

Note

An Improved Framework for Analyzing “Substantially Similar” Patent Claims with Respect to the Inequitable Conduct Defense

*Michael Buschbach**

With its decisions in *Dayco Products*¹ and *McKesson*,² the Court of Appeals for the Federal Circuit expanded the scope of the materiality leg of the inequitable conduct defense. A patent prosecutor's duty of disclosure, the court found, extends to rejections by the Patent and Trademark Office (“PTO”) examiner of “substantially similar” claims in co-pending applications.

This Note addresses criticisms of those Federal Circuit cases in the context of the purposes of the inequitable conduct defense in order to formulate an improved framework for analysis. Part I of this Note traces the development of the inequitable conduct defense through *Dayco Products* and *McKesson* as the Federal Circuit seeks an appropriate standard for determining whether information is material and therefore subject to disclosure. Part II of this Note analyzes those decisions, discusses the difficulties inherent in substantial similarity analysis, and considers the importance of prior art in patent validity, infringement cases, and inequitable conduct charges. This Note concludes that the Federal Circuit should incorporate a comparison of the prior art referenced by the applications into its substantial similarity framework.

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* Michael Buschbach is a J.D. candidate at the University of Minnesota. He would like to thank his adored wife, Heidi, and his beloved daughters, Acacia and Evelyn, for their patience and support during the writing of this article.

1. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003).

2. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir. 2007).

I. THE DEVELOPMENT OF AN APPROPRIATE STANDARD OF MATERIALITY FOR MISREPRESENTATIONS AND FAILURES TO DISCLOSE

A. PATENTS AS A VOLUNTARY EXCHANGE WITH THE GOVERNMENT

The United States Constitution authorizes Congress to grant an inventor an exclusive right to the exercise of his invention,³ and that body has obliged through passage of the Patent Act, which grants patent holders “the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States”⁴ This exclusionary power is properly characterized as a property right;⁵ a patent, therefore, is a Congressional grant of property. However, only “things which add to the sum of useful knowledge” are to be granted patents.⁶ In exchange for the government grant of property, the government requires actual innovation and that the inventor set forth, via a written description, “the manner and process of making and using [the invention, with sufficient specificity] . . . as to enable any person skilled in the art . . . to make and use [it]”⁷ The description enters the public

3. “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” U.S. CONST., art. I, § 8, cl. 1–8.

4. 35 U.S.C. § 154(a)(1) (2000).

5. See *College Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 673 (1999) (“The hallmark of a protected property interest is the right to exclude others.”); see also *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989) (“The federal patent system thus embodies a carefully crafted bargain encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.”); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002) (“The patent laws ‘promote the Progress of Science and useful Arts’ by rewarding innovation with a temporary monopoly. The monopoly is a property right” (internal citations omitted)).

6. *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966). This important limitation, rooted in England’s Statute of Monopolies, prevents Congress from granting patents to politically favored groups that provide little or no public benefit. See *id.* at 5–6.

7. 35 U.S.C. § 112, ¶ 1 (2000); see also *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 142 (2001) (“The disclosure required by the Patent Act is ‘the *quid pro quo* of the right to exclude.’”) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974)); *Grant v. Raymond*, 31 U.S. (6

domain as a result, and the sum of society's useful knowledge increases.

B. CREATION OF THE INEQUITABLE CONDUCT DEFENSE

Like any system of voluntary exchange, the patent system is subject to misrepresentation, both fraudulent and innocent. In contract law, one of the available remedies for misrepresentation is rescission, even where fraudulent intent is absent or not proved.⁸ Congress, through successive Patent Acts, has provided for the repeal of a patent upon a showing that, for example, the patent “was obtained surreptitiously by, or upon false suggestion.”⁹ In addition, federal courts seek to ensure that the public as a contractual party with the putative inventor receives the benefit for which its government has granted exclusive rights.¹⁰ One of the most important common law developments in this regard was the creation of an inequitable conduct defense to patent infringement.

An owner of a patent relies on the courts to enforce his property rights against infringers—those using, making, selling, or offering to sell, without authorization, inventions covered by his patents.¹¹ In 1945 in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, the Supreme Court, relying on the equitable doctrine of clean hands,¹² announced that for the protection of the public:

Pet.) 218, 242 (1832) (referring to patent rights in exchange for innovation as a “contract”).

8. RESTATEMENT (SECOND) OF CONTRACTS § 164(1) (1979) (contract is voidable where “a party’s manifestation of assent is induced by either a fraudulent or material misrepresentation by the other party”). The test for inequitable conduct in contract law is different from that found in patent law because it requires *either* fraudulent intent *or* a material misrepresentation, but not both.

9. Act of Apr. 10, 1790, ch. 7, § 5, 1 Stat. 111 (1790); *see also* Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARV. J.L. & TECH. 37, 37–38 (1993) (summarizing development of the inequitable conduct defense).

10. *See* Scott D. Anderson, *Inequitable Conduct: Persistent Problems and Recommended Resolutions*, 82 MARQ. L. REV. 845, 846–47 (1999) (“[s]ociety at large is damaged when it receives a poor bargain.”). Chief Justice Marshall wrote that the laws passed by Congress to provide a reward for innovation are to be construed so as not to “countenance[e] acts which are fraudulent or may prove mischievous.” *Grant*, 31 U.S. at 242. “The public yields nothing which it has not agreed to yield; it receives all which it has contracted to receive.” *Id.*

11. 35 U.S.C. § 271(a) (2000).

12. “[H]e who comes into equity must come with clean hands.” *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945).

Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue. This duty is not excused by reasonable doubts as to the sufficiency of the proof of the inequitable conduct nor by resort to independent legal advice. Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies. Only in that way can the Patent Office and the public escape from being classed among the “mute and helpless victims of deception and fraud.”¹³

The respondent in *Precision* had repeatedly and egregiously violated this rule during prosecution of its patents at issue.¹⁴ As a result, the Court found those patents unenforceable against the accused infringer.¹⁵

C. EVOLVING STANDARDS OF MATERIALITY

1. Striking a Balance to Avoid Overreaching

Presently, in order “[t]o prove inequitable conduct in the prosecution of a patent, [the defendant] must have provided evidence of affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.”¹⁶ The analysis is performed in two steps comprising “first, a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all the circumstances to determine whether the applicant’s conduct is so culpable that the patent should be held unenforceable.”¹⁷ “Both intent and materiality are questions of fact that must be proven by clear and convincing evidence.”¹⁸

13. *Id.* at 818 (citations omitted).

14. *Id.* at 816–20.

15. *Id.* at 816.

16. *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001) (quoting *Baxter Int’l, Inc. v. McGaw, Inc.* 149 F.3d 1321, 1327 (Fed. Cir. 1998)) (internal quotation omitted).

17. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362–63 (Fed. Cir. 2003) (quoting *Purdue Pharma*, 237 F.3d at 1366).

18. *Id.* at 1362–63. If either materiality or intent fails to rise to the requisite threshold, a court need not engage in the further analysis of balancing the equities. *See Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 398

Questions of 'materiality' and 'culpability' are often interrelated and intertwined, so that a lesser showing of the materiality of the withheld information may suffice when an intentional scheme to defraud is established, whereas a greater showing of the materiality of withheld information would necessarily create an inference that its nondisclosure was 'wrongful.'¹⁹

But more than just those two factors will be considered. A court must weigh materiality and intent in the totality of the circumstances to find whether the equities warrant a conclusion that inequitable conduct occurred.²⁰

Since *Precision*, courts have struggled to establish a test for materiality that properly balances the costs and benefits of the defense of inequitable conduct. Provide a standard that is too lenient, and charges of inequitable conduct are raised during infringement hearings as a matter of course.²¹ A lenient standard also makes it more likely that an otherwise valid patent will be rendered unenforceable due to innocent mistakes during prosecution or to errors during the trial. This fear is compounded by the severity of the punishment: a finding of inequitable conduct with respect to only one claim during the prosecution of a patent application renders the *entire* patent unenforceable.²² Thus, it is possible that claims otherwise

(Fed. Cir. 1996).

19. *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1363 (Fed. Cir. 1984) (quoting *Digital Equipment Corp. v. Diamond*, 653 F.2d 701, 716 (1st Cir. 1981)).

20. *B.F. Goodrich Co. v. Aircraft Braking Systems Corp.*, 72 F.3d 1577, 1584 (Fed. Cir. 1996). A conclusive list of the equities that may affect the decision has not been established, but in the *B.F. Goodrich* case, the Federal Circuit accepted the lower court's determination that the complexity and uncertainty of the on-sale bar and obviousness doctrines at the time justified giving the patentee "the benefit of the doubt" with regard to intent. *Id.*

21. *See, e.g., Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) ("[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague."). The court went on to remark that these accusations were: (1) rarely successful, (2) destroying attorneys' respect for one another, (3) when unsupported, a negative contribution to justice. *Id.*; *see also* Ad Hoc Comm. on Rule 56 and Inequitable Conduct, Am. Intellectual Prop. Law Ass'n, *The Doctrine of Inequitable Conduct and the Duty of Candor in Patent Procurement: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74, 75 (1988) ("Estimates are that inequitable conduct is raised as a defense to claims of patent infringement in 80% of the cases before the courts.").

22. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988). Unenforceability may extend to other related patents, but not necessarily. Donald S. Chisum, *Best Mode Concealment and Inequitable Conduct in Patent Procurement: A Nutshell, a Review of Recent Federal Circuit Cases and a Plea for Modest Reform*, 13 SANTA CLARA COMPUTER & HIGH

unrelated to the particular act of inequitable conduct will be unenforceable by virtue of their inclusion with a tainted claim in a patent specification. In addition, the attorney that prosecuted the patent faces sanction,²³ and the exceptional nature of inequitable conduct often justifies an award of attorney fees when the patent is litigated.²⁴ Of course, these consequences redound to the party that raises the inequitable conduct defense, when it is successful. It is unremarkable then that the charge is so frequently raised when the benefits are so great in relation to the simple expediency of the defense.²⁵

An overly strict standard, meanwhile, risks unduly restricting courts from pursuing the purposes that the inequitable conduct doctrine is meant to serve, which are: (1) to ensure that the PTO receives all facts relevant to a pending patent application, and (2) to punish inequitable conduct to protect the public against “fraudulent patent monopolies.”²⁶

TECH. L.J. 277, 305 (1997). For example, patents bound by a terminal disclaimer are not affected when inequitable conduct is found with respect to a sister patent. *Pharmacia Corp. v. Par Pharma., Inc.* 417 F.3d 1369, 1375 (Fed. Cir. 2005); *Baxter Int'l., Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1332 (Fed. Cir. 1998) (“[W]here the claims are subsequently separated from those tainted by inequitable conduct through a divisional application, and where the issued claims have no relation to the omitted prior art, the patent issued from the divisional application will not also be unenforceable due to inequitable conduct committed in the parent application.”). The qualifications of the holding in *Baxter* suggest that claims tainted by a prior finding of inequitable conduct cannot be made clean simply by moving them from one application to another. Rather, it is claims that are carriers of the inequitable conduct infection. See *Baxter*, 149 F.3d at 1331.

23. See Edwin S. Flores & Sanford E. Warren, *Inequitable Conduct, Fraud, and Your License to Practice Before the United States Patent and Trademark Office*, 8 TEX. INTEL. PROP. L.J. 299, 314 (2000). The Commissioner of the PTO has authority to regulate patent attorneys, see 35 U.S.C. § 2(b)(2)(D), and may impose sanctions that include reprimands (public and potentially private), suspensions, and exclusions, Flores & Warren, *supra*.

24. See *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001). Professor Chisum describes additional possible consequences such as:

[L]iability for damages under the antitrust laws, . . . liability under the Federal Trade Commission Act, [] liability under the federal securities laws, and . . . recovery of prior royalties paid to the patentee, [] loss of the attorney-client and work product privileges, . . . and disciplinary action against the attorney or agent who is registered to practice before the Patent and Trademark Office.

6 DONALD S. CHISUM, CHISUM ON PATENTS § 19.03[6] (1992).

25. Lisa A. Dolak, *The Inequitable Conduct Doctrine: Lessons from Recent Cases*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 719, 719 (2002).

26. See *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S.

Because of the difficulty inherent in foreseeing the myriad ways by which patent prosecutors may attempt to subvert the process, as well as the myriad ways in which honest practitioners suffer from benign negligence, the PTO and the Federal Circuit continue to make adjustments to the inequitable conduct standard.

2. Limitations of the Defense

Patent rights discourage additional innovation by third parties in areas encompassed by a particular patent. An unnecessarily granted patent, whether innocently or scurrilously obtained, therefore comes at a high cost without a concomitant benefit. Not only are there high potential monopoly costs,²⁷ but the public also may be forced to wait until the patent expires before new developments in the area are forthcoming. The prospect of potential monopoly pricing and an empty competitive field provides strong incentive for applicants to commit fraud.

Patents, once granted, carry a presumption of validity. The inequitable conduct defense is one of the few means available for overturning a patent and thus aids the public in combating fraud. While it is an equitable defense and “serves as a shield”²⁸ for the alleged infringer, society benefits from that infringer’s

806, 818 (1945). These policies have the secondary effect of improving the quality of patents through the production and verification of information related to patentability. CHRISTOPHER A. COTROPIA, RECENT DEVELOPMENTS IN THE INEQUITABLE CONDUCT DOCTRINE AND THEIR IMPACT ON PATENT QUALITY 3 (2007), available at http://www.ipso.org/AM/Template.cfm?Section=IPO_Annual_Meeting2&Template=/CM/ContentDisplay.cfm&ContentID=15882.

27. Reference to patents as automatically conferring a temporary monopoly is not necessarily accurate; rather, patents provide a meaningful right to exclude. See *Carl Schenck, A.G. v. Nortron Corp.*, 713 F.2d 782, 786 n.3 (Fed. Cir. 1983) (“Nowhere in any statute is a patent described as a monopoly. The patent right is but the right to exclude others, the very definition of ‘property.’ That the property right represented by a patent, like other property rights, may be *used* in a scheme violative of antitrust laws creates no ‘conflict’ between laws establishing any of those property rights and the antitrust laws.”). *But see Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002) (“The patent laws . . . reward[] innovation with a temporary monopoly.”). Despite the conflict in the attitudes of the Supreme Court and the Federal Circuit towards the idea of patents as *per se* monopolies, one can see the logic in both positions. Patents may provide substantial economic power, but there cannot be a monopoly in the ordinary sense over a particular invention where there is no market for it.

28. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed. Cir. 1998).

wielding of the shield when an improperly granted patent is rendered unenforceable.²⁹

Yet despite its potential, the inequitable conduct defense is ineffective against many fraudulently obtained patents. Its main limitation, apparent from its title, is that it can only be raised by an accused infringer in a suit for infringement. The patentee has no need to expose himself to the danger of losing his monopoly where no infringement or arguable infringement is taking place. Fortunately, this limitation is less likely to be a significant bar in competitive fields where the inequitable conduct defense is most useful in ensuring that the public receives the benefit of its bargain.

Recall that under the contract theory rationale for the patent system, the inequitable conduct defense is a means for preventing a fraud on the public.³⁰ The more likely it is that the public has already been exposed to the information contained in a patent application, the more vigilant the system must be to avoid conferring duplicative benefits. Fields that are crowded with patents make obtaining a new patent in the field difficult because of an abundance of prior art.³¹ Applicants for patents are more likely in such situations to engage in inequitable conduct out of their desire for a patent.³² But the crowded

29. In this respect, the inequitable conduct “shield” not only deflects the plaintiff’s attack but causes it to backfire.

30. Anderson, *supra* note 10.

31. If an invention has already been patented by a prior inventor, it is not patentable by another, later inventor. 35 U.S.C. §§ 102(a), 102(g) (2000). In addition, if the invention is only a meager (or “obvious”) improvement over what is already in the public domain through patenting, publication, or other public use (the prior art), the inventor is not entitled to a patent. *Id.* § 103.

32. One commentator noted that for new ventures in the pharmaceutical and medical device industry,

[Y]ears of research and development, millions of dollars in costs, massive venture capital funding, and extensive FDA related costs have been expended to produce the one product around which the company will be entirely built. For this company, all that work and money must result in a patent, otherwise more mature companies will drive the first company out. This is very real for a “one hit wonder” genetic engineering company that has only one blockbuster drug and the entire market capitalization is based on that drug. Therefore, for this company, the *sin qua non* of its very existence is obtaining adequate patent protection. The desire to obtain the patent becomes obviously paramount.

Shashank Upadhye, *Liar Liar Pants on Fire: Towards a Narrow Construction for Inequitable Conduct as Applied to the Prosecution of Medical Device and Drug Patent Applications*, 72 U. MO. KAN. CITY L. REV. 669, 676 (2004).

nature of the field also makes it more likely that a pertinent new patent will be challenged, either during an infringement action brought by the patentee³³ or by a request for a declaratory judgment by another party (most likely a competitor).³⁴ The competition, in other words, will do what is necessary to avoid ceding the field. Though pursuing its own interests, it acts as a private patent examiner that ensures the public receives “all which it has contracted to receive.”³⁵

Another weakness of the defense is that it is difficult to prove. Soon after being established, the Federal Circuit adopted the standard of proof for fraud announced by its predecessor, the Court of Customs and Patent Appeals (C.C.P.A.).³⁶ The C.C.P.A. in *Norton v. Curtiss* held that “proof of fraud must be clear and convincing . . . [and] the one asserting misconduct carries a heavy burden”³⁷

The private nature of the inequitable conduct defense, most useful in a competitive field, as well as its “heavy burden,”³⁸ are important to keep in mind when considering the standard that should apply to any subset of the defense’s elements.

3. The Patent and Trademark Office’s Administrative Efforts at Balancing Risks

Inequitable conduct is a breach of the duty of candor toward the PTO.³⁹ Patent examiners, seeking to guard against improvidently granted patents, have a difficult mandate. The PTO has the burden of proving by a preponderance of the evidence that a claimed invention is not entitled to a patent.⁴⁰ A decreasing “number of examiners per thousand patents” are

33. “A patentee shall have remedy by civil action for infringement of his patent.” 35 U.S.C. § 281 (2000).

34. 28 U.S.C. § 2201(a) (2000) (“[A]ny court of the United States . . . may declare the rights and other legal relations of any interested party seeking [a declaratory judgment].”).

35. *Grant v. Raymond*, 31 U.S. (6 Pet.) 218, 242 (1832).

36. *Goldman*, *supra* note 9, at 70; *Kan. Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1151 (Fed. Cir. 1983).

37. *Norton v. Curtiss*, 433 F.2d 779, 797 (C.C.P.A. 1970).

38. *Id.*

39. *See Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1457 (Fed. Cir. 1984).

40. Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 *Berkeley Tech. L.J.* 147, 156 (2005).

evaluating an increasing number of patent applications.⁴¹ The PTO does not have full research facilities of its own to conduct exhaustive searches of the prior art.⁴² In addition, the United States does not subject patent applicants to a formal opposition proceeding where competitors may produce relevant prior art in order to prevent a patent from issuing.⁴³ Rather, the PTO imposes a duty of disclosure upon the applicant⁴⁴ to ensure that known prior art is set before the examiner so that he may make an informed decision as to patentability.⁴⁵

The PTO sets forth the duty to disclose in 37 C.F.R. § 1.56 (“Rule 56”), which explains the rationale of the rule and describes its intended scope.⁴⁶ Rule 56 imposes a duty upon all individuals associated with a claim to disclose information known to them that is material to patentability.⁴⁷ The duty “exists with respect to each pending claim until the claim is

41. *Id.*

42. *Beckman Instruments, Inc. v. Chemtronics, Inc.* 439 F.2d 1369, 1378 (5th Cir. 1970).

43. *Nolan-Stevaux*, *supra* note 40, at 156.

44. 37 C.F.R. § 1.56(a,c) (2000).

Individuals associated with the filing or prosecution of a patent application within the meaning of this section [and thus subject to the duty to disclose information related to patentability] are: (1) Each inventor named in the application; (2) Each attorney or agent who prepares or prosecutes the application; and (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

Id.

45. *Nolan-Stevaux*, *supra* note 40 at 156. *See Beckman Instruments*, 439 F.2d at 1379 (“[O]ur patent system could not function successfully if applicants were allowed to approach the Patent Office as an arm’s length adversary.”).

46. “The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability.” 37 C.F.R. § 1.56(a).

47. *Id.* Once an applicant hires an attorney to prosecute a patent, the scope of the duty greatly expands “because the knowledge and actions of applicant’s attorney are chargeable to applicant.” *FMC Corp. v. Manitowoc Co.* 835 F.2d 1411, 1415 n.8 (Fed. Cir. 1987). An applicant ignorant of material information or its importance can nevertheless have his patent held unenforceable for inequitable conduct. *See David Hricik, The Risks and Responsibilities of Attorneys and Firms Prosecuting Patents for Different Clients in Related Technologies*, 8 TEX. INTELL. PROP. L.J. 331, 333 (2000). This could occur as a result of knowledge that his attorney happens to have as a result of prosecuting a prior unrelated patent for a different client. *Id.*

cancelled or withdrawn from consideration, or the application becomes abandoned.”⁴⁸ There is no duty to disclose information that is not material to the patentability of any existing claim.⁴⁹ Neither is there a duty to conduct a search for prior art that may invalidate the applicant’s claim.⁵⁰ Disclosures are accomplished by filing information disclosure statements with the PTO.⁵¹ All disclosures must include “[a] list of all patents, publications, applications, or other information submitted for consideration by the Office.”⁵²

In 1992, the PTO narrowed its definition of materiality in Rule 56. The modified rule reiterated the PTO’s admonishment that:

[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.⁵³

However, where the former rule defined materiality as the extent to which “a reasonable examiner would consider [the information] important in deciding whether to allow the application to issue as a patent,”⁵⁴ the 1992 amendment opted for more precision.

Under the amended Rule 56(b), the subjective standard of the reasonable patent examiner is subjugated to an objective standard.⁵⁵ Rule 56(b)(1) identifies as material information

48. 37 C.F.R. § 1.56(a–c).

49. *Id.*

50. *Nordberg Inc. v. Telsmith, Inc.*, 82 F.3d 394, 397 (Fed. Cir. 1996). The relevant standard is “should have known.” *Id.* Therefore, “applicants may not cultivate ignorance by ‘disregard[ing] numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that information or prior art.’” Jeanne C. Curtis et al., *Litigation Issues Relevant to Patent Prosecution—The Defense of Inequitable Conduct*, in *FUNDAMENTALS OF PATENT PROSECUTION 2007* 227, 233 (2007) (quoting *FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 526 (1987)).

51. *See* 37 C.F.R. § 1.97 (2000).

52. *Id.* § 1.98.

53. *Id.* § 1.56(a).

54. 37 C.F.R. § 1.56(a) (1991). Under the former standard, the information must nevertheless be minimally relevant to the patentability of a claim. *See American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 n.2 (Fed. Cir. 1984) (“We also emphasize that the pertinent inquiry is not whether a reasonable examiner would want to be aware of a particular thing, but whether, after he was aware of it, he would ‘consider it important’ in deciding whether to reject one or more claims.”).

55. The new rule was not, however, “intended to constitute a significant substantive break with the previous standard.” *Hoffmann-La Roche, Inc. v.*

that contributes to establishing “a prima facie case of unpatentability of a claim.”⁵⁶ Rule 56(b)(2) provides an alternative definition ascribing materiality to information contrary to an argument made by the applicant in regard to a dispute with the PTO over the patentability of a claim.⁵⁷ Both prongs of the standard disclaim information that is cumulative to information already of record in the application.⁵⁸ That is, an applicant is not required to submit information similar to prior art or other facts relevant to patentability when such information is already before the examiner.

4. The Federal Circuit Ultimately Decides the Scope of the Duty to Disclose Information Material to Patentability

The Federal Circuit has exclusive jurisdiction over appeals from a judgment in a civil action for patent infringement.⁵⁹ Because inequitable conduct claims are limited to patent infringement actions, that court also has exclusive jurisdiction over such claims concerning the prosecution of a patent.⁶⁰

The rules promulgated by the PTO are not binding on the Federal Circuit,⁶¹ but that court has generally tracked the relatively broad scope of materiality set forth in Rule 56. The court “has continually rejected a ‘but for’ standard for materiality”⁶² and given deference to the version of Rule 56

Promega Corp., 323 F.3d 1354, 1368 n.2 (Fed. Cir. 2003) (citing Duty of Disclosure, 57 Fed. Reg. 2021, 2023 (Jan. 17, 1992) (to be codified at 37 C.F.R. pts. 1 and 10) (explaining that the amendment to section 1.56 was intended to clarify the lack of certainty in the previous materiality standard)).

56. Information is material where “[i]t establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim . . .” 37 C.F.R. § 1.56(b)(1) (2000).

57. Information is material if “[i]t refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.” § 1.56(b)(2).

58. § 1.56(b).

59. 28 U.S.C. § 1292(c)(2) (2000).

60. See Cedric A. D’Hue, *Disclosing an Improper Verb Tense: Are Scientists Knaves and Patent Attorneys Jackals Regarding the Effects of Inequitable Conduct?*, 14 U. BALT. INTELL. PROP. L.J. 121, 124 (2006); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1574 (Fed. Cir. 1996).

61. See *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1364 (Fed. Cir. 2003) (“[W]e have not decided whether the standard for materiality in inequitable conduct cases is governed by equitable principles or by the Patent Office’s rules.”).

62. D’Hue, *supra* note 60, at 125. A “but for” standard in this context

being applied by the PTO at the time the patent application at issue is being processed.⁶³ Applications processed after 1992 are therefore evaluated according to the more definite standard of materiality found in the amended Rule 56.⁶⁴

The Federal Circuit has held certain information to be *per se* material and thus subject to the disclosure requirement. These include, *inter alia*:

- (1) prior art references not known to the examiner; (2) conduct relevant to statutory bars; (3) documents required by the PTO, submitted by the applicant, including data, date of invention affidavit, and enablement affidavit; (4) references made immaterial by amendments or deletion of claims; and (5) foreign patent office search reports on a companion application⁶⁵

It is not necessary that information be directly associated with a particular claim in order for it to be material to that claim's patentability. For example, the Manual of Patent Examiner Procedure states that "if a particular inventor has different applications pending in which similar subject matter but patently indistinct claims are present that fact must be disclosed to the examiner of each of the involved applications."⁶⁶ The Federal Circuit stated this duty through

would mean that only information that actually affected patentability, most likely the existence of prior art, would be material. *See Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1420–21 (Fed. Cir. 1989). In *Merck*, the plaintiff essentially argued for a "but for" test when it asserted that withheld prior art that did not render a patented invention obvious could not be material. *Id.* at 1420. The Federal Circuit rejected that contention and determined that because a reasonable examiner would consider the withheld prior art important in deciding whether to issue the patent, it was material. *Id.* at 1421. In other words, the information need only be within the reasonable examiner's realm of consideration. *Id.*

63. *See Purdue Pharma L.P. v. Endo Pharm. Inc.*, 410 F.3d 690, 696 (Fed. Cir. 2005); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1353 (Fed. Cir. 2005); *see also Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1363 (Fed. Cir. 1984) ("The PTO 'standard' is an appropriate starting point for any discussion of materiality . . . because that materiality boundary most closely aligns with how one ought to conduct business with the PTO.").

64. This rule was in doubt as late as 2003, when the Federal Circuit in *Dayco Products* declined to decide between the old and amended Rule 56 where, in the facts before it, the infringer had met the threshold of materiality under either standard. *Dayco Prods.*, 329 F.3d at 1364.

65. *Anderson, supra* note 10, at 856.

66. 2 U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE § 2001.06(b) (8th ed. 2007). The Manual of Patent Examining Procedure does not have the force of law but does reflect the proper orientation of a patent attorney toward the PTO. It strongly encourages disclosure and warns against assumptions regarding the examiner:

the lens of materiality when it earlier held in *Akron Polymer* that “[a co-pending] application was highly material to the prosecution of the [patent-in-suit], because it could have conceivably served as the basis of a double patenting rejection.”⁶⁷ In 2003 that court further expanded the obligations of an applicant with regard to co-pending applications in *Dayco Products*.⁶⁸

D. A REJECTION OF SUBSTANTIALLY SIMILAR CLAIMS IS MATERIAL TO PATENTABILITY

1. *Dayco Products*—A Rejection of Substantially Similar Claims is Material to Patentability

In *Dayco Products*, the Federal Circuit favorably reviewed a lower court’s analysis of the materiality element of an inequitable conduct defense.⁶⁹ *Dayco*, the plaintiff in an infringement action, had filed two families of related patent applications with the patent office.⁷⁰ The ‘196 applications and the applications for the patents-in-suit were assigned to

Do not rely on the examiner of a particular application to be aware of other applications belonging to the same applicant or assignee. It is desirable to call such applications to the attention of the examiner even if there is only a question that they might be “material to patentability” of the application the examiner is considering. It is desirable to be particularly careful that prior art or other information in one application is cited to the examiner in other applications to which it would be material. Do not assume that an examiner will necessarily remember, when examining a particular application, other applications which the examiner is examining, or has examined.

Id. § 2004(9) (internal citations omitted). The attitude reflected in the Manual brings to mind the real estate admonition: “when in doubt, disclose, disclose, disclose!” See Peter Zura, *CAFC Affirms Finding of Inequitable Conduct for Failing to Disclose Information*, PETER ZURA’S 271 PATENT BLOG, May 22, 2007, <http://271patent.blogspot.com/2007/05/cafc-affirms-finding-of-inequitable.html> (discussing *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir. 2007)); see also *LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) (“Close cases should be resolved by disclosure, not unilaterally by the applicant.”).

67. *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382 (Fed. Cir. 1998). Both applications were prosecuted before different examiners in the PTO by the same law firm. *Id.* at 1381. The district court found that “the responsible lawyers in [the firm] were well aware of the existence and details of both applications.” *Id.*

68. See *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003).

69. *Id.* at 1367–68.

70. *Id.* at 1361.

separate patent examiners.⁷¹ “The claims submitted in the ‘196 family of applications were in some respects substantially identical to the claims in the patents-in-suit,”⁷² and “[t]he applications in the ‘196 family included specific references to members of the family of applications that issued as the patents-in-suit.”⁷³ Dayco did not inform the examiner of the patents-in-suit of the pendency of the ‘196 applications before the other examiner.⁷⁴ On three separate occasions, the examiner assigned to the ‘196 applications rejected them on obvious grounds,⁷⁵ but Dayco’s prosecuting attorney never notified the examiner of the patents-in-suit of these rejections nor even of the patent on which the rejection was based.⁷⁶ The district court relied on this withholding of relevant information as one of three reasons for granting summary judgment to the defendant, rendering the patents-in-suit unenforceable.⁷⁷

Dayco appealed the judgment, arguing that the existence of the ‘196 application was irrelevant because, although it could have served as the basis of a double patenting rejection of the patents-in-suit, the patents-in-suit were subject to a terminal disclaimer. The disclaimer limited the term of the patents-in-suit to a period “much shorter than that of any patent that conceivably could have issued from the [‘196] application.”⁷⁸ In other words, Dayco asserted that the ‘196 application did not affect the patent rights that Dayco eventually received for the patents-in-suit and that this was an appropriate test for inequitable conduct.⁷⁹ The Federal Circuit did not reject that argument outright, opting instead to rely on the fact that non-disclosure of the ‘196 application permitted Dayco to receive what was in effect a double patent that was not subject to a common ownership limitation with respect to the patents-in-suit.⁸⁰ This limitation is an additional requirement for overcoming a double patenting rejection by using a terminal disclaimer.⁸¹ Consequently, Dayco’s non-disclosure of the

71. *Id.*

72. *Id.*

73. *Id.*

74. *See id.*

75. *Id.*

76. *Id.* at 1365.

77. *Id.* at 1367.

78. *Id.* at 1365 (quoting Brief of Appellant).

79. *See id.*

80. *Id.* at 1365–66.

81. *See* 37 C.F.R. § 1.321(e)(3) (2005).

existence of the '196 application to the examiner did in fact affect the rights of the patents-in-suit and were material.⁸²

Having found that the '196 application was relevant, the Federal Circuit turned to the district court's determination that the existence of an outstanding rejection of substantially similar claims in that application was material. The court affirmed this ground for unenforceability, holding that where an examiner has issued a contrary decision after reviewing a claim substantially similar to claims at issue in the patents-in-suit, that "information meets the threshold level of materiality under new Rule 56, in that '[i]t refutes, or is inconsistent with, a position the applicant takes in . . . [a]sserting an argument of patentability.'"⁸³ The court also held that a reasonable examiner would be substantially likely to consider such information "important in deciding whether to allow an application to issue as a patent"; thus, it also met the standard for materiality under the former Rule 56.⁸⁴

In addition to the references to Rule 56, the court stated that "[w]ithout such a disclosure requirement 'applicants [may] surreptitiously file repeated or multiple applications in an attempt to find a "friendly" Examiner.'"⁸⁵ "Friendly" in this context can refer to an examiner that is unsophisticated or inexperienced, for patent applications and disclosures can be complex and subject to different interpretations by examiners with different technical backgrounds and experience.⁸⁶ Two heads are better than one, the court reasoned; therefore knowledge of a potentially different interpretation (that rejected a substantially similar claim) is information that an examiner would consider important. Because the district court did not engage in an analysis of intent to deceive the PTO with regard to the rejection, however, the Federal Circuit remanded for further proceedings on that issue.⁸⁷

2. *McKesson*—"Substantially Similar" is not a Strict Standard

Four years after *Dayco Products*, the Federal Circuit again

82. *Dayco Prods.*, 329 F.3d at 1365-66.

83. *Id.* at 1368 (quoting 37 C.F.R. § 1.56(b)(2) (2002)).

84. *Id.* at 1368.

85. *Id.* at 1367 (quoting ABA SECTION OF INTELLECTUAL PROP. LAW, ANNUAL REPORT 1993-1994 (1994)).

86. *Id.* at 1368.

87. *Id.*

confronted the issue of a non-disclosure of the rejection of substantially similar claims in *McKesson*.⁸⁸ The plaintiff appealed the district court's finding that the patent-in-suit was unenforceable due to inequitable conduct by the prosecuting attorney, Schumann.⁸⁹

The facts of the case that concern the rejection of claims by another examiner are similar to those of *Dayco Products*. Schumann simultaneously prosecuted the application that led to the patent-in-suit and another, similar application (the '149 application).⁹⁰ The invention set forth in the '149 application was "so similar" to the invention of the patent-in-suit "that Schumann initially disclosed the same body of art with both applications."⁹¹ However, the applications were before different examiners.⁹² Twice, the examiner of the '149 application rejected the claims therein as anticipated by the prior art, but in neither case did Schumann disclose these rejections to the examiner of what became the patent-in-suit.⁹³

The district court relied heavily on *Dayco Products* in its analysis, restating its holding that "rejections are material if the rejected claims were 'substantially similar' to the claims pending . . . [within the application for the patent-in-suit]."⁹⁴ Claims 15 and 16 within the '149 application "substantially overlapped with the limitations" of a claim within the patent-in-suit, and when those claims were rejected, that standard was satisfied.⁹⁵ In the second rejection, there again were "substantially similar" claims that were rejected and those that were permitted in the patents-in-suit. In describing the similarity between the claims, the court noted that there was a "striking resemblance" in elements of the claims.⁹⁶ For instance, the claims in both applications referenced a portable handheld terminal, a "keyboard means," a "display means," elements related to bar code readers, electromagnetic wave

88. See *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir. 2007).

89. *Id.* at 901, 912.

90. *Id.* at 904.

91. *Id.*

92. *Id.* at 906.

93. *Id.* at 905–06.

94. *Id.* at 910–11 (quoting slip opinion quoting *Dayco Prod., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003)).

95. *Id.* at 911 (quoting slip opinion).

96. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 2006 WL 1652518, at *6 (E.D. Cal. June 13, 2006).

transceivers, and some form of wireless communication.⁹⁷ In addition, there were structural similarities. They all described a three-node system involving a portable handheld terminal communicating wirelessly with base stations that are linked to a central computer, and they shared many important limitations of the communication protocol.⁹⁸ In its materiality analysis the district court noted that *Dayco Products* found that claims were “substantially similar” when “claims submitted in the ‘196 family of applications were in *some respects* substantially identical”⁹⁹ It then applied this sub-test to find the rejected ‘009 claims material to the prosecution of the patent-in-suit.¹⁰⁰

In its appeal, the petitioner argued that the “in some respects identical test” was a less rigorous comparison than was required by the *Dayco Products* holding; thus it failed to respect the differences between the claims.¹⁰¹ A divided Federal Circuit panel responded that materiality can be proven in a number of ways,¹⁰² and that *Dayco Products* is simply a particular example of what suffices.¹⁰³ The court then diluted the *Dayco Products* holding by stating although a showing of substantial similarity between claims is sufficient, “rejected claims in a co-pending application also need not be

97. *Id.*

98. *Id.*

99. *Id.* at *17 (quoting *Dayco Prod., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1361 (Fed. Cir. 2003)) (emphasis in original).

100. *Id.* (“[T]he rejected ‘009 claims were ‘in some respects’ identical to the ‘716’s Claim 1, directly implicating the materiality of the ‘009 rejections to the ‘716 prosecution.”).

101. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 919 (Fed. Cir. 2007). The *McKesson* court identified four differences between the patent-in-suit and the ‘149 application that were ignored by the district court. *Id.* at 920. The court noted that these limitations were peripheral. *Id.* at 921. Even if the district court had considered them (which the Federal Circuit did not concede), the similarities regarding the overall structure of the systems disclosed in the applications are far more important to the analysis. *See id.* at 920. It was this common structure that Schumann (the patent prosecutor) relied upon when asserting his patentability argument. *Id.* Therefore, a rejection of that assertion vis-à-vis the ‘149 application “would have been considered important by any reasonable examiner” reviewing the application of the patent-in-suit. *Id.* Presumably, the court accepted the old Rule 56 “reasonable examiner” standard in *McKesson* because the allegedly inequitable conduct occurred in 1987, prior to the 1992 amendment to the rule.

102. *Id.* at 919 (citing *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006)).

103. *See id.*

substantially similar in order to be material.”¹⁰⁴ Thus, the terminology of the subtest that is used, whether “in some respects identical,” “substantially similar,” or “substantial similarity ‘in content and scope,’” is irrelevant.¹⁰⁵ The important and underlying question is whether the evidence “clearly and convincingly proves materiality in one of the accepted ways.”¹⁰⁶ The court found that the proffered differences between the claims in the ‘149 application and the patent-in-suit were insufficient to deprive the examiner’s rejections of materiality.¹⁰⁷

The Federal Circuit’s analysis in *McKesson* broadened its holding in *Dayco Products* by turning that holding back around on itself. In *Dayco Products*, the court held that claims needed to be substantially similar before a rejection of one would be material information with respect to the prosecution of another. This was so because a reasonable examiner would find such information helpful. In *McKesson* however, the court dismissed the requirement of substantial similarity, referring to it as sufficient, but not necessary. Instead, it inflated the relatively narrow standard of materiality (vis-à-vis claim rejections) established by *Dayco Products* to encompass whatever “would have been considered important by any reasonable examiner.”¹⁰⁸ The extension has multiplied the anxieties of patent prosecutors.¹⁰⁹

104. *Id.*

105. *Id.* at 920.

106. *Id.* Courts have applied many standards of materiality since the Supreme Court created the inequitable conduct defense, though not all have been accepted by the Federal Circuit. They include (1) the objective “but for” test, where the patent should not have issued due to the information; (2) the subjective “but for” test, where the examiner would not have approved the application without the misrepresentation; (3) the “but it may have” test, where the information may have influenced the examiner; (4) the “reasonable examiner” test (old Rule 56); and the (5) new Rule 56 test. See *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315–16 (Fed. Cir. 2006); 37 C.F.R. § 1.56(a). For patent applicants, the result is that they must consider information under all five standards and disclose if it meets the materiality level for any of them; it is impossible to foresee *a priori* which test a court may decide to apply.

107. *McKesson*, 487 F.3d at 921.

108. *Id.* at 920.

109. See Kevin E. Noonan, *Federal Circuit Increases Risk for Biotechnology Patent Prosecutors*, PATENT DOCS, May 23, 2007, http://patentdocs.typepad.com/patent_docs/2007/05/the_federal_cir.html.

II. ANALYSIS

A. THE BROAD RULE OF MCKESSON IMPOSES ADDITIONAL BURDENS ON PATENT PROSECUTORS WARY OF FUTURE LITIGATION

With *McKesson*, the Federal Circuit may have unwittingly contributed to the plague of charges of inequitable conduct while simultaneously increasing the difficulty in procuring complex patents.

1. The *McKesson* holding provides a vague standard that increases the uncertainty of patent validity.

An open-ended test, variously described in *McKesson* as “in some respects identical,” “substantially similar,” or “substantial similarity in content and scope,” provides opportunity for infringement defendants to assert the inequitable conduct defense through creative wordsmithing. Such defendants can point to negligible similarities between two previously co-pending applications and claim that these similarities make the applications “in some respects identical.” In like manner, broad similarity of subject matter between two previously co-pending applications provides fertile ground for arguments regarding their “substantial similarity in content and scope.” For complex patents, such as those found in the biotechnology arena, sweeping similarity arguments will be difficult for opponents to rebut and for courts to evaluate.¹¹⁰ These examples demonstrate that *McKesson* considerably slackened the constraints on potential arguments that may be raised by infringement defendants whenever such defendants have the fortuity of co-pending applications by the plaintiff during the prosecution of its patent-in-suit. This effect contravenes the PTO’s and the Federal Circuit’s goal of reducing the frequency of inequitable conduct charges and increases the burden on the federal courts.¹¹¹ Moreover, the unpredictability that results

110. This concern is reflected in a dissent by Judge Newman from a case in which the Federal Circuit sustained a finding of inequitable conduct. She feared that “[t]he uncertainties of the processes of scientific research, the vagaries of the inductive method, the complexities of patent procedures, and the twists of hindsight, all provided grist for this pernicious mill [of inequitable conduct accusations].” *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1372 (Fed. Cir. 2003) (Newman, J., dissenting).

111. See *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed.

from the vague and open-ended *McKesson* rule will likely attenuate business investment in innovation, with concomitant harms to actual invention.¹¹²

2. The vague standard of the *McKesson* holding increases the cost of procuring complex patents.

To avoid the possible consequences of a *McKesson*-based challenge to the enforceability of a patent, patent prosecutors now face a heightened burden in researching the course of prosecution for co-pending applications that may have similarities that would meet the open-ended *McKesson* test. In *Dayco Products*, the Federal Circuit established that applicants must research office actions directed toward related applications to determine whether the examiner had rejected “substantially similar” claims.¹¹³ *McKesson* affirmed that principle, and expanded the duty by expanding the meaning of “substantially similar” to include the rejection of any claim that “clearly and convincingly proves materiality in one of the accepted ways.”¹¹⁴ Because this limitation is commensurate with the ability of an infringement defendant to establish similarities between two applications, the applicant must bring creativity to the research process in order to anticipate

Cir. 1988); Duty of Disclosure, 57 Fed. Reg. 2021, 2023 (“The [amended Rule 56] as promulgated will provide greater clarity and hopefully minimize the burden of litigation on the question of inequitable conduct before the Office . . .”). Judge Newman expressed similar concern in her brief *McKesson* dissent. Focusing on what she viewed as the failure of the defendant to demonstrate clear and convincing evidence of deceptive intent, Judge Newman wrote, “[t]o avoid the inequity resulting from litigation-driven distortion of the complex procedures of patent prosecution, [clear and convincing evidence was required]. This court returns to the ‘plague’ of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here succeeded despite consistently contrary precedent.” *McKesson*, 487 F.3d at 926–27.

112. See Paul M. Janicke, *On the Causes of Unpredictability of Federal Circuit Decisions in Patent Cases*, 3 NW. J. TECH. & INTELL. PROP. 93, 93 (2005). Professor Janicke mentions three benefits of legal predictability in the patent arena. First, companies face less risk in their business decisions relating to patents. *Id.* A second reason, strongly related to the first, is that “[l]awyers are better enabled to advise clients on the impact of a particular course of action.” *Id.* Finally, on a societal level, “we feel a certain sense of added stability if we have a statutory legal system . . . [where] we can tell which side is ‘right under the law.’” *Id.*

113. See David Hricik, *Where the Bodies Are: Current Exemplars of Inequitable Conduct and How to Avoid Them*, 12 TEX. INTELL. PROP. L.J. 287, 314 (2004).

114. *McKesson*, 487 F.3d at 920.

arguments that may be propounded in future litigation. Such creative research is time-consuming and expensive, particularly for small to mid-size firms that may not have the resources to create and maintain a database containing readily searchable details of a particular patent's prosecution history. To be sure, the establishment of the Patent Application Information Retrieval ("PAIR") system by the PTO can reduce this burden to some degree.¹¹⁵ PAIR provides a means for obtaining patent application status, including real-time status information for all action taken by the PTO for an application that is in the process of examination.¹¹⁶ Nevertheless, the task of comparing applications to one another under the broad rubric of "substantial similarity" still falls to the applicant.

The *McKesson* rule should not affect the majority of most patent practitioners' applications. Its effects will be felt disproportionately by those practicing in the biotechnology field and fields of similar high complexity. This is a result of the relatively larger number of divisional and continuation applications filed in support of biotechnology inventions as opposed to those filed in other technical fields.¹¹⁷ Divisional and continuation applications result in patent prosecutors having multiple applications simultaneously pending with the PTO.¹¹⁸ This situation tends to increase the probability of having a substantially similar claim in a co-pending application rejected, thus triggering the duty to disclose under the *Dayco Products* and *McKesson* standards.

However, the fact that the consequences of *McKesson* will be felt primarily by those prosecuting complex patents over a relatively long period of time is not an argument in its favor. Rather, it is an additional cost born by those already seeking

115. See Noonan, *supra* note 109.

116. U.S. Patent & Trademark Office, FAQ—Patent Application Information Retrieval (PAIR), http://www.uspto.gov/ebc/pair/pair_faq.html (last visited Oct. 17, 2008).

117. See Noonan, *supra* note 109.

118. A "continuation application" is a patent application filed by an applicant who wishes to pursue additional claims to an invention disclosed, but not claimed, in an earlier application that is still pending before the PTO and has not been abandoned. See 35 U.S.C. § 120 (2000). A "divisional application" may be filed where an original application contains two or more independent and distinct inventions, prompting the PTO to require that the applicant restrict his application to one of the inventions. *Id.* § 121. Any remaining inventions may be claimed in other applications that will share the filing date of the original invention. *Id.*

the most expensive and thus typically among the most economically significant patents.¹¹⁹ Patent prosecution costs are a function of, *inter alia*, the number of claims, the complexity of the application's subject matter, and the time to ultimate disposition of the application.¹²⁰ Highly complex patents involving continuation and divisional applications are thus among the most expensive to procure. The *McKesson* rule will increase these expenses by requiring patent prosecutors to investigate and bring to the attention of the examiner the course of prosecution of co-pending applications, provided that PTO activity on those applications might be material to the patent under examination. These added transaction costs resulting from *McKesson* are funds that could be more productively directed toward research and development or investment returns.¹²¹

B. SUBSTANTIAL SIMILARITY, PRIOR ART, AND A PROPOSAL FOR AN IMPROVED SUBSTANTIAL SIMILARITY FRAMEWORK

1. There are difficulties inherent in determining substantial similarity.

Determining substantial similarity is a challenge for courts in a number of contexts.¹²² Within the patent field alone, issues regarding similarity are found in such topics as the doctrine of equivalents,¹²³ double patenting rejections,¹²⁴ and obviousness

119. See generally John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 31 (2007). Economically trivial patents are not worth the cost of procuring them, because they provide little, if any, return on the investment in prosecution. See *id.*

120. Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 639 n.44 (2002).

121. See Donald S. Chisum, *supra* note 22, at 317–18. Professor Chisum writes that the severe sanction for violating the duty of candor requirements, such as that found in *McKesson*, creates substantial incentives for patent prosecutors to tread carefully. *Id.* at 317. He notes that this incentive is not cost free, however, because the excessive assertion of the sanction “retard[s] the overall policies supporting the patent system, which include providing incentives for research and development and the disclosure of new technology.” *Id.* at 317–18.

122. See Donald F. McGahn II, *Copyright Infringement of Protected Computer Software: An Analytical Method to Determine Substantial Similarity*, 21 RUTGERS COMPUTER & TECH. L.J. 88, 90–91 (1995) (discussing the variety of tests for substantial similarity fashioned by courts in the context of copyright infringement).

123. Under the doctrine of equivalents, “a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is ‘equivalence’ between the elements of the accused

analysis.¹²⁵ Many of the challenges parallel the criticisms of the *McKesson* rule made in this Note. For instance, a vague standard of similarity leads to uncertainty in the field in which the standard is applied. Unable to determine the proper scope of a patent's (or a copyright's) exclusionary right, competitors may be reluctant to invest in competing, but similar, technologies and arts. On the other hand, an inflexible rule may not sufficiently protect inventors and artists from competitors that are able to produce a competing product that appears substantially identical to the original in form and function.¹²⁶ Thus, the choice of test for substantial similarity in any legal context must be carefully crafted to reflect the competing policies in that context.

2. The prior art is the statutory focus of validity analysis but not of inequitable conduct analysis.

The public should receive "all which it has contracted to receive."¹²⁷ It was for this purpose that the inequitable conduct defense was created.¹²⁸ The invention that the prospective patentee brings to the government must be an advance over what is already known to the public. If this requirement is not met, the person's application for a patent shall be denied according to any of the novelty or statutory bar provisions

product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 17 (1997) (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950)).

124. See 35 U.S.C. § 101 (2000) (granting inventors the right to "a patent"). Courts have fashioned a rule against granting multiple patents for the same or for a substantially similar invention based upon the article "a" within 35 U.S.C. § 101, subject to certain exceptions for common ownership. See *In re Vogel*, 422 F.2d 438, 441-42 (C.C.P.A. 1970).

125. See 35 U.S.C. § 103(a) (2000) ("A patent may not be obtained though the invention is not identically disclosed or described . . . [in the written description] . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious . . .").

126. This consideration is the policy foundation for the judicially created doctrine of equivalents. See *Winans v. Denmead*, 56 U.S. (15 How.) 330, 343 (1854) ("The exclusive right to the thing patented is not secured, if the public are at liberty to make substantial copies of it, varying its form or proportions.").

127. *Grant v. Raymond*, 31 U.S. (6 Pet.) 218, 242 (1832).

128. See *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 818 (1945).

relating to prior art found in the Patent Act.¹²⁹ Because the validity of a patent depends primarily upon overcoming the relevant prior art, a court's evaluation of the conduct of an applicant toward the PTO should likewise focus primarily on the relationship between the claims and any references that will defeat the patentability of those claims. The PTO appears to recognize this through the duty of disclosure that it imposes.

Recall that, as revised in 1992, Rule 56 identifies as material, and thus subject to disclosure, information that contributes to establishing "a prima facie case of unpatentability of a claim."¹³⁰ The prior art provides the majority of the basis for what a reasonable examiner should consider useful in determining the patentability of an invention; it is also the most significant source of information that may establish a prima facie case of unpatentability of a claim. Indeed, it was the criticism of the reasonable examiner standard as excessively vague and unrelated to other, more fundamental concepts in patent law that led the PTO to revise the prior Rule 56 toward a standard of prima facie unpatentability.¹³¹ The revision properly shifts the focus of the duty of disclosure from the examiner toward the prior art.¹³²

In the context of an inequitable conduct analysis considering PTO actions on co-pending applications, such as that presented in *Dayco Products* and *McKesson*, the prior art has not been central to the Federal Circuit's holdings. In the *Dayco Products* and *McKesson* holdings discussed in Part I, the court ignored its recent trend in materiality analysis toward the prior art and away from the actions of the examiner. In both cases, the basis for finding inequitable conduct on the part of the patentee was a rejection of similar claims in a co-pending

129. 35 U.S.C. § 102(a)–(b) (2000). The novelty and statutory bars, as these provisions are known, prevent a person from receiving a patent on inventions that, *inter alia*, are already patented, "described in printed publication," or "known or used by others." *Id.*

130. Information is material where "[i]t establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim . . ." 37 C.F.R. § 1.56(b)(1).

131. Chisum, *supra* note 22, at 296.

132. The revised Rule 56 does not ignore the course of patent prosecution before the examiner, however. Section 1.56(b) retains reference to the Patent Office, although it does so in a manner that likewise shifts the focus to patentability. *See* 37 C.F.R. § 1.56(b)(2); *see also* Goldman, *supra* note 9, at 72 ("[I]t is clear that the courts believed that the underlying purpose of requiring the disclosure of material art was to enable the PTO to assess fairly the merits of an application against the statutory criteria for patentability.").

application by an examiner. The court did not scrutinize the basis for the rejection of the similar claims in the co-pending application. It did not consider whether such rejections were proper in light of the prior art, and consequently, whether the basis of those rejections would have actually served to undermine the patentability of the claims in the patents-in-suit. In other words, the materiality inquiry did not align with the purpose of the inequitable conduct defense, which is to give force to the duty of disclosure, thus increasing the likelihood that a granted patent will in fact be an improvement over the relevant prior art. The Federal Circuit should reconsider its approach in this arena.

3. The Federal Circuit should include a comparison of the prior art shared by the co-pending applications as a means of screening for substantial similarity.

Federal Circuit jurisprudence in the materiality prong of inequitable conduct analysis would be improved were it to focus not on the similarities between the claims shared by co-pending applications, but on a comparison of the prior art referenced among the applications. In this proposed revision of its current framework, a determination of substantial similarity between the claims of co-pending applications will only be found where there is a substantial amount of overlapping prior art that could be referenced against the co-pending applications. The proposed framework will not prevent a finding of substantial similarity where the applications do not share overlapping prior art. However, such a finding should become significantly less likely in the absence of such overlap. Neither will the revision necessitate a finding of substantial similarity where the applications do share overlapping prior art, though such a finding will be significantly more likely where such overlap is present. The degree to which substantial similarity is present will be commensurate with the proportion of prior art in common.

A comparison of the common prior art will have several salutary effects and help to ameliorate many of the criticisms leveled against the Federal Circuit in this area. First, it will reduce the ambiguity of the open-ended *McKesson* holding. Prior art is, unlike claims, discrete and easily comparable. Other benefits, which are related to the decrease in ambiguity, are that while the proposed framework does not fully obviate

the need to analyze claims in all cases, it should clarify and ease the duties of patent prosecutors and make inequitable conduct litigation more predictable.

Patent prosecutors by now know of their responsibility to disclose co-pending applications where the examiner has rejected “substantially similar” claims,¹³³ but the difficulty under the current jurisprudence remains in knowing which applications’ claims will satisfy that test. Where prior art is the focus of the inquiry, a relatively simple check of other applications pending with the PTO will permit an applicant to determine the general scope of his obligations to the PTO in this area. It is likely that large firms prosecuting many complex patents, such as those in the biotechnology arena, already have a database application containing pending applications and their characteristics (including prior art disclosed in the information disclosure statement). In this instance, a query of this database for prior art in common will perform the bulk of the necessary research, greatly reducing the burden on patent prosecutors.

A less ambiguous standard will likely lead to fewer charges of inequitable conduct. This consequence follows for two reasons. First, patent prosecutors will better understand their duty toward the PTO, the burden accompanying that duty will be lower, and thus prosecutors will be more prone to carry it out. Second, a focus on the prior art does not lend itself to interminable arguments regarding the substantial similarity of one claim to another. Instead, comparing the references shared between applications is a simple matter; this practice has the effect of changing the cost-benefit calculus of charging inequitable conduct. For where creative comparisons of claims that are substantially unrelated may nevertheless be accepted under the *McKesson* tests of “substantially similar in content and scope” or “in some respects identical,” they are less likely to withstand scrutiny where a comparison of the relevant prior art does not reveal any substantial degree of overlap. Because they are therefore less likely to succeed, fewer meritless charges of inequitable conduct will be brought as a result of this revision, thus providing some relief from the present “plague.”¹³⁴

133. See Hricik, *supra* note 113, at 311–13.

134. See, e.g., *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d at 1421 (Fed. Cir. 1988) (“[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”).

Finally, a focus on the prior art under this proposed revision more closely aligns inequitable conduct analysis with patent validity analysis. This creates consistency between those two areas of patent law. It also, in accordance with the revised Rule 56 and recent trends in the materiality determination, will move the Federal Circuit toward scrutinizing the relevant prior art as opposed to the actions of the examiner. Recall that a *Dayco Products* and *McKesson*-style analysis directs federal courts to determine whether the claims of the patent-in-suit are substantially similar to already rejected claims of another application at the time the patent-in-suit was being prosecuted. This question is one step removed from the question typically relevant for determining whether a claim is valid: “Is this claim a nonobvious improvement over the prior art?” A necessary ingredient for answering that question is the content of the prior art. By comparing the prior art in common, rather than the claims, the proposed framework is more relevant to the determination of whether the claims of the patent-in-suit are novel and nonobvious. This has the effect of ensuring that the alleged inequitable conduct under scrutiny was actually relevant to the disposition of the claims by the examiner, an important goal if the scope of the inequitable conduct defense is to be constrained.

4. The Proposed Framework for Analysis Leads to Results Consistent with *Dayco Products* and *McKesson*.

Changing the framework for analysis in this area to focus on the prior art would not require the Federal Circuit to abandon its results in *Dayco Products* or *McKesson*. In *Dayco Products*, the applications in the ‘196 family, which contained the rejected claims on which the inequitable conduct holding was based, “included specific references to members of the family of applications that issued as the patents-in-suit.”¹³⁵ The overlapping prior art was the application for the patent-in-suit itself. According to the proposed framework, the overlap is substantial; it includes the whole of another application. This makes it highly likely that a rejection of claims in either the application for the patents-in-suit or the application in the ‘196 family will be highly material to the disposition of the claims in

135. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1361(Fed. Cir. 2003).

the co-pending application and thus subject to the duty of disclosure. The Federal Circuit in *Dayco Products* likewise determined that the rejections were subject to disclosure, though on the basis of the substantial similarity between the claims.¹³⁶

McKesson leads to a similar conclusion. In that case, the attorney prosecuting the patents simultaneously prosecuted the application that led to the patent-in-suit and another, similar application (the '149 application).¹³⁷ The attorney had "disclosed the same body of prior art with both applications."¹³⁸ The Federal Circuit found that the proffered differences between the claims in the '149 application and the patent-in-suit were sufficiently similar to make a rejection of claims in either material to the disposition of claims in the other.¹³⁹ Under the proposed framework, however, a court would not look primarily to the similarity between the claims; it would consider the prior art. Clearly, the identical set of prior art disclosed in both applications at issue in *McKesson* is substantially overlapping. Therefore, this method of analysis results in a similar result—a finding of the materiality of the rejection of claims in a co-pending application.

III. CONCLUSION

The Federal Circuit in *Dayco Products* and *McKesson* established an ambiguous standard for substantial similarity among patent claims in inequitable conduct cases. The court's jurisprudence in this area is justly criticized for increasing the burden on patent prosecutors, contributing to the plague of inequitable conduct charges, and discounting the importance of prior art to the evaluation of a patent's validity. By incorporating a comparison of prior art among co-pending applications and focusing less on the similarity between claims, the court could clarify the duty of disclosure and attenuate many of these criticisms. Comparison of referenced prior art is a simple and discrete process, which would ease the burden on patent prosecutors. In addition, it will make a determination of the materiality of a rejected claim in a co-pending application

136. *Id.* at 1366 ("The basis for establishing unpatentability is the potential double patenting rejection . . .").

137. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 904 (Fed. Cir. 2007).

138. *Id.*

139. *Id.* at 921.

clearer and more predictable, resulting in fewer charges of inequitable conduct. Finally, because prior art is typically central to a determination of patent validity, the proposed revision brings inequitable conduct jurisprudence in closer alignment with patent validity analysis.