hartford-Empire Co. 322 U.S. 238 (1944); Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806 (1945); Keystone Driller Co. v. General Excavator Co., 290 U.S. 240 (1933).

²⁰⁸ *Id.* at 27.



37 C.F.R. § 1.56 /

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1988 *Kingsdown*

Kingsdown

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a “deliberate decision” to deceive ²¹²

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²⁰⁹ *Id.* at 36.

²¹⁰ *Id.* at 24.

²¹¹ *Id.* at 26.

²¹² *Id.* at 25.

²¹³ *Id.*



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1988 *Kingsdown*

²¹⁴ *Id.* at 36.

²¹⁵ *Id.* at 28.

²¹⁶ *Id.* at 28-29

²¹⁷ *Id.* at 28.



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