
DISTILLING A RULE FOR INFERRING INTENT TO DECEIVE
THE PATENT OFFICE*

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I. INTRODUCTION

A patent applicant owes a duty of candor to the Patent Office. If the applicant breaches this duty, the courts may hold the procured patent unenforceable due to inequitable conduct. In *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*,¹ the U.S. Court of Appeals for the Federal Circuit sitting en banc sought to resolve a conflict in its precedent, holding that gross negligence is not sufficient to establish the required intent to deceive.² After *Kingsdown*, however, a negligence-like rule for inferring intent has reemerged, and tension is once again apparent in the Federal Circuit case law concerning the requisite level of intent to support a finding of inequitable conduct. While the Federal Circuit's recent en banc decision in *Therasense, Inc. v. Becton, Dickinson & Co.*³ tightened the standard for intent,⁴ it did not fully resolve this tension.

After presenting a brief overview of the patent system, Part II of this Comment discusses *Kingsdown* and the reemergence of the negligence-like rule. This rule, which most recently appeared in *Praxair, Inc. v. ATMI, Inc.*,⁵ has been met with criticism, and is in tension with the principles articulated in other recent cases such as *Therasense* and *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*⁶ The rule, which is referred to here as the "Praxair rule," allows an inference of intent where the applicant (1) failed to disclose highly material information, (2) knew of the information and knew or should have known of its materiality, and (3) failed to provide a credible explanation for the withholding.⁷ Part II shows that although *Therasense* adjusted the standard for intent, it did not overrule *Praxair* or reject the *Praxair* rule.⁸

Part II continues with a close look at the *Praxair* rule, its criticism, and its origins. The most pointed criticism of the *Praxair* rule is that it is, at least in part, it is "bad

1. 863 F.2d 867 (Fed. Cir. 1988) (en banc in relevant portion).

2. *Kingsdown*, 863 F.2d at 876.

3. No. 2008-1595, 2011 WL 2028255 (Fed. Cir. May 25, 2011) (en banc).

4. *Therasense*, slip op. at 24, 2011 WL 2028255 at *9.

5. 543 F.3d 1306 (Fed. Cir. 2008).

6. 537 F.3d 1357 (Fed. Cir. 2008).

7. *Praxair*, 543 F.3d at 1313-14 (citing *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006)). See *infra* Part II.F.2 for a discussion of *Praxair* and a presentation of its rule.

8. See *infra* Part II.G.2 for a discussion of *Therasense*'s impact on the inference of intent.

law” because it ultimately derives from *Driscoll v. Cebalo*,⁹ a case the Federal Circuit explicitly overruled en banc in *Kingsdown*.¹⁰ In examining the origins of the *Praxair* rule, Part II explains that it derives partly, but not solely, from overruled precedent.¹¹ The rule can also be traced to *FMC Corp. v. Manitowoc Co.*,¹² which *Kingsdown* identified as requiring more than gross negligence.¹³ Part II concludes with a presentation of some proposals other commentators have made for improving the inequitable conduct doctrine.¹⁴

Part III argues that the negligence-like *Praxair* rule should be changed. It argues that the *Praxair* rule can be harmonized with its origins, with the weight of authority, and with the policy considerations underlying the inequitable conduct doctrine, by explicitly incorporating two limitations that are arguably already inherent in the case law applying the rule.¹⁵ As recast, the rule would not allow an inference of intent unless: (1) material information was withheld amidst some related, *aggravating conduct* of the applicant; (2) the applicant actually knew of the information; (3) the applicant *actually knew of, or deliberately avoided learning of*, the information’s materiality; and (4) the applicant failed to provide a credible explanation of the withholding. Part III concludes by presenting the benefits and addressing some limitations of the proposed rule.¹⁶

II. OVERVIEW

A. *The Patent System*

The United States patent system is almost as old as the country itself,¹⁷ and finds its basis and purpose in the Constitution: “The Congress shall have Power To . . . promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹⁸ A patent confers upon its holder the right to exclude others from making, using, or selling the patented invention.¹⁹ A patent holder may enforce this right against anyone who practices the patented invention by filing a suit for patent

9. 731 F.2d 878 (Fed. Cir. 1984).

10. *E.g., Ferring*, 437 F.3d at 1202 (Newman, J., dissenting).

11. See *infra* Part II.E.2 for a discussion of the “two roots” of *Praxair*’s “should have known” rule.

12. 835 F.2d 1411 (Fed. Cir. 1987).

13. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc).

14. See *infra* Part II.H for a discussion of other commentators’ suggestions.

15. See *infra* Part III.A.

16. See *infra* Part III.C.

17. Congress passed the first Patent Act in 1790. Act of Apr. 10, 1790, ch. 7, 1 Stat. 109.

18. U.S. CONST. art. I, § 8, cl. 8. This clause is unique among the enumerated powers of Congress, being the only one to recite a purpose. This clause also forms the basis for the Copyright Act. 17 U.S.C. (2008). See *Eldred v. Ashcroft*, 537 U.S. 186, 221–22 (2003) (upholding constitutionality of copyright term extension).

19. 35 U.S.C. § 271 (2006) (defining liability for patent infringement).

infringement in a United States district court.²⁰ A patent does not give its holder the right to practice his own invention; it merely confers the right to exclude others from doing so.²¹

The only way to obtain a patent (other than assignment)²² is to submit an application to the United States Patent and Trademark Office (PTO). The PTO will assign the application to a patent examiner—a PTO employee who will review the application for compliance with the requirements of patentability.²³ The principal requirements for patentability are that the claimed invention be new,²⁴ useful,²⁵ non-obvious,²⁶ directed to patentable subject matter,²⁷ and that the application discloses the claimed invention in sufficient detail.²⁸ If the examiner determines that the application satisfies all requirements, a patent will issue to the applicant after the payment of fees²⁹ and will become available to the public.³⁰

The patent system fulfills its purpose—promoting progress in science and the useful arts—with an inherent quid pro quo.³¹ The inventor gives his invention to the public by fully disclosing it in a portion of the patent called the specification,³² and in exchange he receives the right, for a limited time, to exclude others from practicing the invention as set out in a portion of the patent called the claims.³³ This encourages inventors to disclose their inventions so that others may expand upon them, rather than

20. 28 U.S.C. § 1338 (granting federal district courts exclusive jurisdiction over cases arising under federal patent laws). Anyone who makes, uses, sells, offers for sale, or imports the patented invention may be held liable for infringement. 35 U.S.C. § 271(a).

21. This distinction can be important as it is possible for an inventor's practice of his own invention to infringe another inventor's patent. For example, if a later inventor patents an improvement on an earlier patented invention, the later inventor may infringe the earlier patent by practicing the improved version of the invention. See 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.02(1) (2010) (describing right to exclude others).

22. See 35 U.S.C. § 261 (“[P]atents shall have the attributes of personal property.”).

23. See MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW § 10.1(a) (3d ed. 2009) (providing overview of patent prosecution process).

24. 35 U.S.C. § 102.

25. 35 U.S.C. § 101.

26. 35 U.S.C. § 103.

27. Patentable subject matter includes any “process, machine, manufacture, or composition of matter, or any . . . improvement thereof,” 35 U.S.C. § 101, but does not extend to laws of nature, natural phenomena, abstract ideas, or mathematical formulae. *Diamond v. Diehr*, 450 U.S. 175, 185–86 (1981).

28. 35 U.S.C. § 112 para. 1.

29. 35 U.S.C. § 151.

30. The PTO, which must make patents available to the public, 35 U.S.C. § 41(h)(2)(i)(1), hosts a searchable patent database on its website. See *Search for Patents*, UNITED STATES PATENT AND TRADEMARK OFFICE, <http://www.uspto.gov/patents/process/search/index.jsp> (last visited Mar. 20, 2011).

31. See *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 15–16 (1829) (holding that inventor who allowed public use of his invention cannot later apply for patent because no quid pro quo would support grant of monopoly).

32. The patent's specification must disclose the invention and how to make it in sufficient detail that another person in the relevant field could make and use it. 35 U.S.C. § 112 para. 1.

33. “The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112 para. 2. Just as a deed to real property defines that property's boundaries, the claims define the scope of the invention—the scope of what infringes.

to keep their inventions secret to avoid business competition.³⁴ It also encourages prospective inventors to devote resources to research and development of new inventions in the hopes of being the first to secure exclusive rights to them.³⁵

Submission of an application to the PTO begins a process of negotiation with the patent examiner called patent prosecution.³⁶ During this process, the examiner may reject some or all of the patent's claims, insisting that the applicant narrow the claims or more fully disclose the invention in order to comply with the requirements for patentability.³⁷ This gatekeeping function of the examiner serves as a check against the applicant's incentive to seek broad claims.³⁸

B. *The Basics of Inequitable Conduct*

All persons involved in the prosecution of a patent application owe a duty of candor to the PTO, including a duty to disclose known references that are material to patentability.³⁹ The need for this duty and the need to enforce it are described well in a popular casebook:

Patent acquisition procedures are conducted *ex parte*. A consequence of this administrative setting is that the usual advantages of an adversarial system are unavailable. In addition, the [PTO] does not operate laboratories, perform product testing, or verify submitted data attesting to commercial success The result is that the patent system relies to a great extent upon applicant observance of a duty of truthfulness towards the PTO. Experience teaches, however, that applicant obligations of candor may be tempered by the great incentive they possess not to disclose information that might deleteriously impact their prospective patent rights.⁴⁰

That is, an applicant who withholds information from or makes misrepresentations to the PTO may convince the patent examiner to issue claims that are improperly broad or that should not issue at all. The inequitable conduct doctrine counters applicants' incentive to breach their duty of candor, as courts will not enforce patents that result from such misconduct.

The basic operation of the inequitable conduct doctrine is well settled, at least on a superficial level. Inequitable conduct is a defense to patent infringement, and the

34. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1028–30 (1989).

35. *Id.* at 1024–28.

36. BLACK'S LAW DICTIONARY 1258 (9th Ed. 2009).

37. See ADELMAN ET AL., *supra* note 23, § 10.1(a) (providing overview of patent prosecution process). See *supra* notes 20–24 for the principal requirements for patentability.

38. The potential power of patents drives this incentive to seek broad claims. In one recent case, for example, a federal district court in Texas awarded 1.6 billion dollars in damages for patent infringement. Final Judgment at 2, *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, No. 2:07-CV-139-TJW (E.D. Tex. Dec. 18, 2009). This has been termed the largest patent verdict in U.S. history. Diane Mastrull, *A Record-Breaking Verdict for Centocor*, PHILA. INQUIRER, June 30, 2009, at C1.

39. 37 C.F.R. § 1.56(a) (2010).

40. ADELMAN ET AL., *supra* note 23, § 10.3.

party raising the defense bears the burden of proving it.⁴¹ The party raising the defense must prove it by an elevated standard of “clear and convincing evidence,” which, as the courts have noted, is “a heavy burden.”⁴² To discharge this burden, the party alleging inequitable conduct must show that during prosecution, “the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO].”⁴³

Inequitable conduct requires a two-part analysis. First, the court must find threshold levels of both materiality and intent by clear and convincing evidence.⁴⁴ Second, it must “balance the equities to determine whether the applicant’s conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable.”⁴⁵

The typical consequence of inequitable conduct has been described as an “atomic bomb” remedy:⁴⁶ a finding of inequitable conduct renders the affected patent unenforceable in its entirety.⁴⁷ This can be more severe than a finding of invalidity, which will only affect the particular claims found to be invalid.⁴⁸ Inequitable conduct can lead to a variety of other consequences as well.⁴⁹ For example, the Patent Act allows a court to award attorneys’ fees to the prevailing party in “exceptional cases,”⁵⁰ and a finding of inequitable conduct can support finding a case to be exceptional for this purpose.⁵¹ Inequitable conduct can also help to establish liability under antitrust, unfair competition, and even RICO.⁵²

41. *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 19, 2011 WL 2028255 at *6 (Fed. Cir. May 25, 2011) (en banc); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

42. *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1151 (Fed. Cir. 1983) (quoting *Norton v. Curtiss*, 433 F.2d 779, 797 (C.C.P.A. 1970)); accord *Therasense*, slip op. at 19, 2011 WL 2028255 at *6; *Star Scientific*, 537 F.3d at 1365.

43. *Star Scientific*, 537 F.3d at 1365 (alteration in original) (quoting *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1363 (Fed. Cir. 2007)).

44. *Id.* at 1365 (citing *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006)).

45. *Id.* (citing *Monsanto Co. v. Bayer BioScience N.V.*, 363 F.3d 1235, 1239 (Fed. Cir. 2004)); accord *Therasense*, slip op. at 19, 2011 WL 2028255 at *6.

46. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting).

47. *Therasense*, slip op. at 19, 2011 WL 2028255 at *6; *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) (en banc); see also 6 CHISUM, *supra* note 21, § 19.03(6)(b)(iii) (2010) (describing inequitable conduct’s “all claims” rule).

48. 6 CHISUM, *supra* note 21, § 19.02 n.14 (noting most courts analyze questions of validity on claim-by-claim basis).

49. See *Therasense*, slip op. at 22, 2011 WL 2028255 at *8 (listing potential consequences of inequitable conduct); 6 CHISUM, *supra* note 21, § 19.03 (providing survey of consequences of inequitable conduct).

50. 35 U.S.C. § 285 (2006).

51. *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 182 F.3d 1356, 1359 (Fed. Cir. 1999) (noting that inequitable conduct is substantive patent issue that must be taken into consideration in determinations under § 285).

52. See 6 CHISUM, *supra* note 21, § 19.03(6)(e) (discussing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965), which held fraudulent procurement of patent could establish antitrust liability); *id.* § 19.03(6)(k) (stating fraudulent procurement of patents may create basis for RICO claim); *id.* §

C. *Origins of the Modern Inequitable Conduct Doctrine*

The modern doctrine of inequitable conduct is a judge-made doctrine that operates as a defense to patent infringement.⁵³ With roots in the equitable doctrine of unclean hands,⁵⁴ the modern inequitable conduct doctrine originated in three Supreme Court cases in the 1930s and 1940s.⁵⁵ The last of these decisions, in language reflecting the apprehension of monopolies prevalent at the time,⁵⁶ expressed the public policy underlying the inequitable conduct doctrine as follows:

[A] patent is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.⁵⁷

Each of the three Supreme Court cases involved acts of “egregious misconduct.”⁵⁸ For example, in *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*,⁵⁹ the applicant secured allowance of the claims, in the face of “insurmountable [PTO] opposition,”⁶⁰ by

19.03(6)(l) (stating one injured by another’s inequitable conduct in obtaining patent can seek relief under tort theory of unfair competition).

53. While this Comment includes only a brief summary of the development of this doctrine, other sources provide a more thorough review. See generally Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARV. J.L. & TECH. 37 (1993); 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, 169–82 (2009).

54. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1364 n.3 (Fed. Cir. 2003) (citing *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945)); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1394 (Fed. Cir. 1988).

55. *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 15, 2011 WL 2028255 at *4 (Fed. Cir. May 25, 2011) (en banc); *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006); see also Goldman, *supra* note 53, at 45–51 (discussing three aforementioned Supreme Court decisions). The three cases in this series are *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), *overruled on other grounds by Standard Oil Co. v. United States*, 429 U.S. 17 (1976), and *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933).

56. During and in the wake of the Great Depression and Franklin D. Roosevelt’s New Deal, monopoly power was a subject of frequent debate and concern, often resulting in restrictions on patent rights. See Steven Wilf, *The Making of the Post-War Paradigm in American Intellectual Property Law*, 31 COLUM. J.L. & ARTS 139, 150–52 (2008) (describing role monopoly power played in public debate during and after Great Depression); *id.* at 191–98 (describing how Roosevelt administration and courts restricted patent protection during 1930s and 1940s); 1 CHISUM, *supra* note 21, overview, subsec. 5(c) (discussing ways in which Supreme Court limited patent rights between 1930 and 1950).

57. Goldman, *supra* note 53, at 50 (quoting *Precision Instrument*, 324 U.S. at 816).

58. *Therasense*, slip op. at 15, 2011 WL 2028255 at *4; see also *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1343 (Fed. Cir. 2009) (Linn, J., concurring) (noting that trio of Supreme Court cases involved “overt fraud”); Sobel, *supra* note 53, at 170–73 (arguing that Supreme Court cases applied doctrine only in extreme cases).

59. 322 U.S. 238 (1944).

60. *Hazel-Atlas Glass*, 322 U.S. at 240.

submitting to the PTO a false trade publication commissioned from an “ostensibly disinterested expert.”⁶¹

In the wake of the three Supreme Court’s cases, the courts of appeal applied a doctrine “somewhat akin to that of common law fraud, albeit broader.”⁶² The regional circuits split on aspects of the doctrine,⁶³ but such splits became largely irrelevant when Congress created the Court of Appeals for the Federal Circuit in 1982.⁶⁴ Since the Supreme Court has not ruled on inequitable conduct since 1945,⁶⁵ it is now the Federal Circuit that bears primary responsibility for shaping the doctrine.⁶⁶

D. Regulatory Influences and the Standard of Materiality

Under the Federal Circuit’s recent en banc decision in *Therasense*, “as a general matter, the materiality required to establish inequitable conduct is but-for materiality.”⁶⁷ A failure to disclose is material if the PTO would not have allowed a claim if it had been aware of the undisclosed prior art.⁶⁸ In making this determination, a court must focus on whether the PTO would have allowed the claims under PTO examination standards.⁶⁹ This but-for materiality rule supports “basic fairness” by ensuring that the inequitable conduct doctrine will only apply “where the the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.”⁷⁰

An exception to the requirement of but-for materiality exists for “cases of affirmative egregious misconduct.”⁷¹ In such cases, which might include filing an unmistakably false affidavit, “the misconduct is material.”⁷² This exception aims to allow flexibility to capture extraordinary circumstances and to maintain consistency with the trio of Supreme Court cases on point.⁷³

Though the Federal Circuit in *Therasense* explicitly declined to adopt the PTO’s regulatory definition of materiality,⁷⁴ courts once looked to PTO regulations as “an

61. *Id.*

62. *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006).

63. *See Goldman, supra* note 53, at 52–67 (discussing development of inequitable conduct doctrine in regional circuit courts prior to creation of Federal Circuit).

64. The Court of Appeals for the Federal Circuit has exclusive jurisdiction over appeals from patent suits both from district courts, 28 U.S.C. § 1295(a)(1) (2006), and from the Board of Patent Appeals and Interferences at the PTO, *id.* § 1295(a)(4). *But see* 8 CHISUM, *supra* note 21, § 21.02(1)(e) (discussing limited circumstances in which state courts can adjudicate patent questions).

65. The Supreme Court last ruled on inequitable conduct in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945). *See generally* Sobel, *supra* note 53 (comparing current inequitable conduct jurisprudence with Supreme Court precedent).

66. The need for national uniformity in the patent laws was among the reasons for consolidating appellate jurisdiction over them in the Federal Circuit. *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 649–52 (1999) (Stevens, J., dissenting).

67. *Therasense*, slip op. at 27, 2011 WL 2028255 at *11.

68. *Id.*, 2011 WL 2028255 at *11.

69. *Id.* at 27–28, 2011 WL 2028255 at *11.

70. *Id.* at 28, 2011 WL 2028255 at *12.

71. *Id.* at 29, 2011 WL 2028255 at *12.

72. *Id.*, 2011 WL 2028255 at *12.

73. *Id.* at 30, 2011 WL 2028255 at *13.

74. *Id.* at 32, 2011 WL 2028255 at *14.

appropriate starting point for any discussion of materiality.”⁷⁵ Perhaps the most frequently cited source was PTO Rule 56. This rule sets out a “duty of candor and good faith in dealing with the [Patent] Office.”⁷⁶ Its current version defines information to be material if it is “not cumulative”⁷⁷ and either establishes “a prima facie case of unpatentability of a claim” or “refutes, or is inconsistent with, a position the applicant takes.”⁷⁸ Prior to 1992, Rule 56 set out a broader standard of materiality, including any information with “a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”⁷⁹ Until *Therasense*, courts had applied this “reasonable examiner” standard.⁸⁰

In addition to the pre-1992 version of Rule 56, the Federal Circuit has also looked to the Manual of Patent Examining Procedure (“MPEP”)⁸¹ to inform the standard of materiality. In *Dayco Products, Inc. v. Total Containment, Inc.*,⁸² the court relied on language in the MPEP to support its conclusion that the existence of a copending patent application with claims that were “in some respects substantially identical”⁸³ was material to the application for the patent in suit.⁸⁴ The current version of the MPEP references *Dayco* on this point.⁸⁵

E. Reigning in the Inference of Intent: Kingsdown and the Divergent Lines of Federal Circuit Case Law that Followed

1. The “Plague” and *Kingsdown*

When a federal appellate judge uses such a powerful expression as “absolute plague” in a majority opinion,⁸⁶ commentary is sure to ensue. And indeed it did after Judge Nichols lamented, “the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”⁸⁷ The development of this “plague,” what may have been an attempt to resolve it en banc in 1988, and the developments

75. *Id.*, 2011 WL 2028255 at *14.

76. 37 C.F.R. § 1.56(a) (2009).

77. *Id.* § 1.56(b).

78. *Id.*

79. 37 C.F.R. § 1.56(a) (1991).

80. *See, e.g.*, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1367 (Fed. Cir. 2008) (quoting *Symantec Corp. v. Computer Assocs. Int’l*, 522 F.3d 1279, 1297 (Fed. Cir. 2008); *see also* Tom Brody, *Duty to Disclose: Dayco Products v. Total Containment*, 7 J. MARSHALL REV. INTELL. PROP. L. 325, 329–32 (2008) (discussing and comparing standards of materiality).

81. U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (8th ed. rev. 8, 2010) [hereinafter MPEP].

82. 329 F.3d 1358 (Fed. Cir. 2003).

83. *Dayco*, 329 F.3d at 1361.

84. *Id.* at 1365–66.

85. MPEP, *supra* note 81, § 2001.06(b).

86. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

87. *Id.*

that followed have been thoroughly researched and explained.⁸⁸ What follows is a synopsis.

The early decisions of the Federal Circuit made the inequitable conduct defense considerably easier to establish than had been the case under the Supreme Court rulings.⁸⁹ Despite its roots in unclean hands and the strong showing it initially required, the courts broadened the inequitable conduct doctrine to include not only intentional concealment and misrepresentation, but also gross negligence.⁹⁰ This expansion, coupled with both the Federal Circuit's standard of review for inequitable conduct⁹¹ and its "case-by-case" approach, was "all but an invitation to bring issues of inequitable conduct before the court."⁹² The resulting increase in the number of cases involving allegations of inequitable conduct led the court to express its disapproval—from Judge Nichols' characterization the claims being a "plague,"⁹³ to Judge Markey's comment that "[i]nequitable conduct" is not, or should not be, a magic incantation to be asserted against every patentee.⁹⁴

An en banc portion of the Federal Circuit's decision in *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*⁹⁵ took action to reduce the number of inequitable conduct cases.⁹⁶ Holding that gross negligence alone does not justify an inference of intent to deceive the PTO,⁹⁷ the court required that "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."⁹⁸ In so holding, the court seemed to overrule contrary suggestions in at least two prior cases.⁹⁹ The court also emphasized the equitable underpinnings of the defense, committing the ultimate

88. See, e.g., Goldman, *supra* note 53 (thoroughly discussing history of inequitable conduct doctrine); Erik R. Puknys & Jared D. Schuettenhelm, *Application of the Inequitable Conduct Doctrine After Kingsdown*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 839, 842–70 (2009) (discussing development of inequitable conduct doctrine, attempt to pull it back in *Kingsdown*, and case law following *Kingsdown*); Lynn C. Tyler, *Kingsdown Fifteen Years Later: What Does It Take to Prove Inequitable Conduct?*, 13 FED. CIR. B.J. 267 *passim* (2004) (discussing tension in cases following *Kingsdown* and arguing for return to *Kingsdown* standard).

89. Goldman, *supra* note 53, at 70; *cf.* *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 19, 2011 WL 2028255 at *6 (Fed. Cir. May 25, 2011) (doctrine "came to embrace a broader scope of misconduct").

90. See *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc) (citing *In re Jerabek*, 789 F.2d 886, 891 (Fed. Cir. 1986); *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984)); Puknys & Schuettenhelm, *supra* note 88, at 845–46.

91. In the mid-1980's, the Federal Circuit considered the ultimate question of inequitable conduct to be a question of law. E.g., *Jerabek*, 789 F.2d at 890; *Argus Chem. v. Fibre Glass-Evercoat*, 759 F.2d 10, 13 (Fed. Cir. 1985); *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1363–64 n.4 (Fed. Cir. 1984).

92. Goldman, *supra* note 53, at 85.

93. See text accompanying *supra* note 87 for a presentation of Judge Nichols' comment.

94. *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987).

95. 863 F.2d 867 (Fed. Cir. 1988) (en banc in relevant portion).

96. Goldman, *supra* note 53, at 86–87.

97. *Kingsdown*, 863 F.2d at 876.

98. *Id.*

99. *Kingsdown* did not explicitly state that it overruled these prior cases, but it clearly took a contrary position. *Id.* at 876 (citing *In re Jerabek*, 789 F.2d 886, 891 (Fed. Cir. 1986); *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984)).

question of inequitable conduct to the discretion of the trial court and specifying an abuse of discretion standard on appeal.¹⁰⁰

2. A Negligence-Like Standard Reemerges

Although many of the cases after *Kingsdown* applied its strict requirement of intent to deceive,¹⁰¹ a line of cases developed that seemed to apply a lower standard.¹⁰² In *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*,¹⁰³ the Federal Circuit inferred intent to deceive “where a patent applicant knew, or should have known, that withheld information would be material to the PTO’s consideration of the patent application.”¹⁰⁴ This is essentially a negligence standard, and the court supported it only with a citation to *Driscoll v. Cebalo*,¹⁰⁵ one of the gross negligence cases *Kingsdown* arguably overruled on precisely this point.¹⁰⁶ While the disposition in *Critikon* may have been consistent with *Kingsdown*,¹⁰⁷ its post-*Kingsdown* pronouncement of a “should have known” rule laid the foundation for a negligence-like standard to reemerge.¹⁰⁸

Following *Critikon*, a line of cases employed language indicating that an inference of intent may be properly drawn where a patent applicant “should have known” of a reference’s materiality.¹⁰⁹ This language may have lowered the threshold for the requisite showing of intent below what *Critikon* required. For example, some commentators have suggested that *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*¹¹⁰ further expanded the reach of the “should have known”

100. *Id.*

101. See Tyler, *supra* note 88, at 273–76 (discussing post-*Kingsdown* cases strictly applying *Kingsdown*’s standard for intent).

102. See Tyler, *supra* note 88, at 276–83 (discussing post-*Kingsdown* cases applying seemingly relaxed standard of intent).

103. 120 F.3d 1253 (Fed. Cir. 1997).

104. *Critikon*, 120 F.3d at 1256 (citing *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984)).

105. *Id.* (citing *Driscoll*, 731 F.2d at 885).

106. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988); see also *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1344 n.1 (Fed. Cir. 2009) (Linn, J., concurring) (stating that *Driscoll* was “explicitly overruled by *Kingsdown* on the issue of gross negligence”); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1202 (Fed. Cir. 2006) (Newman, J., dissenting) (observing that *Driscoll* “was overruled *en banc* by *Kingsdown* on this very point”); Tyler, *supra* note 88, at 278 (observing “*Driscoll* . . . was overruled *en banc* by *Kingsdown* on this very point”).

107. Tyler, *supra* note 88, at 278.

108. *Ferring*, 437 F.3d at 1202–03 (Newman, J., dissenting).

109. See Tyler, *supra* note 88, at 276–83 (describing three such cases, including: *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268 (Fed. Cir. 2001); *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368 (Fed. Cir. 2000)); see also *Puknys & Schuettenhelm*, *supra* note 88, at 855–69 (discussing four additional cases, including: *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334 (Fed. Cir. 2008); *Ferring*, 437 F.3d 1181; *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337 (Fed. Cir. 2007); *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347 (Fed. Cir. 2005)).

110. 424 F.3d 1347 (Fed. Cir. 2005).

standard.¹¹¹ In *Novo Nordisk*, the Danish inventors filed an example¹¹² with the PTO describing an embodiment of their patented process in order to establish an early priority date.¹¹³ The inventors worded the example in the past tense, although at the time they wrote it the inventors had not yet actually performed the steps described.¹¹⁴ Despite finding that one inventor's use of the past tense "was merely an oversight on his part, likely due to the fact that [he] is trained as a scientist,"¹¹⁵ the district court nonetheless inferred intent to deceive the PTO.¹¹⁶ The Federal Circuit affirmed the district court's ruling,¹¹⁷ reasoning that "knowledge of the law is chargeable to the inventor."¹¹⁸ "The law" in this case included a provision of the MPEP prohibiting applicants from wording such examples in the past tense.¹¹⁹

3. Tension Within the Federal Circuit Case Law

Tension is evident between the lines of cases after *Kingsdown* with respect to inferring intent. Some cases seem to strictly enforce the rule that "materiality does not presume intent, which is a separate and essential component of inequitable conduct,"¹²⁰ while others recognize that "materiality and intent to deceive are necessarily intertwined."¹²¹ For example, in *Molins PLC v. Textron, Inc.*,¹²² the court required that "clear and convincing evidence must prove that an applicant had the specific intent" to deceive,¹²³ and that, in cases of non-disclosure, "clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference."¹²⁴ On the other hand, *Ferring B.V. v. Barr Laboratories, Inc.*¹²⁵ adopted the

111. James E. Hanft & Stacey S. Kerns, *The Return of the Inequitable Conduct Plague: When "I Did Not Know" Unexpectedly Becomes "You Should Have Known,"* INTELL. PROP. & TECH. L.J., Feb. 2007, at 1, 2-3.

112. An "example" is a disclosure of one particular implementation or embodiment of the claimed invention. An example can be either "working" (based on work actually performed) or "prophetic" (based on predicted results rather than achieved results). See MPEP, *supra* note 81, § 2164.02.

113. *Novo Nordisk*, 424 F.3d at 1359. The date to which an inventor claims priority can be very important in assessing an invention's novelty, as it was in this case. See *id.* at 1359-60 (noting that examiner relied upon example to establish priority, thereby avoiding a prior art patent).

114. *Id.* at 1357.

115. *Id.* at 1361 n.12 (quoting *Bio-Tech. Corp. v. Novo Nordisk Pharm., Inc.*, No. Civ. 02-235-SLR, 2004 WL 1739722, at *32 (D. Del. Aug. 3, 2004)).

116. *Id.* at 1352.

117. *Id.* at 1362-63.

118. *Id.* at 1361 (quoting *Brasseler v. Stryker Sales Corp.*, 267 F.3d 1370, 1385 (Fed. Cir. 2001)).

119. MPEP, *supra* note 81, § 2004(8).

120. *E.g.*, *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2002) (quoting *Allen Organ Co. v. Kimball Int'l, Inc.*, 839 F.2d 1556, 1567 (Fed. Cir. 1988)).

121. *E.g.*, *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1344 (Fed. Cir. 2008) (citing *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1455 (Fed. Cir. 1984)).

122. 48 F.3d 1172 (Fed. Cir. 1995).

123. *Molins*, 48 F.3d at 1181.

124. *Id.*

125. 437 F.3d 1181 (Fed. Cir. 2006).

Critikon rule, which would allow an inference of intent where the applicant should have known (but did not in fact know) of the materiality.¹²⁶

F. *Recent Cases Furthering Diverging Lines of Case Law*

The diverging lines of authority within the Federal Circuit on the issue of intent to deceive continue to develop. A good example can be found in a pair of 2008 cases handed down within about a month of each other: *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*,¹²⁷ and *Praxair, Inc. v. ATMI, Inc.*¹²⁸ The subsequent case of *Larson Manufacturing Co. of South Dakota v. Aluminart Products, Ltd.*¹²⁹ further highlights the tension in these lines of cases, aligning itself with *Star Scientific* and including a concurring opinion sharply criticizing the *Praxair* rule.¹³⁰

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

In *Star Scientific*, the Federal Circuit reversed the district court's finding of inequitable conduct.¹³¹ Star sued R.J. Reynolds ("RJR") for infringement of two patents, which claimed processes for curing tobacco that reduced the levels of toxins in the cured leaves.¹³² RJR alleged inequitable conduct during prosecution of the patents, claiming that Star had failed to disclose a reference indicating that prior art processes were already similarly capable of reducing toxin levels.¹³³ To establish intent, RJR alleged that Star had replaced its patent counsel midway through prosecution in order to avoid disclosure of the reference; that is, that Star had intentionally "quarantine[d]" the reference by replacing its attorneys.¹³⁴ Star, however, advanced other reasons for replacing its counsel, including the passing of a key partner in the counsel's firm and poor performance on an unrelated patent prosecution.¹³⁵

At the beginning of its discussion, the court in *Star Scientific* emphasized the high showing required to establish inequitable conduct and clarified that "materiality does not presume intent."¹³⁶ The court acknowledged that intent could be inferred from circumstantial evidence, but stressed that "such evidence must still be clear and convincing"¹³⁷ and, perhaps more importantly, that "it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and

126. *Ferring*, 437 F.3d at 1191 (citing *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997)).

127. 537 F.3d 1357 (Fed. Cir. 2008).

128. 543 F.3d 1306 (Fed. Cir. 2008).

129. 559 F.3d 1317 (Fed. Cir. 2009).

130. See *infra* Part II.F.3 for a discussion of *Larson*.

131. *Star Scientific*, 537 F.3d at 1373.

132. The second patent was a continuation of the first, and issued while the case was pending. *Id.* at 1361–63.

133. *Id.* at 1367.

134. *Id.*

135. *Id.* at 1368.

136. *Id.* at 1366 (quoting *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001)).

137. *Id.* (citing *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1186 (Fed. Cir. 2006)).

convincing standard.”¹³⁸ For materiality, the court adopted the “reasonable examiner” standard.¹³⁹

In applying these standards to the facts, the court found that RJR had failed to establish intent to deceive with respect to the first patent at issue because it could not support its “quarantine” theory with clear and convincing evidence.¹⁴⁰ The Federal Circuit rejected the district court’s reliance on Star’s lack of a credible explanation for switching law firms to infer intent. Instead, the court strictly enforced the burden of proof, reasoning that the “patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence.”¹⁴¹ Since RJR had failed to produce any evidence that the Star executives responsible for the decision to switch law firms were even aware of the allegedly material reference, the court held that RJR lacked “any evidence at all on the crux of its theory, let alone clear and convincing evidence.”¹⁴²

With respect to the second patent in suit, the court reversed the district court’s finding of inequitable conduct based solely on materiality.¹⁴³ The second patent was issued while the lawsuit was pending.¹⁴⁴ The Federal Circuit held that the reference in question was not material because it was cumulative of other materials submitted to the PTO.¹⁴⁵ RJR’s responses to interrogatories, which Star disclosed to the PTO, “contained the critical information that the prior art had achieved low to insignificant levels of [toxins].”¹⁴⁶

By maintaining the separation of materiality and intent and by strictly applying the burden of proof, *Star Scientific* follows the line of cases that remain closer to *Kingsdown* in rejecting an inference of intent based on a “should have known” standard.¹⁴⁷ Indeed, the court resolved the question of intent with respect to the first patent without even considering materiality.¹⁴⁸

2. *Praxair, Inc. v. ATMI, Inc.*

In *Praxair*, decided just over a month after *Star Scientific*,¹⁴⁹ the court took a somewhat different approach, placing it in the *Critikon* line of cases. Praxair sued ATMI for infringing three patents that claimed technology for safely pressurizing gas

138. *Id.* (citing *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008)).

139. *Id.* at 1367. *But see* *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 27, 32, 2011 WL 2028255 at *11, *14 (Fed. Cir. May 25, 2011) (adopting but-for materiality standard, rejecting reasonable examiner standard).

140. *Star Scientific*, 537 F.3d at 1367–68.

141. *Id.* at 1368 (citing *Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 398 (Fed. Cir. 1996)).

142. *Id.*

143. *Id.* at 1370.

144. *Id.* at 1369–70.

145. *Id.* at 1370.

146. *Id.* at 1371.

147. *See* Puknys & Schuettenehelm, *supra* note 88, at 841, 875 (noting that *Kingsdown* rejected “should have known” standard, and that *Star Scientific* applied reasoning similar to *Kingsdown*).

148. *Star Scientific*, 537 F.3d at 1367–69.

149. *Star Scientific* was decided on August 25, 2008. *Id.* at 1357. *Praxair* was decided on September 29, 2008. *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1306 (Fed. Cir. 2008).

containers.¹⁵⁰ The district court held two of these patents unenforceable due to inequitable conduct.¹⁵¹ The Federal Circuit affirmed unenforceability of one, but reversed unenforceability of the other.¹⁵² The claims of these two patents included “capillary flow restrictor[s],” devices that limit the rate at which gas or fluid can flow through them.¹⁵³ During prosecution, the applicants failed to disclose the prior, widespread industry use of restricted flow orifice (“RFO”) devices, which perform a similar function as the capillary flow restrictors at issue.¹⁵⁴ The district court inferred intent to deceive after finding that the applicant had knowledge of the RFO devices and that the applicant had made four statements to the PTO in support of patentability that contradicted the existence of the RFO devices.¹⁵⁵

While acknowledging that “materiality and intent are separate,”¹⁵⁶ the court adopted the rule from *Ferring*, derived from the *Critikon* line of cases. The court articulated the rule (the “*Praxair* rule”) as follows:

An inference of intent to deceive is generally appropriate . . . when (1) highly material information is withheld; (2) ‘the applicant knew of the information [and] . . . knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.’¹⁵⁷

This rule for inferring intent places *Praxair* in the *Critikon* line of cases and in tension with the *Star Scientific* rule that intent may be inferred only when it is the “single most reasonable inference able to be drawn.”¹⁵⁸ The Federal Circuit found that the RFO devices were material because they, like the patented inventions, used “a narrow passageway to restrict fluid flow,” and this was “sufficient to meet the threshold for materiality.”¹⁵⁹

Applying each element of its inferred intent rule to the first patent, the court first found that the RFO devices were “highly material in the context of four statements made in the course of the [first patent’s] prosecution.”¹⁶⁰ Second, testimony of the attorney and the inventor established their knowledge of the prior art, and “[the attorney] at least was aware of its obvious materiality in light of the four statements quoted above made by him to the examiner.”¹⁶¹ Finally, the court rejected *Praxair*’s

150. *Praxair*, 543 F.3d at 1310.

151. *Id.* at 1309.

152. *Id.* at 1310.

153. *Id.*

154. *Id.* at 1312.

155. *Id.*

156. *Id.* at 1313 (citing *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988)).

157. *Id.* at 1313–14 (alteration in original) (second omission in original) (quoting *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006)).

158. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008).

159. *Praxair*, 543 F.3d at 1314. The court noted that *Praxair* waived the argument that the RFO devices were cumulative by failing to raise the issue below. *Id.* at 1315.

160. *Id.* at 1315.

161. *Id.* at 1317.

explanations, stating that “[h]indsight construction of reasons why a reference might have been withheld cannot suffice as a credible explanation” for its withholding.¹⁶²

With respect to the second patent, however, the Federal Circuit reversed the district court’s finding of inequitable conduct.¹⁶³ Because the four statements were made only in the prosecution of the first patent, the RFO devices were not highly material with respect to the second patent.¹⁶⁴ Without high materiality, the inference of intent was improper.¹⁶⁵

Judge Lourie filed an opinion concurring in all respects except for the court’s affirmance of inequitable conduct with respect to the first patent.¹⁶⁶ He disputed the majority’s inference of intent to deceive because, as he argued, the majority improperly conflated intent with materiality.¹⁶⁷ Though he seemed to accept the majority’s rule for inferring intent—based on a finding that the applicant knew or should have known of the materiality of the art—he explicitly rejected the majority’s conclusion that the prosecuting attorney was “aware of [the art’s] obvious materiality.”¹⁶⁸ Judge Lourie argued that this conclusion was unsupported by any finding of the district court and not demonstrated by any evidence in the record.¹⁶⁹ Though Judge Lourie recited the “should have known” standard, his opinion did not explicitly address whether these applicants should have known of the materiality of the art in question.¹⁷⁰

3. *Larson Manufacturing Co. of South Dakota v. Aluminart Products Ltd.*

In *Larson*, the Federal Circuit vacated the district court’s finding of inequitable conduct and remanded for further proceedings on the element of intent and on the ultimate issue of inequitable conduct.¹⁷¹ Aluminart alleged inequitable conduct during both prosecution and reexamination of the patent, and the district court agreed, finding that Larson failed to disclose three prior art references and two office actions from a related application.¹⁷²

The Federal Circuit examined in detail the three pieces of prior art Larson failed to disclose¹⁷³ and found that all of the material features of these references were fully disclosed in other references already before the PTO.¹⁷⁴ These three references were therefore cumulative, not material, and could not serve as the basis for a finding of

162. *Id.* at 1318.

163. *Id.*

164. *Id.* The court also rested this conclusion on the fact that at the time the applicant made the four statements with respect to the first patent, the PTO had already given notice that it would allow the second application to issue as a patent. *Id.*

165. *Id.* at 1318–19.

166. *Id.* at 1329 (Lourie, J., concurring in part and dissenting in part).

167. *Id.*

168. *Id.* at 1330.

169. *Id.*

170. *Id.*

171. *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1342 (Fed. Cir. 2009).

172. *Id.* at 1320, 1325. The patent in suit claimed a storm door with a sliding glass insert attached to a retractable screen. *Id.* at 1321.

173. *Id.* at 1327–37.

174. *Id.* at 1331, 1337.

inequitable conduct.¹⁷⁵ By contrast, the Federal Circuit, relying on its decision in *Dayco Products, Inc. v. Total Containment, Inc.*,¹⁷⁶ affirmed the district court's finding that two office actions in a related patent application were material.¹⁷⁷

On the question of intent, the Federal Circuit vacated the district court's findings because the district court had not considered intent separately for each reference.¹⁷⁸ Because it reversed the district court's finding of materiality with respect to three of the five references on which the district court had relied, the Federal Circuit remanded for further examination of intent.¹⁷⁹

"[I]n the interest of judicial economy,"¹⁸⁰ the *Larson* opinion included a section providing guidance to the district court for its reconsideration of intent on remand.¹⁸¹ Relying heavily on *Star Scientific*, this section seems to embrace the principles of the stricter line of post-*Kingsdown* cases.¹⁸² It reiterates the standard of "clear and convincing evidence [by] a specific intent to deceive,"¹⁸³ and announces intent rules such as "materiality does not presume intent,"¹⁸⁴ the "single most reasonable inference" rule,¹⁸⁵ the insufficiency of "absence of a credible good faith explanation,"¹⁸⁶ and the need to "take into account any evidence of good faith."¹⁸⁷

Despite the majority's announcement of some of the more stringent standards for inferring intent, Judge Linn wrote a concurrence sharply criticizing the intent standard found in the *Critikon* line of cases,¹⁸⁸ lamenting the perpetuation of the "plague,"¹⁸⁹ and calling for a rehearing of the issue en banc.¹⁹⁰ Judge Linn began with his own account of the facts:

Symptoms of this plague are apparent from the facts of this case. The patent-in-suit has undergone examination twice in the PTO, and the patentee has been accused of inequitable conduct on each occasion During original prosecution, the PTO considered 143 references, 135 of which the patentee itself had submitted. . . . With all parties' eyes on the reexamination, the patentee submitted an *additional* 210 references with its first information disclosure statement ("IDS"), including a copy of the competitor's inequitable conduct allegations. . . . With full knowledge of the co-pending

175. *Id.* at 1320, 1339.

176. *Id.* at 1338 (citing *Dayco Prods. Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367–68 (Fed. Cir. 2003)). See *supra* notes 82–84 and accompanying text for a discussion of *Dayco*.

177. *Larson*, 559 F.3d at 1339.

178. *Id.* at 1320.

179. *Id.* at 1342.

180. *Id.* at 1340.

181. *Id.* 1340–42.

182. *See id.*

183. *Id.* at 1340 (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

184. *Id.* (citing *Star Scientific*, 537 F.3d at 1366).

185. *Id.* (quoting *Star Scientific*, 537 F.3d at 1366).

186. *Id.* at 1341 (citing *Star Scientific*, 537 F.3d at 1368).

187. *Id.*

188. *Id.* at 1343–44 (Linn, J., concurring).

189. *Id.* at 1342.

190. *Id.* at 1344.

application, the PTO confirmed the patent . . . [T]he litigation will continue to focus on inequitable conduct, to the exclusion of the patentee's infringement contentions.¹⁹¹

Judge Linn then directly criticized the intent rule from the *Critikon* line of cases, citing its most recent articulation in *Praxair*.¹⁹² Judge Linn argued that this standard improperly conflates materiality and intent, introduces a negligence standard at odds with *Kingsdown*, and improperly “shifts the burden to the patentee to prove a negative.”¹⁹³

G. A Close Look at the Praxair Rule

This section examines the state of the *Praxair* rule.¹⁹⁴ It discusses minority-opinion criticism of the rule, the Federal Circuit's recent decision in *Therasense*, the origins of the “should have known” element, and the standard for “high materiality.”

1. A Standard Under Fire: Minority-Opinion Criticism

Prior to *Therasense*, the *Praxair* rule for inferring intent was not fully accepted within the Federal Circuit as evident from Judge Linn's concurrence in *Larson*¹⁹⁵ and Judge Lourie's partial dissent in *Praxair*.¹⁹⁶ This section briefly discusses other recent minority opinions criticizing loose standards for inferring intent.

Praxair took its rule from *Ferring*,¹⁹⁷ a case that included a vigorous *Ferring* dissent by Judge Newman directly criticizing what would become the *Praxair* rule.¹⁹⁸ Judge Newman characterized as “bad law” the proposition that intent may be inferred where the applicant “should have known” of the materiality of a reference.¹⁹⁹ Newman criticized the court in *Critikon* for importing this standard from precedent explicitly overruled en banc in *Kingsdown*,²⁰⁰ and argued that panels applying this standard cannot overrule *Kingsdown* or the numerous panel decisions applying a stricter standard.²⁰¹

191. *Id.* at 1342–43.

192. *Id.* at 1343 (citing *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313–14 (Fed. Cir. 2008)). See *supra* note 157 and accompanying text for the articulation of this rule.

193. *Id.* at 1344.

194. See *supra* note 157 and accompanying text for the articulation of this rule.

195. See *supra* notes 188–93 and accompanying text for a discussion of Judge Linn's concurrence in *Larson*.

196. See *supra* notes 166–70 and accompanying text for a discussion of Judge Lourie's opinion concurring and dissenting in *Praxair*.

197. See *supra* note 156–57 and accompanying text for a discussion of the *Praxair* rule and noting *Praxair*'s reliance on *Ferring*.

198. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1195 (Fed. Cir. 2006) (Newman, J., dissenting); see also *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926 (Fed. Cir. 2007) (Newman, J., dissenting) (disputing majority's inference of intent to deceive PTO).

199. *Ferring*, 437 F.3d at 1202.

200. *Id.* (citing Tyler, *supra* note 88, at 276–78).

201. *Id.*

Although not criticizing the *Praxair* rule explicitly, Judge Rader's dissent in *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*²⁰² criticized the related tendency of some panels to improperly conflate materiality and intent, and to focus on materiality almost to the exclusion of the intent requirement.²⁰³ This parallels Judge Lourie's dissenting opinion in *Praxair*, which criticized the *Praxair* majority for improperly conflating intent with materiality.²⁰⁴

2. The Impact of *Therasense* on the Inference of Intent

Revisiting the issue en banc for the first time since *Kingsdown*, the Federal Circuit in *Therasense* tightened the standard for finding intent.²⁰⁵ In a short section on the intent requirement, *Therasense* reaffirmed that a "misrepresentation or omission [that] amounts to gross negligence or negligence under a 'should have known' standard does not satisfy" the intent requirement.²⁰⁶ In cases of nondisclosure, therefore, the party alleging inequitable conduct "must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it."²⁰⁷ The court also reemphasized that materiality and intent are separate requirements by holding that the mere fact "the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive."²⁰⁸ The court also adopted the principle from *Star Scientific* that in order to infer intent from circumstantial evidence, "the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'"²⁰⁹

Interestingly, however, *Therasense* appears to have left the *Praxair* rule largely intact. The Federal Circuit did not take the opportunity to overrule *Praxair* or explicitly reject the *Praxair* rule. Indeed, despite aiming to tighten the standard, *Therasense* did not overrule or even criticize any specific cases on the issue of intent.²¹⁰ Moreover, the "should have known" rule that *Therasense* rejected differs from the *Praxair* rule by omitting the elements of high materiality and failure to provide an explanation for the nondisclosure.²¹¹ Finally, *Therasense* rejected the "should have known" rule without

202. 525 F.3d 1334 (Fed. Cir. 2008).

203. *Aventis*, 525 F.3d at 1350 (Rader, J., dissenting).

204. See *supra* notes 166–70 and accompanying text for a discussion of Judge Lourie's concurring and dissenting opinion in *Praxair*.

205. *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 24, 2011 WL 2028255 at *9 (Fed. Cir. May 25, 2011) (en banc).

206. *Id.*, 2011 WL 2028255 at *9 (citing *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant portion)).

207. *Id.*, 2011 WL 2028255 at *9.

208. *Id.* at 25, 2011 WL 2028255 at *10.

209. *Id.*, 2011 WL 2028255 at *10 (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

210. *Id.* at 24–26, 2011 WL 2028255 at *24–26.

211. Compare *id.* at 25, 2011 WL 2028255 at *10 ("[T]he applicant knew of a reference, should have known of its materiality, and decided not to submit it."), with *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1306 (Fed. Cir. 2008) ("(1) [H]ighly material information is withheld; (2) 'the applicant knew of the information

discussing the possibility of inferring intent from indirect and circumstantial evidence.²¹² Thus, the *Praxair* rule, which concerns the inference of intent, appears to have survived *Therasense*, at least so long as the evidence also satisfies the “single most reasonable inference” principle.

3. “Should Have Known”: A Rule With Two Roots

The “should have known” component of the *Praxair* rule²¹³ can ultimately be traced to the arguably overruled *Driscoll* case²¹⁴: *Praxair* cited *Ferring*,²¹⁵ *Ferring* cited *Critikon*,²¹⁶ and *Critikon* cited *Driscoll*.²¹⁷

Though it has received the most attention,²¹⁸ *Critikon* is not the “should have known” rule’s only root in post-*Kingsdown* case law. To support this rule, *Ferring* cited both *Critikon* and the post-*Kingsdown* case *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Inc.*²¹⁹ As with *Critikon*, *Bruno* inferred intent to deceive where the applicant “should have known” of the withheld reference’s materiality.²²⁰ *Bruno* did not rely on *Critikon*, however, for this rule; instead, it cited the pre-*Kingsdown* case of *FMC Corp. v. Manitowoc Co.*²²¹ This is significant because, unlike *Driscoll*, *FMC* was not “overruled *en banc* by *Kingsdown* on this very point.”²²² In fact, *Kingsdown* cited *FMC* favorably as an example of a case requiring more than gross negligence.²²³ So the “should have known” component of the *Praxair* rule owes its origin not only to *Driscoll*, which *Kingsdown* arguably overruled, but also to *FMC*, which *Kingsdown* cited with approval.²²⁴ The “should have known” rule from *FMC*, however, seems to accompany a purpose: to draw an inference of intent to deceive, “an applicant must be chargeable with knowledge of the materiality of the art or

[and] . . . knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation.”).

212. *Therasense*, slip op. at 25, 2011 WL 2028255 at *10.

213. See *supra* note 157 and surrounding text for an articulation and discussion of this rule.

214. See *supra* note 105–06 and accompanying text for an argument that *Driscoll* was overruled.

215. *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313–14 (Fed. Cir. 2008) (citing *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006)).

216. *Ferring*, 437 F.3d at 1191 (citing *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997)).

217. *Critikon*, 120 F.3d at 1256 (citing *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984)). See *supra* Part II.E.2 for a discussion of *Critikon*’s citation to *Driscoll* and the reemergence of a negligence-like standard. See also Tyler, *supra* note 88, at 276–78 (noting *Critikon* cited only *Driscoll* as basis for “should have known” proposition, yet *Kingsdown* overruled *Driscoll* on that very point).

218. See, e.g., *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1344 n.1 (Fed. Cir. 2009) (Linn, J., concurring) (citing Tyler, *supra* note 88, at 276–83); *Ferring*, 437 F.3d at 1202 (Newman, J., dissenting) (citing Tyler, *supra* note 88, at 276–78); Tyler, *supra* note 88, at 276–78 (discussing *Critikon*).

219. *Ferring*, 437 F.3d at 1191 (citing *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005)).

220. *Bruno*, 394 F.3d at 1352.

221. *Id.* (citing *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987)).

222. *Ferring*, 437 F.3d at 1202 (Newman, J., dissenting).

223. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc*) (citing *FMC*, 835 F.2d at 1415 n.9).

224. *Id.*

information; yet an applicant who knew of the art or information cannot intentionally avoid learning of its materiality through gross negligence, i.e., it may be found that the applicant ‘should have known’ of that materiality.”²²⁵ The court in *FMC* affirmed the district court’s finding of no intent to deceive,²²⁶ and included strong cautionary language regarding inequitable conduct.²²⁷

It is not clear whether *Bruno*’s “should have known” rule incorporated this purpose of foreclosing intentional avoidance of knowledge—*Bruno* recites the “should have known” standard twice on one page, once with and once without this limitation.²²⁸ The language stating this purpose does not appear in either *Ferring*’s or *PraxAir*’s rules for inferring intent.²²⁹

4. The Standard for High Materiality

Whether the threshold requirement of materiality is the but-for or reasonable examiner standard,²³⁰ the question remains what the standard is for the “high materiality” that serves as a basis for inferring intent under the *Praxair* rule.²³¹ There appears to be no articulation of a rule for high materiality, though some cases do indicate that materiality may be measured on a continuum or scale.²³² It is not clear how much higher on this scale high materiality must be, but a finding of high materiality seems to be unrelated to the but-for standard applicable under *Therasense*.²³³

Rather than requiring a particular level or quantum of materiality, courts look to certain specific factors in finding references to be highly material. For example, courts

225. *FMC*, 835 F.2d at 1415.

226. *Id.* at 1417.

227. The court stated:

“Inequitable conduct” is not, or should not be, a magic incantation to be asserted against every patentee. Nor is that allegation established upon a mere showing that art or information having some degree of materiality was not disclosed. To be guilty of inequitable conduct, one must have intended to act inequitably.

Id. at 1415.

228. First, “[t]he record supports the district court’s finding that Bruno possessed actual knowledge of the [prior art]—and that it knew or should have known of its materiality.” *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1352 (Fed. Cir. 2005). Second, “because ‘an applicant who knew of the art or information cannot intentionally avoid learning of its materiality . . . it may be found that the applicant ‘should have known’ of that materiality.’” *Id.* (omission in original) (quoting *FMC*, 835 F.2d at 1415).

229. See *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313–14 (Fed. Cir. 2008); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006).

230. See *supra* Part II.D for a discussion of the standard of materiality.

231. The *Praxair* rule requires a demonstration that “highly material information [was] withheld.” *Praxair*, 543 F.3d at 1313–14 (citing *Ferring*, 437 F.3d at 1191). See *supra* note 157–59 and accompanying text for a full articulation of the *Praxair* rule.

232. See *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006) (discussing four standards reflecting different levels of materiality, any of which is sufficient).

233. *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 27, 2011 WL 2028255 at *11 (Fed. Cir. May 25, 2011). See generally Goldman, *supra* note 53, at 54–55 (discussing subjective and objective “but for” standards of materiality that some courts once applied).

often look to arguments made during prosecution.²³⁴ For example, in *Praxair* the court found withheld information about prior use of related technology to be highly material not in isolation, but “in the context of four statements made in the course of . . . prosecution.”²³⁵ In *Bruno*, the court relied on language from the definition of material in the PTO regulations²³⁶ to find a withheld reference material because its disclosure would have precluded arguments made during prosecution.²³⁷ Later, when examining intent, the court noted the “high materiality” of the same reference.²³⁸

Courts may also look to other factors. For example, in *Ferring* the applicant failed to disclose the past and present financial ties of allegedly disinterested experts who submitted affidavits to the PTO on the applicant’s behalf.²³⁹ Because of the PTO’s explicit requests for non-inventor affidavits, its expression of concerns about objectivity, and because the information in the affidavits addressed a “central concern” of the PTO, the Federal Circuit found the non-disclosure to be highly material.²⁴⁰

H. Commentators’ Criticism and Proposed Solutions

The commentary on inequitable conduct touches on many aspects of the doctrine, from substance to procedure to remedy. This section will discuss some of the commentary on the substantive rules surrounding the inference of intent, and will then present a few commentators’ suggestions of ways to improve the effect and operation of the doctrine. This commentary all predates *Therasense*, which reflects the Federal Circuit’s own attempt to rectify the doctrine.²⁴¹

Several commentators have weighed in on the standard for inferring intent. In 2003, practitioner Lynn Tyler pointed out that the *Critikon* line of cases can be traced to overruled precedent and argued that the inference of intent they purport to allow is bad law.²⁴² Federal Circuit Judges Newman and Linn have both raised this argument as

234. See, e.g., *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367 (Fed. Cir. 2003) (citing *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983)) (noting that affirmative misrepresentations are more likely to be considered material than omissions).

235. *Praxair*, 543 F.3d at 1315.

236. “[I]nformation is material to patentability when: [I]t is not cumulative . . . and . . . [i]t refutes, or is inconsistent with, a position the applicant takes in . . . [a]sserting an argument of patentability.” *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1352 (Fed. Cir. 2005) (second alteration in original) (quoting 37 C.F.R. § 1.56(b) (2004)). See *supra* Part II.D for a discussion of regulatory influences on the inequitable conduct standards.

237. *Bruno*, 394 F.3d at 1353.

238. *Id.* at 1354.

239. In response to the examiner’s request for non-inventor affidavits, the applicant-corporation submitted several declarations without disclosing the declarants’ past financial ties to the corporation. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1184–85 (Fed. Cir. 2006).

240. *Id.* at 1190.

241. See *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 24, 2011 WL 2028255 at *9 (Fed. Cir. May 25, 2011) (attempting to “redirect a doctrine that has been used to the detriment of the public”).

242. Tyler, *supra* note 88, at 276.

well, citing Tyler.²⁴³ Tyler argues that courts should return to the *Kingsdown* rule²⁴⁴ and should refuse to infer intent solely based on the failure to disclose a known material reference.²⁴⁵ Other commentators have also argued for a “return to the *Kingsdown* standard,”²⁴⁶ challenging the validity of the “should have known” rule.²⁴⁷

Commentators have also argued that the courts should require a stronger showing more generally.²⁴⁸ One argued that the standards for both materiality and intent have deviated substantially from Supreme Court precedent.²⁴⁹ In a recent issue of this publication, David Taylor argued that findings of inequitable conduct should be reserved for cases of “patent fraud.”²⁵⁰ In this view, the doctrine would require a showing similar to a *Walker Process* antitrust claim.²⁵¹ Another commentator has argued that the courts should apply a standard of objective recklessness, which would allow an inference of intent where a person skilled in the relevant technical field “would recognize . . . an objectively high likelihood that the patentee’s actions constituted . . . a failure to disclose material information.”²⁵² This recklessness standard would be consistent with the Federal Circuit’s willful infringement jurisprudence.²⁵³

Commentators have advanced several rationales for requiring a stronger showing of intent (or a stronger showing in general). Some have argued that a higher standard is legally required, either by the weight of the en banc *Kingsdown* decision²⁵⁴ or for consistency with Supreme Court precedent.²⁵⁵ Some have argued that a strong showing is necessary in view of inequitable conduct’s harsh remedy of unenforceability.²⁵⁶ Some have cautioned against the danger of overcompliance by arguing that the pressure on applicants to flood the PTO with voluminous disclosures will hurt patent quality and

243. *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1344 n.1 (Fed. Cir. 2009) (Linn, J., concurring) (citing Tyler, *supra* note 88 at 276–83); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1202 (Fed. Cir. 2006) (Newman, J., dissenting) (citing Tyler, *supra* note 82, at 276–78).

244. Tyler, *supra* note 88, at 287.

245. *Id.* at 268–69.

246. Hanft & Kerns, *supra* note 111, at 5.

247. *Id.* at 1 (internal quotation marks omitted).

248. See, e.g., Puknys & Schuettenehelm, *supra* note 88, at 842 (asserting that *Kingsdown* requires both intent and materiality to be “independently proven by clear and convincing evidence”).

249. Sobel, *supra* note 53, at 173–83. Judge Linn also argued that the Federal Circuit has significantly diverged from Supreme Court precedent. *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1342 (Fed. Cir. 2009) (Linn, J., concurring).

250. See generally David O. Taylor, *Patent Fraud*, 83 TEMP. L. REV. 49 (2010).

251. *Id.* at 73–80 (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965)).

252. Chris Henry, Note, *Inequitable Conduct Inequitably Inferred: When Do Patent Applicants’ Actions Intend to Deceive*, 65 WASH. & LEE L. REV. 1159, 1163 (2008).

253. *Id.* The Patent Act authorizes treble damages, 35 U.S.C. § 284 (2006), which may be awarded in cases of willful infringement. 7 CHISUM, *supra* note 21, § 20.03(4)(b).

254. Tyler, *supra* note 88, at 276–83.

255. See Sobel, *supra* note 53, at 170 (arguing that gulf exists between inequitable conduct decisions of Federal Circuit and those of Supreme Court).

256. See Puknys & Schuettenehelm, *supra* note 88, at 870–71; Tyler, *supra* note 88, at 286.

increase costs.²⁵⁷ A more stringent intent standard may lead to investor confidence in the development of new technologies²⁵⁸ by strengthening any resulting patents and reducing their exposure to risk.²⁵⁹ A low threshold for intent makes it easier for litigants, with the benefit of hindsight, to frame innocent mistakes with improper intentions.²⁶⁰ A low threshold also leads to far more inequitable conduct allegations going to trial, resulting in “acrimonious discovery battles” and intrusion on attorney-client privilege.²⁶¹

Finally, in addition to changes to the substantive standard of intent, commentators have also suggested procedural changes to help alleviate the ill effects of inequitable conduct. After presenting a statistical analysis of recent inequitable conduct adjudications,²⁶² one commentator suggested enacting legislative reform to reduce meritless allegations of inequitable conduct. Rather than modifying the Patent Act’s substantive requirements, the commentator called for modifying the Act²⁶³ to award attorney fees, in whole or in part, if the inequitable conduct allegations do not survive summary judgment.²⁶⁴ Another commentator suggested requiring pleading with particularity under Rule 9(b)²⁶⁵ to address concerns that the defense is over-pled.²⁶⁶ This call seems to have been answered by the recent case of *Exergen Corp. v. Wal-Mart Stores, Inc.*²⁶⁷ which, in an opinion by Judge Linn, the Federal Circuit held that inequitable conduct does require pleading with particularity under Rule 9(b).²⁶⁸

III. DISCUSSION

The *Praxair* rule for inferring intent to deceive the PTO²⁶⁹ should not stand in its present form. It is against the weight of authority in the Federal Circuit, especially under *Therasense*, and is in tension with other well-established rules. This section analyzes the origin and application of the *Praxair* rule in order to reformulate it in a

257. See Christopher A. Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 729 (2009) (arguing that current inequitable conduct doctrine leads to costly overcompliance).

258. Henry, *supra* note 252, at 1163; see also Sobel, *supra* note 53, at 187 (noting that loss of patent protection can be devastating to innovator, and that even otherwise valid patents may be found unenforceable).

259. Tyler, *supra* note 88, at 287.

260. Puknys & Schuettenehelm, *supra* note 88, at 871–72.

261. Tyler, *supra* note 88, at 287.

262. Benjamin Brown, Comment, *Inequitable Conduct: A Standard in Motion*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 593, 605–15 (2009).

263. Specifically, the commentator suggests amending 35 U.S.C. § 285, which currently allows courts to award attorney fees in “exceptional cases.” *Id.* at 628 (internal quotation marks omitted).

264. *Id.* at 627–28.

265. FED. R. CIV. P. 9(b) (requiring pleading with particularity in cases of fraud or mistake).

266. Kate McElhone, *Inequitable Conduct: Shifting Standards for Patent Applicants, Prosecutors, and Litigators*, 17 TEX. INTELL. PROP. L.J. 385, 405 (2009).

267. 575 F.3d 1312 (Fed. Cir. 2009).

268. *Exergen*, 575 F.3d at 1327; see also 6 CHISUM, *supra* note 21, § 19.03(6)(b)(ii) (noting that, before *Exergen*, some district courts required pleading with particularity under Rule 9(b)).

269. See *supra* note 157 and accompanying text for an articulation of this rule.

way that is more consistent with Federal Circuit precedent and with the competing policies underlying the inequitable conduct doctrine.

A. *Status of the Praxair Rule: In Need of Change*

1. Weight of Authority

Although some Federal Circuit panels may continue to apply the *Praxair* rule, the weight of authority is against it. Under the Federal Circuit's recent en banc decision in *Therasense*, the *Praxair* rule, at least in its present form including a "should have known" component, is no longer good law. *Therasense* adopted many of the more stringent principles in the case law with respect to the element of intent²⁷⁰ and in cases of nondisclosure requires proof that the applicant actually knew of the nondisclosed reference's materiality.²⁷¹ This directly contradicts the "should have known" component of the *Praxair* rule.

Even before *Therasense*, however, the *Praxair* rule was against the weight of authority. Of nine post-*Kingsdown* cases applying a standard similar to *Praxair*,²⁷² three involved split panels with the minority opinion criticizing the inference of intent,²⁷³ while others received criticism from minority opinions in other cases.²⁷⁴ Not only do these minority opinions weaken the authority for the *Praxair* standard by serving as votes against it, some also directly call into question the authority on which the standard rests.²⁷⁵ Moreover, many of the opinions that apply the *Praxair* rule can be traced to authority that the Federal Circuit directly criticized, if not overruled, in the en banc portion of *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*²⁷⁶ Finally, post-*Kingsdown* cases adopting a more stringent standard for intent to deceive are more

270. *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 24–26, 2011 WL 2028255 at *9–10 (Fed. Cir. May 25, 2011).

271. *Id.* at 24, 2011 WL 2028255 at *9. See *supra* Part II.G.2 for a discussion of the impact of *Therasense* on the intent inquiry.

272. *E.g.*, *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313–14 (Fed. Cir. 2008); *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 916 (Fed. Cir. 2007); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006); *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1359, 1362 (Fed. Cir. 2005); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1352 (Fed. Cir. 2005); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239 (Fed. Cir. 2003); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1275 (Fed. Cir. 2001); *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1375 (Fed. Cir. 2000); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997). See *supra* Parts II.E.2 and II.E.3 for a discussion of the development of this line of cases.

273. *Praxair*, 543 F.3d at 1329 (Lourie, J., concurring in part and dissenting in part); *McKesson*, 487 F.3d at 926 (Newman, J., dissenting); *Ferring*, 437 F.3d at 1195 (Newman, J., dissenting).

274. *E.g.*, *Larson Mfg. Co. of S.D. v. Aluminart Prod. Ltd.*, 559 F.3d 1317, 1343–44 (Fed. Cir. 2009) (Linn, J., concurring) (criticizing the intent standard of *Ferring*, *Praxair*, and *Critikon*); *Ferring*, 437 F.3d at 1200–02 (Newman, J., dissenting) (criticizing *Critikon* and narrowly interpreting *Bruno*).

275. *E.g.*, *Larson*, 559 F.3d at 1344 n.1 (Linn, J., dissenting); *Ferring* 437 F.3d at 1202 (Newman, J., dissenting).

276. 863 F.2d 867 (Fed. Cir. 1988). See *supra* Parts II.E.2, II.E.3, and II.F.1 for a discussion of the development of the line of post-*Kingsdown* case law leading to the *Praxair* rule.

prevalent than those taking the *Praxair* approach,²⁷⁷ and such cases have been unaccompanied by dissents criticizing their standards for inferring intent.²⁷⁸ Indeed, out of eleven cases previously cited,²⁷⁹ none included a dissent arguing for anything like the *Praxair* rule.

2. Tension with Established Rules

The *Praxair* rule effects a burden shift to the patentee that is in tension with other rules.²⁸⁰ Some courts applying the *Praxair* rule have declared that “a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent the drawing of an inference of intent to mislead.”²⁸¹ The ease with which the party alleging inequitable conduct can shift the burden, however, is in tension with the presumption of validity that issued patents enjoy²⁸²—a presumption that can only be overcome by clear and convincing evidence.²⁸³ Indeed, cases in the *Star Scientific* lineage have cautioned that “[t]he burden of proving inequitable conduct lies with the accused infringer”²⁸⁴ and that “[t]he patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence.”²⁸⁵

For the burden shifting effect of the *Praxair* rule to be consistent with the presumption of validity applied in *Star Scientific* line of cases, the rule would need to

277. Judge Newman compiled several such cases. *Ferring*, 437 F.3d at 1202–03 (Newman, J., dissenting) (citing *Allen Eng’g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1351 (Fed. Cir. 2002); *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1289 (Fed. Cir. 2002); *Jazz Photo Corp. v. Int’l Trade Comm’n*, 264 F.3d 1094, 1110 (Fed. Cir. 2001); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995); *Therma-Tru Corp. v. Peachtree Doors Inc.*, 44 F.3d 988, 996 (Fed. Cir. 1995); *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1443 (Fed. Cir. 1991); *Allen Organ Co. v. Kimball Int’l, Inc.*, 839 F.2d 1556, 1567 (Fed. Cir. 1988)); *see also, Larson*, 559 F.3d at 1340–41 (stating inference of intent must “be the single most reasonable inference able to be drawn from the evidence” (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008))); *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1340 (Fed. Cir. 2006) (“Intent to deceive can not be inferred solely from the fact that information was not disclosed” (quoting *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996)) (internal quotation marks omitted)).

278. Of the eleven cases cited at *supra* note 277, two include dissents with respect to the majority’s inequitable conduct holdings. These dissents, however, are directed primarily toward the standard of review, not the rule for inferring intent. *Molins*, 48 F.3d at 1187–92 (Nies, J., dissenting in part) (arguing for more deference to district court’s findings and more stringent requirements for curing past inequitable conduct); *Therma-Tru*, 44 F.3d at 997–98 (Mayer, J., concurring in part and dissenting in part) (arguing that district court’s findings of materiality and intent were not clearly erroneous).

279. The cases are listed at *supra* note 277.

280. *See Larson*, 559 F.3d at 1344 (Linn, J., concurring) (criticizing *Praxair* rule’s effect of shifting burden to patentee).

281. *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997), *quoted in Ferring*, 437 F.3d at 1191.

282. 35 U.S.C. § 282 (2006).

283. 6 CHISUM, *supra* note 21, § 19.03(5)(a).

284. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008) (citing *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1146 (Fed. Cir. 2003)).

285. *Id.* at 1368 (citing *Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 398 (Fed. Cir. 1996)).

require clear and convincing evidence of intent before shifting the burden. But under the *Praxair* rule, the party alleging inequitable conduct can discharge this initial burden by showing (1) high materiality of the withheld reference, (2) the applicant knew of the reference, and (3) should have known of its materiality.²⁸⁶ The third of these elements is likely of little practical significance because once a court finds that a reference is highly material and the applicant knew of its existence, only in rare cases would the court decline to find that the applicant should have known of its materiality.²⁸⁷

In this way, the threshold showing of intent under the *Praxair* standard may be reduced to only high materiality and knowledge of the existence of the withheld reference before the burden shifts to the patentee. A rule allowing such a meager initial showing is in tension with the established rule that inequitable conduct requires “clear and convincing evidence that the material information was withheld with the specific intent to deceive the PTO.”²⁸⁸ Acknowledging the scarcity of smoking gun memos²⁸⁹ and allowing intent to be “inferred from the facts and circumstances,”²⁹⁰ does not demand that courts permit an inference of intent from knowledge and materiality alone. Such a low initial burden is in tension with *Kingsdown*’s requirement of “sufficient culpability to require a finding of intent to deceive,”²⁹¹ and with *Star Scientific*’s admonition of the paramount “need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context . . . because the penalty for inequitable conduct is so severe.”²⁹²

B. Recasting the Praxair Rule

1. A Close Look at *Kingsdown*

A compelling argument can be made that the “should have known” element of the *Praxair* rule is simply bad law. Judge Newman raised this argument,²⁹³ Judge Linn

286. Here the second element of the *Praxair* rule, “the applicant knew of the information [and] . . . knew or should have known of the materiality of the information,” is broken into two parts. *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313 (Fed. Cir. 2008) (alteration in original) (omission in original) (internal quotation mark omitted).

287. Judge Linn raised precisely this argument. *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1344 (Fed. Cir. 2009) (Linn, J., concurring).

288. *Star Scientific*, 537 F.3d at 1366 (citing *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1340 (Fed. Cir. 2006)).

289. See *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1189–90 (Fed. Cir. 1993) (noting that “smoking gun” evidence is not required to establish intent); *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989) (noting that intent can rarely be shown by direct evidence).

290. *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005).

291. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part) (emphasis added); *accord Therasense, Inc. v. Becton, Dickinson, & Co.*, No. 2008-1595, slip op. at 25–26, 2011 WL 2028255 at *10 (Fed. Cir. May 25, 2011) (en banc).

292. *Star Scientific*, 537 F.3d at 1365.

293. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1202 (Fed. Cir. 2006) (Newman, J., dissenting) (citing Tyler, *supra* note 88, at 276–78).

alluded to it,²⁹⁴ and *Therasense* strengthens it by again rejecting a “should have known” standard.²⁹⁵ The *Praxair* rule can ultimately be traced to the overruled *Driscoll v. Cebalo*,²⁹⁶ and thus the panels relying on this overruled precedent were arguably without the authority to do so because a Federal Circuit panel cannot modify an en banc decision.²⁹⁷

The en banc language in *Kingsdown* pertaining to inferring intent deserves careful attention. It comprises only five sentences and appears to be carefully crafted; the entire section on intent reads as follows:

Some of our opinions have suggested that a finding of gross negligence compels a finding of an intent to deceive. Others have indicated that gross negligence alone does not mandate a finding of intent to deceive.

“Gross negligence” has been used as a label for various patterns of conduct. It is definable, however, only in terms of a particular act or acts viewed in light of all the circumstances. *We adopt the view that a finding that 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.²⁹⁸

This language is not so broad as to completely eradicate any trace of negligence from the rules; it requires only that gross negligence, with nothing more, is insufficient to establish an inference of intent to deceive. The language of *Kingsdown* seems to allow that gross negligence in combination with some other aggravating circumstance, and in view of all the evidence, may “indicate sufficient culpability to require a finding of intent to deceive.”²⁹⁹

With this reading of *Kingsdown*, one might argue that the *Praxair* rule is not necessarily bad law since the rule comprises more than the “should have known” standard alone. The second root of the “should have known” standard,³⁰⁰ in *FMC Corp. v. Manitowoc Co.*,³⁰¹ bolsters this argument because *Kingsdown* cited *FMC* with approval.³⁰² While this reading of *Kingsdown* does not resolve the tension in the case law, change the weight of authority, or resolve the tension between the *Praxair* rule’s “should have known” standard and *Kingsdown*’s requirement of culpability, it does suggest that the *Praxair* rule may not need to be completely jettisoned.

294. *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1344 n.1 (Fed. Cir. 2009) (Linn, J., concurring) (citing Tyler, *supra* note 88, at 276–83).

295. *Therasense*, slip op. at 25, 2011 WL 2028255 at *10.

296. 731 F.2d 878 (Fed. Cir. 1984). See *supra* notes 103–08 and accompanying text for a discussion of *Crittikon*’s reliance on *Driscoll*.

297. Only when the Federal Circuit sits en banc can it overrule its own precedent. *E.g.*, *Kingsdown*, 863 F.2d at 876 n.16 (citing *South Corp. v. United States*, 690 F.2d 1368, 1370 n.2 (Fed. Cir. 1982) (en banc)).

298. *Id.* at 876 (emphasis added) (citations omitted).

299. *Id.*; see also Goldman, *supra* note 53, at 84 & n.250 (noting that, as of 1993, post-*Kingsdown* cases in Federal Circuit have required non-disclosure plus some aggravating circumstance).

300. See *supra* Part II.G.3 for a discussion of the two roots of the “should have known” standard.

301. 835 F.2d 1411 (Fed. Cir. 1987).

302. *Kingsdown*, 863 F.2d at 876 (citing *FMC*, 835 F.2d at 1415 n.9).

Therasense likewise does not require that the *Praxair* rule be completely jettisoned, although it likely requires modification of its “should have known” element. Although it could have, *Therasense* did not overrule *Praxair* or explicitly reject the *Praxair* rule.³⁰³ While acknowledging that courts must generally assess intent on the basis of circumstantial evidence alone, *Therasense* provides little guidance regarding the circumstances under which a district court may infer intent to deceive, other than requiring that it be the “single most reasonable inference.”³⁰⁴ *Therasense*, like *Kingsdown*, thus leaves room for a recast *Praxair* rule to govern the inference of intent.

2. “Should Have Known:” A Rule with Only One Valid Root

Although the “should have known” component of the *Praxair* rule is rooted in two pre-*Kingsdown* cases, only one of these roots survived *Kingsdown*. This one valid root incorporated an important limitation that should remain part of the recast *Praxair* rule: prohibiting the deliberate avoidance of knowledge.

Praxair’s “should have known” standard can be traced to both *Driscoll* and to *FMC*, but only *FMC* received approval and avoided criticism from the en banc Federal Circuit in *Kingsdown*.³⁰⁵ In *FMC*, the “should have known” standard in *FMC* served the limited purpose of defeating the “ostrich defense”³⁰⁶—deliberate avoidance of knowledge. The “should have known” standard in *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*,³⁰⁷ the case that imported this standard into the post-*Kingsdown* case law from *FMC*,³⁰⁸ should be read, therefore, as limited to *FMC*’s purpose of defeating the ostrich defense. *Bruno* included this limiting language when it cited *FMC*.³⁰⁹

At least two judges on the *Bruno* panel that brought forward the “should have known” rule favor a more stringent standard for intent than that applied in *Praxair*. Judge Lourie, who wrote the *Bruno* opinion,³¹⁰ dissented from *Praxair* on the intent finding, explicitly distinguishing *Bruno* as having more egregious facts supporting a finding of intent.³¹¹ Most interestingly, Judge Linn joined the *Bruno* opinion³¹² four

303. See *supra* Part II.G.2 for a discussion of *Therasense*’s impact on the intent standard.

304. *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 25, 2011 WL 2028255 at *10 (Fed. Cir. May 25, 2011) (en banc).

305. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant portion).

306. BLACK’S LAW DICTIONARY 451–52 (9th ed. 2009).

307. 394 F.3d 1348 (Fed. Cir. 2005).

308. See *supra* notes 220–22 and accompanying text for a discussion of *Bruno*’s reliance on *FMC*.

309. *Bruno* noted (1) that “an applicant who knew of the art or information cannot intentionally avoid learning of its materiality” and (2) that intentional avoidance may warrant a finding that “the applicant *should have known* of that materiality.” *Bruno*, 394 F.3d at 1352 (omission in original) (emphasis added) (quoting *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987) (internal quotation marks omitted)). But see *supra* note 228 and accompanying text for a discussion of the uncertainty underlying *Bruno*’s articulation of the “should have known” standard.

310. *Bruno*, 394 F.3d at 1350.

311. *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1329 (Fed. Cir. 2008) (Lourie, J., concurring in part and dissenting in part). Judge Lourie’s opinion did not dispute *Praxair*’s “should have known” standard. See *supra* Part II.F.2 for a discussion of *Praxair* and Judge Lourie’s opinion.

312. *Bruno*, 394 F.3d at 1350.

years before his vigorous criticism of the descendant *Praxair* rule.³¹³ While it is possible that Judge Linn had a change of heart, it seems at least as likely that he understood *Bruno*'s "should have known" standard to be more limited than that articulated in *Praxair*.

Judge Newman has also read *Bruno*'s "should have known" standard to be limited to defeating the ostrich defense. In her dissent in *Ferring B.V. v. Barr Laboratories, Inc.*,³¹⁴ Newman argued that *Bruno*'s "should have known" rule did not apply in that case because there was no evidence or argument that the applicants deliberately avoided learning of the nondisclosed reference's materiality.³¹⁵

While the *Ferring* majority may have read this limitation out of *Bruno* in formulating its rule for inferring intent, *Ferring* is an outlier and represents relatively weak authority on this point. First, *Ferring*'s rule—which became the *Praxair* rule³¹⁶—is against the weight of authority.³¹⁷ Second, the majority opinion is accompanied by a powerful dissent.³¹⁸ Finally, *Ferring* supports its rule for inferring intent by citing the "should have known" standard in *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*,³¹⁹ which can be traced to the overruled *Driscoll*.³²⁰

The "should have known" standard, at least without the limitations present in *FMC*,³²¹ stands on a shaky foundation. In view of *Kingsdown*'s approval of *FMC*, it is difficult to argue that *Kingsdown* rejected *FMC*'s "should have known" standard. But this does not mean that the *Praxair* standard, derived from *Critikon* and *Bruno*,³²² is consistent with *Kingsdown*, *Therasense*, or with the weight of authority in the Federal Circuit. Nor does it redeem *Critikon*'s reliance on the overruled *Driscoll*,³²³ to which the *Praxair* rule can also be traced.³²⁴

3. Clarifying the Standard for "High Materiality"

Though the courts have not clearly articulated the standard for high materiality, they generally require an inquiry into factors beyond the relationship between the reference and the claimed invention. Courts finding high materiality have looked to

313. *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1342 (Fed. Cir. 2009) (Linn, J., concurring). See *supra* Part II.F.3 for a discussion of *Larson* and Judge Linn's concurrence.

314. 437 F.3d 1181 (Fed. Cir. 2006).

315. *Ferring*, 437 F.3d at 1201–02 (Newman, J., dissenting).

316. See *supra* notes 156–157 and accompanying text for *Praxair*'s reliance on *Ferring*.

317. See *supra* Part III.A.1 for a discussion of the weight of authority.

318. *Ferring*, 437 F.3d at 1195 (Newman, J., dissenting).

319. *Id.* at 1191 (majority opinion) (citing *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997)).

320. See *supra* notes 103–06 and accompanying text for a discussion of *Critikon*'s reliance on *Driscoll*; see also Tyler, *supra* note 88, at 276–78 (noting *Critikon*'s citation to point overruled by *Kingsdown*).

321. See *supra* notes 225–27 and accompanying text for a discussion of the limitations on *FMC*'s "should have known" standard.

322. The *Praxair* rule seems to have first appeared in its present form in *Ferring*, 437 F.3d at 1191 (citing *Bruno*, 394 F.3d at 1354; *Critikon*, 120 F.3d at 1257).

323. *Critikon*, 120 F.3d at 1256 (citing *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984)).

324. See *supra* notes 213–17 and accompanying text for this linkage.

arguments made in the course of prosecution and the financial ties of allegedly disinterested affiants.³²⁵ Other factors might include the filing of unmistakably false affidavits or facts indicating “‘schemes’ to defraud the PTO,” which *Therasense* suggested would be egregious conduct.³²⁶

The standard for high materiality, in effect and as applied, seems to subsume a requirement for aggravating conduct by the patentee that goes beyond gross negligence and justifies drawing an inference of intent under *Kingsdown*.³²⁷ That is, “high materiality” functions as a codeword for “materiality in combination with aggravating circumstances.”

4. Proposing a New Rule

The foregoing discussion reveals two elements of the *Praxair* rule that might serve to reconcile it with *Kingsdown*, *Therasense*, and to some extent with its criticism. First, the “should have known” element contemplates not a negligence standard, but something more akin to recklessness—that the applicant deliberately avoided learning of the reference’s materiality.³²⁸ This interpretation draws support from the element’s only well-grounded root—the *FMC* case that *Kingsdown* cited with approval.³²⁹ Second, the standard for “high materiality” should include a requirement of some extrinsic aggravating circumstance, such as the conduct of the applicant in making arguments in favor of patentability contrary to the nondisclosed reference.³³⁰ Adding this requirement for aggravating circumstances draws support from the facts of the post-*Kingsdown* case law.³³¹

These two additional requirements should become explicit components of the rule for inferring intent. When recast in this way, the *Praxair* rule would be as follows: an inference of intent may not be drawn unless the party alleging inequitable conduct has shown by clear and convincing evidence that (1) material information was withheld amidst some related, aggravating conduct of the applicant; (2) the applicant actually knew of the information; (3) the applicant actually knew of, or deliberately avoided learning of, the information’s materiality; and (4) the applicant failed to provide a credible explanation of the withholding.

325. See *supra* Part II.G.4 for a discussion of the standard for high materiality. See also 37 C.F.R. § 1.56(b)(2) (2009) (defining material information to include references contradicting arguments made during prosecution).

326. *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 29, 2011 WL 2028255 at *12 (Fed. Cir. May 25, 2011) (en banc) (quoting *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 245 (1944)).

327. See *supra* notes 234–40 and accompanying text for examples of circumstances in which courts have found references to be highly material.

328. See Henry, *supra* note 252, at 1163–64 (arguing that inference of intent should require finding of objective recklessness).

329. See *supra* Part II.G.3 for a discussion of the two roots of the “should have known” element of the *Praxair* rule.

330. See *supra* Part II.G.4 for a discussion of the standard for high materiality.

331. See *supra* Part II.F for a discussion of this post-*Kingsdown* case law.

This proposed rule is sufficiently consistent with Federal Circuit precedent³³² that a panel could adopt it without another en banc rehearing. This is important because the Federal Circuit is unlikely to consider inequitable conduct en banc in the near future, having recently done so in *Therasense*.³³³ The rule also may be useful to district courts, not as a rule to be announced and applied, but in predicting the likely outcome of a case if appealed.

C. Assessing the Proposed Rule

1. Consistency with Precedent

Consistency with precedent is an important consideration for any proposed change in patent law. Shifts in the application of patent law doctrines affect the rights and expectations of current patent holders vis-à-vis their competitors.³³⁴ Courts, surely aware of this effect, consider consistency when reshaping existing doctrines.³³⁵ Requiring a stronger showing to support a finding of inequitable conduct will strengthen existing patents by strengthening their owners' position while weakening that of competitors who might seek to challenge the patents. The tension within the Federal Circuit and the resulting uncertainty provide grounds for reform. The extent of the departure from precedent, however, should remain a consideration.³³⁶

a. Aggravating Circumstances

Incorporating a requirement for aggravating circumstances into the *Praxair* rule is highly consistent with Federal Circuit precedent, so incorporating it into the articulation of the rule will improve predictability without sacrificing consistency with precedent. In 1993, one commentator noted, "since *Kingsdown*, the [Federal Circuit] has required non-disclosure plus some aggravating circumstance or an affirmative misrepresentation . . . to support a finding of inequitable conduct."³³⁷ More recent

332. See *infra* Part III.C.1 for a discussion of consistency with precedent.

333. *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, 2011 WL 2028255 (Fed. Cir. May 25, 2011) (en banc).

334. This is so because a court will generally apply the law in effect at the time it renders its decision. *Harper v. Va. Dep't of Taxation*, 509 U.S. 86, 97 (1993). See generally J. Nicholas Bunch, *Takings, Judicial Takings, and Patent Law*, 83 TEX. L. REV. 1747 (2005).

335. For example, when the Supreme Court recently reshaped the test for a patent's obviousness, it emphasized consistency with precedent: "In the years since the Court of Customs and Patent Appeals set forth the essence of the [old] test, the Court of Appeals no doubt has applied the test in accord with [the new test's] principles in many cases." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 419 (2007).

336. This Comment examines the Federal Circuit's use of precedent only in relation to its analysis of intent in the inequitable conduct context. The Federal Circuit has recently raised the standards for intent in other patent law doctrines. See *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc) (rejecting a negligence standard in favor of an objective recklessness standard for willful infringement); *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1304-06 (Fed. Cir. 2006) (en banc) (clarifying high standard for intent for induced infringement); see also Henry, *supra* note 252, at 1163 (arguing that intent for inequitable conduct should require objective recklessness consistent with willful infringement).

337. Goldman, *supra* note 53, at 84 (citing *LaBounty Mfg., v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066 (Fed. Cir. 1992); *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182 (Fed. Cir. 1993); *Fox Indus.*

cases, even those applying the criticized *Praxair* rule, remain consistent with this requirement for aggravating circumstances, and the facts of many of these criticized cases would support a finding of high materiality under the proposed rule.

In *Praxair*, for example, the court inferred intent to deceive from four statements that the applicant made to the examiner during prosecution in support of patentability, that were contrary to the nondisclosed reference.³³⁸ In *Bruno*, aggravating circumstances included prior arguments to the Food and Drug Administration that the patented invention was “similar in design and function” to the nondisclosed prior art device,³³⁹ as well as arguments to the PTO that disclosure would have precluded.³⁴⁰ In *Ferring*, the aggravating circumstances included a conflict of interest in the face of explicit PTO concerns about objectivity,³⁴¹ as well as false testimony at trial indicating intent to deceive.³⁴²

These examples of aggravating circumstances, however, are not necessarily exhaustive. With its roots in equity,³⁴³ the inequitable conduct doctrine remains sensitive to “the facts and circumstances surrounding the applicant’s overall conduct.”³⁴⁴ The rule for inferring intent should remain sufficiently flexible, therefore, to assess new patterns of conduct or new strategies for deceit during what Judge Newman characterized as “the complex procedures of patent prosecution.”³⁴⁵

v. Structural Preservation Sys., 922 F.2d 801, 804 (Fed. Cir. 1990); *Consol. Aluminum Corp. v. Foseco Int’l Ltd.*, 910 F.2d 804, 806 (Fed. Cir. 1990)).

338. *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1315–16 (Fed. Cir. 2008). See *supra* Part II.F.2 for a discussion of *Praxair*. See *supra* notes 234–35 and accompanying text for a discussion of the courts’ frequent reliance on arguments made during prosecution to support findings of high materiality.

339. *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1352 (Fed. Cir. 2005) (quoting letter from Bruno’s chief of engineering to the Food and Drug Administration seeking approval for selling their product) (internal quotation marks omitted).

340. Bruno argued to the FDA that its new device was “similar in design and function” to a competitor’s previously approved device. *Id.* Bruno argued to the PTO that a certain mechanical feature, present in its competitor’s device, distinguished its design over the prior art. *Id.* at 1353. The court concluded Bruno could not have made this argument to the PTO if it had disclosed either its communication to the FDA or the competitor’s device it claimed was similar. *Id.*

341. In response to the examiner’s request for non-inventor affidavits, the applicant-corporation submitted several declarations without disclosing the declarants’ past financial ties to the corporation. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1184–85 (Fed. Cir. 2006). In dissent, Judge Newman argued that the applicants had strictly complied with the examiner’s request, and that the declarants’ financial ties were so remote as to be immaterial. *Id.* at 1197 (Newman, J., dissenting). See *supra* notes 314–15 and accompanying text for a discussion of Judge Newman’s *Ferring* dissent.

342. The inventor “initially stated that he had no contact with the declarants, but later admitted . . . that he had contacted each of the declarants and that he sent . . . ‘draft declarations,’ thus suggesting a desire to conceal the extent of his involvement.” *Ferring*, 437 F.3d at 1193–94 (majority opinion) (citation omitted).

343. See *supra* Part II.C for a discussion of the inequitable conduct doctrine’s origins in the equitable doctrine of unclean hands.

344. *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006).

345. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926 (Fed. Cir. 2007) (Newman, J., dissenting); see also *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 30, 2011 WL 2028255 at *13 (Fed. Cir. May 25, 2011) (en banc) (explaining needed flexibility in materiality standard); *Ferring*, 437 F.3d at 1195 (Newman, J., dissenting) (noting “complexities of patent practice”).

b. Actual Knowledge or Deliberate Avoidance

Incorporating a requirement that the applicant actually knew of, or deliberately avoided learning of, the materiality of the nondisclosed reference is as consistent with precedent as possible in view of the tension within the Federal Circuit on precisely this point.³⁴⁶ First, the proposed rule is consistent with *Kingsdown*. A standard allowing a finding of inequitable conduct where the applicant should have known the information's materiality, but in fact neither knew nor avoided knowing, would be inconsistent with *Kingsdown*'s requirement of "sufficient culpability to require a finding of intent to deceive."³⁴⁷ A requirement for culpable intent cannot possibly be consistent with the "should have known" standard.³⁴⁸ Incorporating the "actual knowledge or deliberate avoidance" requirement is sufficiently consistent with *Kingsdown*'s requirement for culpability, *FMC*'s purpose for announcing the "should have known" standard, and *Therasense*'s requirement of "deliberate action"³⁴⁹ to be a compelling choice for recasting the rule.

Second, the proposed rule is consistent with *Therasense*, which tightened the required showing of intent.³⁵⁰ Specifically, the *Therasense* requirement that "[i]n a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference"³⁵¹ is consistent with the proposed requirement that the applicant actually knew of the materiality. Although allowing an inference of intent where the applicant deliberately avoided learning of the materiality may show some tension with *Therasense*'s "known material" requirement, this requirement applies only to mere nondisclosures and not to affirmative misrepresentations or other aggravating conduct. Because the proposed rule requires aggravating conduct beyond mere nondisclosure, it covers situations in which *Therasense* does not strictly require actual knowledge of materiality. Further, allowing an inference of intent where the applicant deliberately avoided learning of the materiality is also consistent with *Therasense*'s requirement that a "specific intent to deceive" be affirmatively demonstrated by a "*deliberate decision*"³⁵² particularly since

346. See *supra* Parts II.E.2 and II.E.3 for a discussion of the development of this tension. See *supra* Part II.G.1 for a discussion of minority opinion criticism of this aspect of the rule.

347. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc).

348. See *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1343–44 (Fed. Cir. 2009) (Linn, J., concurring) (criticizing "should have known" prong of *Praxair* rule as a simple negligence standard); see also MODEL PENAL CODE § 2.02(2) (1962) (defining four kinds of culpability common to criminal law: acts committed purposely, knowingly, recklessly, and negligently). This Comment does not argue that the Model Penal Code definitions be adopted into patent law, but they might well be used to guide a reasonable interpretation of the en banc language of *Kingsdown*. Under the Model Penal Code definitions, both "purposely" and "knowingly" require actual awareness of relevant circumstances, while "recklessly" requires actual awareness of a substantial and unjustifiable risk. *Id.*

349. *Therasense*, slip op. at 25, 2011 WL 2028255 at *10.

350. *Id.* at 24, 2011 WL 2028255 at *9.

351. *Id.*, 2011 WL 2028255 at *9 (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

352. *Id.* at 25, 24, 2011 WL 2028255 at *10, *9.

Therasense recognizes the scarcity of direct evidence and consequently allows for an inference of intent from indirect and circumstantial evidence.³⁵³

Third, the tension within the Federal Circuit is further resolved by the explicit addition of a requirement for aggravating circumstances. That is, the proposed rule, considering all of its elements in totality, should ensure a sufficiently strong showing of intent to be consistent with the principles announced in *Therasense* and *Star Scientific*. For example, suppose a patent applicant knew of a previously existing technology that performed a very similar function to the claimed invention, but deliberately avoided learning that the prior technology actually had exactly the same elements as the claimed invention. In such a case, the applicant knows of the anticipatory reference and deliberately avoids knowing of its materiality. Under both *Therasense* and the proposed rule, the applicant's deliberate decision to withhold this reference would not establish inequitable conduct. Under *Therasense*, it is a mere nondisclosure case, and the applicant has no actual knowledge of the materiality. Under the proposed rule, there are no aggravating circumstances. If however, the applicant argues to the PTO or submits an affidavit that no similar prior technology exists, this aggravating conduct would raise a permissible inference of intent under both *Therasense* and the proposed rule. Under *Therasense*, the facts no longer involve mere nondisclosure, so actual knowledge of the materiality is not strictly required, and the inference of intent would be permissible. Under the proposed rule, the aggravating conduct in combination with the deliberate avoidance of knowledge would permit the inference of intent.

Finally, although some language in the *Critikon* line of cases³⁵⁴ is not consistent with the proposed requirement that the applicant actually knew or deliberately avoided learning of the materiality, the proposed rule averts a dramatic departure from these cases. Furthermore, although *Therasense* may arguably obviate the need for harmony with *Critikon* and its progeny, these cases have not been overruled and remain in some sense good law. The proposed rule requires a stronger showing than does the "should have known" language in the *Critikon* line of cases. For example, in *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*,³⁵⁵ the court charged the inventor with knowledge of the law and inferred intent to deceive despite acknowledging that the inventor's misrepresentation was inadvertent,³⁵⁶ because the applicant "knew or should have known" that the information was material.³⁵⁷

This inconsistency in language does not, however, indicate that the proposed rule is a dramatic departure from the *Critikon* line of precedent. Indeed, it is not clear that district courts applying the proposed rule to the same fact patterns would necessarily have reached different conclusions. This is because inferring intent where applicants merely "should have known" of an omitted reference's materiality and charging

353. *Id.* at 25, 2011 WL 2028255 at *10 (citing *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009)).

354. See *supra* Part II.E.2 for a discussion of this line of cases.

355. 424 F.3d 1347 (Fed. Cir. 2005).

356. See *supra* notes 110–19 and accompanying text for a discussion of *Novo Nordisk*.

357. *Novo Nordisk*, 424 F.3d at 1362. Similarly, in *Ferring*, the examiner's request for non-inventor affidavits put the applicant "on notice," and the applicants "knew or should have known" that the affiants' affiliations were material. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1192 (Fed. Cir. 2006).

inventors with knowledge³⁵⁸ both involve objective analyses of the facts and circumstances. By contrast, determining that an applicant actually knew or deliberately avoided learning of materiality involves a subjective analysis. This distinction can be subtle, however, because such subjective factual findings might be inferred from objective indicators.

Making this small departure from the *Critikon* line of cases remains true to *Kingsdown* and *Therasense* and resolves the current tension in the inequitable conduct case law³⁵⁹ without completely abandoning the *Critikon* line of precedent or the core purpose of the “should have known” standard. For example, the actual outcome of the most recent such case, *Praxair*,³⁶⁰ is consistent with the proposed rule. In *Praxair*, the Federal Circuit found that the prosecuting attorney knew of the nondisclosed information and “was aware of its obvious materiality.”³⁶¹ Because of the court’s findings of actual knowledge of materiality and of aggravating circumstances,³⁶² the proposed rule would also have led the *Praxair* court to affirm the district court’s finding of inequitable conduct.

2. Consistency with the Policy Considerations Underlying Inequitable Conduct

In addition to being consistent with precedent, the proposed rule is also consistent with the policies underlying the inequitable conduct doctrine and the patent system generally. Its consistency with precedent, in addition to providing a measure of legal legitimacy, provides a policy advantage by minimally disrupting the settled expectations and business decisions of existing patentees. The proposed rule also answers many of the policy arguments other commentators have advanced in support of a generally more stringent standard of intent.³⁶³

First, the inequitable conduct doctrine must be applied in a way that does not undermine the patent system’s overarching purpose to encourage innovation and investment in new technologies.³⁶⁴ The patent system’s substantive requirements of novelty, nonobviousness, disclosure, and the like strike the balance of the patent system’s inherent quid pro quo.³⁶⁵ The lower the bar for the standard of intent, the more the inequitable conduct doctrine will disrupt the delicate balance of this quid pro quo by distracting litigation from the substantive questions of patent validity and

358. Presumably, charging an inventor with knowledge, or placing the inventor on notice of certain information, requires a lower evidentiary showing than does a finding of such knowledge in fact.

359. See *supra* Part II.E.3 for a discussion of this tension.

360. See *supra* Part II.F.2 for a discussion of *Praxair*.

361. *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1317 (Fed. Cir. 2008). *But see id.* at 1330 (Lourie, J., dissenting) (arguing that majority’s knowledge-of-materiality finding was not supported by any finding of district court).

362. See *supra* note 338 and accompanying text for the four statements made during prosecution that constituted aggravating circumstances in the case.

363. See *supra* notes 256–68 and accompanying text for a presentation of these arguments.

364. See *supra* Part II.A for a discussion of the patent system and its underlying policies.

365. See *supra* notes 31–33 and accompanying text for a discussion of this quid pro quo.

infringement.³⁶⁶ Courts, therefore, should not resort to a judge-made equitable doctrine unless the applicant truly acted inequitably.³⁶⁷ By changing the rule from “should have known of the materiality” to “deliberately avoided learning of the materiality” and incorporating a requirement for aggravating circumstances, findings of intent would be limited to situations where the applicant acted inequitably while retaining the core purpose of the “should have known” rule.³⁶⁸

Second, justifying a strict enforcement of the duty of candor toward the PTO with the strong incentive patent applicants have to seek broad claims³⁶⁹ can only carry so much weight. Surely enforcement is necessary, or the duty would have little meaning; and surely applicants want broad patent coverage. But applicants also want enforceable patents. That is, while “applicant obligations of candor may be tempered by the great incentive they possess not to disclose information that might deleteriously impact their prospective patent rights,”³⁷⁰ this incentive to withhold information will be tempered by the fear of unenforceability due to inequitable conduct.³⁷¹ Indeed, the “atomic bomb”³⁷² remedy of unenforceability ensures that, even if the probability of detection is low, the deterrent effect of the doctrine will remain strong.

3. Potential Criticism: Propriety of a Rule

Perhaps the most powerful criticism of the proposed rule is that it is a rule at all. As Judge Linn said of the *Praxair* rule, it “generally permits an inference of deceptive intent to be drawn whenever the three prongs are satisfied.”³⁷³ One might argue that an inquiry into a party’s subjective intent cannot be reduced to a mechanical rule, no matter how complicated and no matter how many elements it may contain, because an assessment must be made of “the involved conduct, viewed in light of all the evidence”³⁷⁴ in order to make a just and proper determination. In this view, the standard for inequitable conduct would be better cast as a series of principles, such as those set out in *Star Scientific*.³⁷⁵ This can be coupled with the related argument that

366. See, e.g., *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1343 (Fed. Cir. 2009) (Linn, J., concurring) (expressing concern that “the litigation will continue to focus on inequitable conduct, to the exclusion of the patentee’s infringement contentions”).

367. See *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987) (“To be guilty of inequitable conduct, one must have intended to act inequitably.”).

368. See *supra* Part III.B.2 for a discussion of the “should have known” standard’s derivation from *FMC*, which employed it to prevent an applicant from intentionally avoiding learning of the materiality. See *FMC*, 835 F.2d at 1415.

369. See *supra* note 40 and accompanying text for a discussion of this incentive.

370. *ADELMAN ET AL.*, *supra* note 23, § 10.3.

371. This is not to say that no applicant would ever intentionally withhold references, but to stress the importance of the subjective inquiry: that “should have known” is not enough to infer intent where the underlying incentives are equivocal.

372. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting) (internal quotation marks omitted).

373. *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1344 (Fed. Cir. 2009) (Linn, J., concurring).

374. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc).

375. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365–67 (Fed. Cir. 2008).

courts do not need a special rule for inferring intent in the context of inequitable conduct because subjective intent inquiries are very familiar to the courts.

This may be true, but the current tension within the Federal Circuit suggests that some concrete standards are required in order to achieve consistent application of the doctrine among Federal Circuit panels. Given the deferential standard of review on appeal³⁷⁶ and the prevalence of forum shopping in patent litigation,³⁷⁷ consistent application among district courts is no less important. As noted in *Therasense*, “Courts have long applied rules and tests in determining whether a particular factual situation falls within the scope of an equitable doctrine.”³⁷⁸ Furthermore, the proposed rule, although somewhat detailed, provides considerable flexibility to address a wide range of fact patterns.³⁷⁹

IV. CONCLUSION

Since the Federal Circuit considered inequitable conduct en banc in *Kingsdown*—holding that gross negligence is insufficient to support a finding of intent to deceive the PTO³⁸⁰—a line of cases has emerged allowing such a finding where “highly material” information is withheld, the applicant knew of the information, and knew or should have known of its materiality.³⁸¹ This standard, referred to herein as the *Praxair* Rule, is in tension with the weight of authority within the Federal Circuit and has been the subject of significant criticism, most pointedly for its reliance on overruled precedent.³⁸² The rule does not rest solely on overruled precedent, however, and at its root lies an important purpose: to prevent applicants from deliberately avoiding learning of materiality.³⁸³

As this Comment has argued, this rule should be modified to incorporate two limitations already inherent in the existing case law. An inference of intent should not be allowed unless the party alleging inequitable conduct has shown by clear and convincing evidence that (1) material information was withheld amidst some related, aggravating conduct of the applicant; (2) the applicant actually knew of the information; (3) the applicant actually knew of, or deliberately avoided learning of, the information’s materiality; and (4) the applicant failed to provide a credible explanation of the withholding.

376. Factual findings are reviewed for clear error, and the ultimate determination is reviewed for abuse of discretion. *Id.* at 1365 (citing *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1364–65 (Fed. Cir. 2007)).

377. See KIMBERLY A. MOORE, ET AL., *PATENT LITIG. & STRATEGY* 93–100 (3d ed. 2008) (discussing forum shopping in patent cases and presenting statistics on specific district courts).

378. *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1595, slip op. at 31, 2011 WL 2028255 at *13 (Fed. Cir. May 25, 2011) (en banc).

379. See *supra* notes 343–45 and accompanying text for a discussion of the proposed rule’s flexibility.

380. *Kingsdown*, 863 F.2d at 876.

381. See *supra* Part II.E.2 for a discussion of the line of cases adopting this rule and *supra* Part II.F.2 for a discussion of its latest articulation in *Praxair*.

382. See *supra* Parts II.G and II.H for a discussion of this criticism.

383. See *supra* Part III.B.2 for a discussion of the “should have known” standard’s origin in a case *Kingsdown* cited with approval.

Explicitly incorporating these requirements when articulating the rule is important to ensure that the rule's application is uniform and in accordance with precedent. The alternative is to leave these requirements as tacit points of interpretation or to be derived from the facts of the cases applying the rule. The tension within the Federal Circuit's inequitable conduct decisions,³⁸⁴ however, reflects the difficulty in this approach. Beyond this practical necessity, the proposed rule for inferring intent is better supported by precedent, more consistent with the Federal Circuit's recent decision in *Therasense*, and more consistent with the underlying policy considerations of the patent system.

384. See *supra* Parts II.E, II.F, and II.G for a discussion of the divergent authority and tension within the Federal Circuit.

