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Inequitable Conduct Inequitably Inferred: When Do Patent Applicants' Actions Intend to Deceive?

Chris Henry

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Inequitable Conduct Inequitably Inferred: When Do Patent Applicants' Actions Intend to Deceive?

Chris Henry*

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* Candidate for J.D., Washington and Lee University School of Law, May, 2009; B.E., The Cooper Union, 2006. I would like to thank Professor Norm Balmer for his helpful advice throughout the writing process. I would also like to thank my beautiful wife, Sarah, for her love, patience, and support.

"[A] patent that is found 'unenforceable' due to a finding of inequitable conduct is dead."¹

I. Introduction

Inequitable conduct, once referred to as "fraud on the Patent Office,"² is an affirmative defense to an allegation of patent infringement³ with a nuclear end result—if a court finds inequitable conduct, the patent is void.⁴ To succeed on a claim of inequitable conduct, an accused infringer must prove, by clear and convincing evidence: (1) a patentee failed to disclose material information or submitted false material information, and (2) a patentee intended to deceive the U.S. Patent and Trademark Office (PTO)⁵ during the patent procurement process.⁶ Alleged infringers raise the defense of inequitable conduct in almost every major patent case, hoping to capitalize on patent applicant oversights in scientific experimentation and patent prosecution.⁷

1. Michael D. Kaminski, *Effective Management of U.S. Patent Litigation*, FOLEY & LARDNER LLP, Oct. 26, 2005, at 25, http://www.foley.com/files/tbl_s31Publications/FileUpload137/2941/Effective%20Management%20of%20US%20Patent%20Litigation.pdf (last visited Sept. 14, 2008) (on file with the Washington and Lee Law Review).

2. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) ("The charge [of inequitable conduct] was formerly known as 'fraud on the Patent Office,' a more pejorative term, but the change of name does not make the thing itself smell any sweeter.").

3. See Kevin Mack, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKELEY TECH. L.J. 147, 147–48 (2006) ("[A]n alleged infringer may assert inequitable conduct as an affirmative defense to patent infringement during litigation.").

4. See *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) ("When a court has finally determined that inequitable conduct occurred, . . . the entire patent in question is rendered unenforceable."). Additionally, a finding of inequitable conduct may also adversely affect patents related to the patent rendered unenforceable. See Mack, *supra* note 3, at 153 & n.48 (2006) (citing *Consol. Aluminum Corp. v. Fosco Int'l Ltd.*, 910 F.2d 804, 809–10 (Fed. Cir. 1990), which held several related patents unenforceable because of inequitable conduct).

5. The United States Patent and Trademark Office (PTO) is an agency of the U.S. Department of Commerce discharged with the duty to examine patent applications and determine if such applications meet the legal requirements for patentability. General Information Concerning Patents, <http://www.uspto.gov/web/offices/pac/doc/general/index.html> (last visited Sept. 14, 2008) (on file with the Washington and Lee Law Review).

6. *Kingsdown*, 863 F.2d at 872 ("Inequitable conduct resides in failure to disclose material information, or submission of false material information, with an intent to deceive, and those two elements, materiality and intent, must be proven by clear and convincing evidence.").

7. See *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990) ("A patentee's oversights are easily magnified out of proportion by one accused of infringement.") (citations omitted). "Given the ease with which a relatively routine act of patent prosecution can

Twenty years ago, the Federal Circuit recognized allegations of inequitable conduct in patent infringement suits as "an absolute plague"⁸ and a "scourge."⁹ *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*,¹⁰ decided en banc, attempted to "put a stop to the mischief associated with defenses of inequitable conduct."¹¹ In a section of the *Kingsdown* opinion entitled "Resolution of Conflicting Precedent," the Federal Circuit emphasized that gross negligence alone does not support a finding of intent to deceive and that courts should not infer intent to deceive in the absence of "sufficient culpability."¹²

Fifteen years later, in *Hoffmann-La Roche v. Promega Corp.*,¹³ a Federal Circuit split panel majority upheld two of the lower district court's three findings of inequitable conduct.¹⁴ The decision brought a strong dissent from Judge Newman, who stated that the panel majority wrongly "[found] misrepresentation in correct science, infer[red] malevolence from verb tense, and ground[ed] intent to deceive on personal slurs by a hostile witness."¹⁵ This Note agrees with Judge Newman that *Hoffmann-La Roche* marks the return of

be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required." *Id.*

8. See *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995) ("[U]njustified accusations of inequitable conduct are offensive and unprofessional, . . . have been called a 'plague' on the patent system, . . . may deprive patentees of their earned property rights, and . . . should be condemned.") (citation omitted); *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*." (emphasis added); see also 6 DONALD S. CHISUM, CHISUM ON PATENTS § 19.03[5][b], at 19-331, 19-331 n.7 (2008) [hereinafter CHISUM ON PATENTS] (noting Federal Circuit disapproval of the frequency with which accused infringers raise the inequitable conduct defense and citing additional cases that refer to inequitable conduct allegations as a "plague" to patent litigation).

9. Kaminski, *supra* note 1, at 26.

10. See *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876-77 (Fed. Cir. 1988) (concluding that "'gross negligence' does not of itself justify an inference of intent to deceive" and reversing the lower district court's finding of such an intent); see also *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1195-96 (Fed. Cir. 2006) (Newman, J., dissenting) (discussing how *Kingsdown* attempted to "bring objectivity to charges of inequitable conduct" to emerge from a national environment in which industrial innovation suffered due to unreliable patents).

11. See Kaminski, *supra* note 1, at 26 (discussing the decline in allegations of inequitable conduct after *Kingsdown*).

12. *Kingsdown*, 863 F.2d at 876-77.

13. *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1360 (Fed. Cir. 2003) (upholding the district court's findings as to two of three categories of asserted inequitable conduct).

14. *Id.*

15. *Id.* at 1373 (Newman, J., dissenting).

inequitable conduct jurisprudence to the "misbegotten era" that existed before *Kingsdown*.¹⁶ Furthermore, this Note argues that after *KSR International Co. v. Teleflex Inc.*,¹⁷ in which the U.S. Supreme Court increased patent law standards for obviousness,¹⁸ the Federal Circuit must adopt a heightened standard of objective recklessness for inferring intent to deceive. Such a standard eliminates the "ease of opportunistic challenge to the conduct of experimental science in [the] patent context."¹⁹

In *KSR*, the Supreme Court rejected the rigidity of the Federal Circuit's approach to determining nonobviousness,²⁰ one of the requirements for patentability.²¹ The Supreme Court called for a more flexible approach to obviousness determinations and intimated, contrary to Federal Circuit precedent, that an invention that is "obvious to try" may be rejected as obvious.²² After *KSR*, patent examiners can make obviousness rejections where they previously could not, and, as a result, patent applicants will more frequently need to advance arguments for patentability.²³ Since arguments for

16. See *id.* at 1372 ("Indeed, [in the past] the prevalence of accusations of inequitable conduct in patent cases led judges to suspect that all scientists are knaves and all patent attorneys jackals. Today this court revives that misbegotten era."); see also Kaminski, *supra* note 1, at 26 (noting that after "the famous *Kingsdown*," the defense of inequitable conduct was much less commonly pled, but that "[i]n more recent years, the defense has been making a comeback"). "According to a survey published in 2000, patents are held unenforceable in 27% of the cases in which the [inequitable conduct] defense is decided and that number seems to have increased since 2000." *Id.*

17. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1745 (2007) (finding the Teleflex patent invalid as obvious).

18. See *infra* Part IV (discussing the *KSR* decision).

19. *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1373 (Fed. Cir. 2003) (Newman, J., dissenting).

20. See *KSR Int'l Co.*, 127 S. Ct. at 1739 ("We begin by rejecting the rigid approach of the Court of Appeals.").

21. See generally 35 U.S.C. § 103(a) (2000).

22. See *KSR Int'l Co.*, 127 S. Ct. at 1739, 1742 (prescribing a more "expansive and flexible" inquiry into obviousness and providing that if a solution to a problem in the field of art is "obvious to try" it is unpatentable as obvious).

23. See Harold C. Wegner, *Post-KSR Patent Procurement: Challenges for Biotech, Chemicals and Pharmaceuticals*, C5'S 13TH BI-ANNUAL FORUM ON BIOTECH PATENTING, Sept. 17-18, 2007, at 6 ("Examiners may [now] be able to make out [] *prima facie* case[s] of obviousness where, before *KSR*, this may not have been possible.") (on file with the Washington and Lee Law Review); see also Stephen J. MacKenzie, *Supreme Court's KSR v. Teleflex Decision*, May 29, 2007, <http://www.wcsr.com/default.asp?id=114&bioID=584&objId=241> (last visited Sept. 14, 2008) ("[T]he Supreme Court made it easier . . . to prove obviousness To overcome these rejections, [an] applicant will have to . . . rely on declarations from the inventor or a person of ordinary skill in the art.") (on file with the Washington and Lee Law Review).

patentability are often the point of attack for alleged infringers claiming inequitable conduct, the *KSR* decision makes it imperative for the Federal Circuit to adopt a higher standard for inferences of intent to deceive.

To establish intent to deceive in an inequitable conduct claim, in the absence of direct evidence of a subjective intent to deceive, an accused infringer should have to prove, by clear and convincing evidence, that a patentee acted objectively reckless—that the patentee acted in the face of what the person having ordinary skill in the art (the PHOSITA)²⁴ would recognize as an objectively high likelihood that the patentee's actions constituted either a failure to disclose material information, or a submission of false material information. Such a standard protects patentees from unjustified deprivations of their property rights and secures investor confidence in commercialization efforts.²⁵ Additionally, this standard is both in harmony with developments in patent law's willful infringement jurisprudence and superior to recent commentator and congressional suggestions for patent reform.²⁶

This Note examines the issue of inferring intent to deceive the PTO in inequitable conduct determinations. Part II briefly summarizes the Supreme Court's *KSR* decision and discusses its effects on obviousness determinations. Then, Part III explores the Federal Circuit case of *Hoffmann-La Roche* and the reasoning behind the split panel majority's affirmation of two of the lower court's three findings of inequitable conduct. Having established the background, Part IV draws support for an objective recklessness standard for intent to deceive the PTO from the Federal Circuit's willful infringement jurisprudence and analyzes recent suggestions for patent reform and for addressing patentee concerns post-*KSR*. Part V applies an objective recklessness standard to two inequitable conduct cases cited with *Hoffmann-La Roche* as evidence of an unfortunate Federal Circuit trend toward low standards

24. Patent law often utilizes the objective standard of the "person having ordinary skill in the art," the PHOSITA. See, e.g., MANUAL OF PATENT EXAMINING PROCEDURE § 2141 (8th ed., 2001) [hereinafter MPEP]. "The hypothetical 'person having ordinary skill in the art' to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art." *Id.* (citation omitted). "A person of ordinary skill in the art is . . . presumed to be one who thinks along the lines of conventional wisdom in the art." ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT 177 (7th ed. 2005).

25. The patent system incentivizes, among other things, invention and the investment in, and commercialization of, inventions. See HARMON, *supra* note 24, at 11–13 (discussing the purpose of the patent system). Inventors are less likely to invent and investors are less likely to invest in commercialization if patent protection is void in the face of baseless allegations of inequitable conduct.

26. See *infra* Part IV (discussing the Federal Circuit's willful infringement jurisprudence and suggested patent reforms).

for inferences of intent. Finally, in Part VI, this Note concludes that the Federal Circuit should adopt an objective recklessness standard for inferences of intent to deceive the PTO.

II. Nonobviousness, KSR, and the Aftermath

A patent grants a patentee "the right to exclude others from making, using, offering for sale, or selling [the patentee's] invention."²⁷ With the exceptions of laws of nature, physical phenomena, and abstract ideas, which are unpatentable, "[t]he classes of [patentable] subject matter taken together include practically everything that is made by man and the processes for making the products."²⁸ To be patentable, an invention must be new,²⁹ useful,³⁰ and nonobvious.³¹

The Supreme Court's *KSR* decision raised the bar for patentability by raising the standards for nonobviousness,³² "the most important and most litigated of the conditions of patentability."³³ In *KSR*, Teleflex Incorporated (Teleflex), the exclusive licensee of the patent at issue, sued KSR International Company (KSR) for infringement.³⁴ KSR argued that Teleflex's patent was invalid as obvious.³⁵ The Supreme Court reversed the Federal Circuit's ruling that Teleflex's patent was valid, deciding that the Federal Circuit erred in its rigid application of the "teaching, suggestion, or motivation" test³⁶ (the TSM test).³⁷ The Federal Circuit had focused on the need to make specific findings

27. See generally 35 U.S.C. § 154(a)(1) (2000).

28. General Information Concerning Patents, *supra* note 5.

29. See 35 U.S.C. § 102 (2000) (providing patent law's novelty requirements).

30. See *id.* § 101 (requiring an invention to be "useful"); *id.* § 112 (requiring that a patent applicant disclose "the manner and process of making and using [the invention]") (emphasis added).

31. See *id.* § 103(a) (describing conditions for patentability and nonobvious subject matter).

32. See Wegner, *supra* note 23, at 3 ("KSR represents a huge signal to the patent community that the standards of patentability in the past have been too low and that both the PTO and the courts need to observe higher standards.") (emphasis in original).

33. 2 CHISUM ON PATENTS, *supra* note 8, § 5.06, at 5-735.

34. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007).

35. *Id.*

36. *KSR Int'l Co.*, 127 S. Ct. at 1734 ("Under [the TSM test] a patent claim is only proved obvious if 'some motivation or suggestion to combine the prior art teachings' can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art.") (citations omitted).

37. See *id.* at 1739 ("We begin by rejecting the rigid approach of the Court of Appeals.").

of a teaching, suggestion, or motivation in the prior art³⁸—the information existing in the public domain as of the inventor's date of invention.³⁹ This interpretation, however, can run counter to patent law's nonobviousness requirement, which seeks to grant patents only to "those inventions that in fact serve to advance the state of the useful arts,"⁴⁰ by making it difficult for examiners to reject obvious inventions for which no *specific* findings of a teaching, suggestion, or motivation in the prior art can be found. Thus, the Court stated that rigid application of the TSM test was inconsistent with its analysis enunciated in *Graham v. John Deere Co. of Kansas City*,⁴¹ which sets forth a more "expansive and flexible" inquiry into obviousness.⁴² The Court

38. The Federal Circuit held:

[T]he district court erred as a matter of law by applying an incomplete teaching-suggestion-motivation test to its obviousness determination. The correct standard requires a court to make specific findings showing a teaching, suggestion, or motivation to combine prior art teachings in the particular manner claimed by the patent at issue.

Teleflex, Inc. v. KSR Int'l Co., 119 F. App'x 282, 290 (Fed. Cir. 2005).

39. See *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 254 F. Supp. 2d 527, 564 (E.D. Pa. 2003) (discussing what constitutes prior art), *rev'd on other grounds*, 357 F.3d 1319 (Fed. Cir. 2004). The *National Steel Car* court stated:

Items included as prior art are: (1) inventions that were patented or described in a printed publication from anywhere in the world before the patent applicant's date of invention; (2) inventions used or known by others in the United States before the applicant's date of invention; (3) inventions that were in public use or on sale in the United States more than one year prior to the date of the patent application; (4) inventions described in another United States patent application filed before the applicant's date of invention; (5) inventions granted a patent after a filing of a United States patent application before the applicant's date of invention; (6) subject matter sought to be patented that was not invented by the applicant; and (7) inventions of another that were made in the United States and not abandoned, suppressed, or concealed before the applicant's date of invention.

Id.

40. 2 CHISUM ON PATENTS, *supra* note 8, § 5.01, at 5-10-11. "A patent monopoly may issue only for those literally new solutions that are beyond the grasp of the ordinary artisan who had a full understanding of the pertinent prior art." *Id.* at 11.

41. See *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17-18 (1966), where the Court held:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Id.

42. See *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007) (discussing the

noted that the TSM test actually captures a "helpful insight"—that a patent is not obvious solely because each element in the patent is already known in the prior art—but also that the TSM test is incompatible with precedent when applied as a rigid and mandatory formula.⁴³

Encouraging an influx of common sense into obviousness determinations, the Court recognized that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton"⁴⁴ and explained that obviousness analyses need not seek out a *precise* teaching, suggestion, or motivation in the prior art.⁴⁵ In a further departure from Federal Circuit precedent,⁴⁶ the Court provided that if a solution to a problem in the field of art is *obvious to try*, it is likely the product of ordinary skill and common sense, not of innovation, and therefore unpatentable as obvious.⁴⁷ The Court's invocation and application of an "obvious to try" standard and the Court's mandated, more flexible approach to the TSM test raise the bar for patentability and nonobviousness.⁴⁸

Graham analysis). Additionally, note that patent law's nonobviousness requirement is codified in 35 U.S.C. § 103, which provides:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, 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 at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103 (2000). Pursuant to Section 103 and the *Graham* analysis, in making *prima facie* obviousness determinations, patent examiners must: "(A) Determin[e] the scope and contents of the prior art; (B) Ascertain[] the differences between the prior art and the claims in issue; (C) Resolv[e] the level of ordinary skill in the pertinent art; and (D) Evaluat[e] evidence of secondary considerations." MPEP, *supra* note 24, at § 2141.

43. *KSR Int'l Co.*, 127 S. Ct. at 1741.

44. *Id.* at 1742.

45. *See id.* at 1741 ("[A] court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."). "Common sense teaches . . . that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* at 1742.

46. *See In re Deuel*, 51 F.3d 1552, 1559 (Fed.Cir.1995) ("'Obvious to try' has long been held not to constitute obviousness.").

47. *KSR Int'l Co.*, 127 S. Ct. at 1742.

48. *See Ex parte Kubin*, APPEAL 2007-0819, 2007 WL 2070495, at *5 (B.P.A.I. May 31, 2007) (affirming a patent examiner obvious rejection under the new *KSR* regime). The court noted:

[W]e note the Supreme Court recently cast doubt on the viability of *Deuel* to the extent the Federal Circuit rejected an "obvious to try" test. . . . Under *KSR*, it's now apparent "obvious to try" may be an appropriate test in more situations than we previously contemplated. . . . [Here], [t]he "problem" facing those in the art was to isolate NAIL cDNA, and there were a limited number of methodologies available to do so. The skilled artisan would have had reason to try these methodologies with

Following *KSR*, the PTO issued a notice containing new examination guidelines for patent examiners.⁴⁹ The PTO provided a nonexhaustive list of rationales to support rejections based on obviousness, including the TSM test and "obvious to try," and discussions of each rationale.⁵⁰ The PTO drew directly from *KSR* to explain the "obvious to try" rationale.⁵¹ In discussing the TSM test, the PTO provided that "[t]he courts have made clear that the teaching, suggestion, or motivation test is flexible and an explicit suggestion to combine the prior art is not necessary."⁵² As a result of the *KSR* decision, and with the support of the PTO's revised guidelines, "[e]xaminers may [now] be able to make out [] *prima facie* case[s] of obviousness where, before *KSR*, this may not have been possible."⁵³

In *KSR*, the Court did not address the issue at the heart of this Note. *KSR* did not solve the issue of inferring intent to deceive in inequitable conduct determinations. However, *KSR* is important to this Note because heightened nonobviousness standards will result in more arguments for patentability,⁵⁴ and alleged infringers' claims of inequitable conduct often attack patentability arguments.⁵⁵

III. Inequitable Conduct and Hoffmann-La Roche: An Improperly Inferred Intent to Deceive

Hoffmann-La Roche exemplifies the problems the defense of inequitable conduct can pose,⁵⁶ and it has been cited as the first step in a reversion to a low

the reasonable expectation that at least one would be successful. Thus, isolating NAIL cDNA was "the product not of innovation but of ordinary skill and common sense," leading us to conclude NAIL cDNA is not patentable as it would have been obvious to isolate it.

Id.

49. Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57,526 (Oct. 10, 2007) [hereinafter Examination Guidelines].

50. See generally *id.* at 57,528–34.

51. See *id.* at 57,532 (discussing the "Obvious to Try" rationale).

52. *Id.* at 57,534.

53. Wegner, *supra* note 23, at 6.

54. See *supra* note 23 and accompanying text (discussing the increased need for submissions of Section 132 affidavits to overcome obviousness rejections, which are now easier to make).

55. See Wegner, *supra* note 23, at 6 n.13 ("[F]iling any declaration . . . will open the door to hindsight criticism . . ." (emphasis in original)).

56. Christopher M. Holman, *Biotechnology's Prescription for Patent Reform*, 5 J.

standard for inferring intent to deceive and as a harbinger of both "the return of the inequitable conduct plague" and of an "open season for patent litigation."⁵⁷ In *Hoffmann-La Roche*, Hoffmann-La Roche brought a patent infringement action against Promega, but Promega counterclaimed, asserting inequitable conduct.⁵⁸ The invention at issue was an enzyme used in DNA replication,⁵⁹ and the district court held the patent on that invention to be unenforceable due to inequitable conduct.⁶⁰ The Federal Circuit affirmed the district court finding that Cetus, the small biotechnology start-up company that developed, patented, and licensed the technology to Hoffmann-La Roche, had engaged in inequitable conduct during the prosecution of the patent.⁶¹ As a result, the patent was invalid, and Hoffmann-La Roche lost its license and faced antitrust suits for licensing a patent obtained by fraud.⁶²

The district court in *Hoffmann-La Roche* based its findings of inequitable conduct on representations Cetus made concerning: (1) the invention's molecular weight; (2) an experimental example which was written in the past tense although it had never been performed exactly as written; and (3) comparative differences between Cetus's invention and inventions described by prior art references, specifically, differences in fidelity and template dependence.⁶³ Cetus advanced these representations in a Section 132

MARSHALL REV. INTELL. PROP. L. 318, 345 (2006) (citing *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354 (Fed. Cir. 2003)).

57. See James E. Hanft & Stacey S. Kerns, *The Return of the Inequitable Conduct Plague: When "I Did Not Know" Unexpectedly Becomes "You Should Have Known,"* 19 NO. 2 INTELL. PROP. & TECH. L.J. 1, 1-2, 5 (2007) (discussing *Hoffmann-La Roche* and noting a reversion in the Federal Circuit's inequitable conduct jurisprudence back to a lower standard for inferring intent).

58. *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed. Cir. 2003).

59. See *id.* at 1358-59 (describing the invention at issue); see also Holman, *supra* note 56, at 345 ("The [*Hoffmann-La Roche*] case involved the patent covering Taq polymerase, a thermostable DNA polymerase used in performing Polymerase Chain Reaction ('PCR')."). PCR allows scientists to generate many copies of DNA from a small amount of DNA. *Hoffmann-La Roche*, 323 F.3d at 1357-58. PCR has led to advances in molecular biology and has been useful in pathology and in identifying trace amounts of blood and hair. *Id.* at 1358. The "Taq" polymerase is derived from the *Thermus aquaticus* bacterium and is useful in PCR because Taq is active and stable at high temperatures. *Id.* By using Taq, scientists can make PCR much faster and more efficient. *Id.*

60. See *Hoffmann-La Roche, Inc. v. Promega Corp.*, No. C-93-1748 VRW, 1999 WL 1797330, at *28 (N.D. Cal. Dec. 7, 1999).

61. Holman, *supra* note 56, at 345.

62. *Id.* at 345-46; see also *Molecular Diagnostics Labs. v. Hoffmann-La Roche, Inc.*, 402 F. Supp. 2d 276, 289 (D.D.C. 2005) (denying *Hoffmann-La Roche's* motion to dismiss *Molecular Diagnostics Laboratories'* complaint alleging antitrust violations).

63. See *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359-60 (Fed. Cir. 2003) (discussing the grounds on which the district court based its findings of inequitable

declaration,⁶⁴ arguing for patentability to overcome an examiner's rejection for anticipation/obviousness.⁶⁵ The Federal Circuit ultimately upheld the district court's findings of inequitable conduct with respect to Cetus's arguments concerning comparative differences between its invention and the inventions described in prior art references and with respect to Cetus's use of the past tense in a purely prophetic example.⁶⁶ In doing so, the Federal Circuit implicitly approved a low standard for inferences of an intent to deceive the PTO and only provided more "grist for [the] pernicious mill" of inequitable conduct allegations.⁶⁷ The reasoning behind each decision is discussed below,⁶⁸ but before examining the Federal Circuit's reasoning in *Hoffmann-La Roche*, it is important to note a few significant attributes of inequitable conduct jurisprudence.

conduct). The court stated:

A DNA polymerase is said to be "template dependant" if it has the ability to read the identity of a nucleotide in the template strand of DNA and then synthesize the appropriate complementary base pair. Fidelity relates to the accuracy of the DNA polymerase in adhering to the complementary base-pairing during synthesis.

Id. at 1368.

64. Patent applicants submit rebuttal evidence in affidavits or declarations under 37 C.F.R. § 1.132. 2 CHISUM ON PATENTS, *supra* note 8, § 5.06[1][b][i], at 5-743; 37 C.F.R. § 1.132 (2007). Section 1.132 provides: "When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section." *Id.* Section 132 affidavits or declarations present two types of evidence: (1) evidence of "'unexpectedly superior properties or advantages' of the claimed invention as compared with the prior art products or processes," and (2) evidence of "commercial success, long-felt need and other 'secondary considerations.'" See 2 CHISUM ON PATENTS, *supra* note 8, § 5.06[1][b][i], at 5-743-44 (discussing factual showings under 37 C.F.R. § 1.132). After submission of rebuttal evidence or argument, patentability is determined by preponderance of the evidence, based on the whole record, with due consideration to the rebuttal's persuasiveness. 2 CHISUM ON PATENTS, *supra* note 8, § 5.06[1][a], at 5-740.

65. See *Hoffmann-La Roche*, 323 F.3d at 1359 (describing Cetus's argument for patentability). In an obviousness determination, the PTO bears the initial burden of proving that a claimed invention is "prima facie obvious." 2 CHISUM ON PATENTS, *supra* note 8, § 5.06[1][a], at 5-735. If an examiner establishes a case of prima facie obviousness, the burden shifts to the patent applicant to put forth evidence or to advance an argument in support of the claimed invention's patentability. See HARMON, *supra* note 24, at 215 (providing that after a PTO examiner makes a prima facie case of obviousness, the patent applicant is then "obliged to come forward with rebuttal, which is merely a showing of facts supporting the opposite conclusion").

66. See *Hoffmann-La Roche*, 323 F.3d at 1359-60 (upholding the district court's findings of inequitable conduct in Cetus's arguments concerning Taq polymerase's fidelity and the inventors' use of the past tense in Example VI).

67. See *id.* at 1372 (Newman, J., dissenting) (stating that the complexities of science provide "grist for [the] pernicious mill" of inequitable conduct claims).

68. See *infra* Part III.A-B (analyzing the Federal Circuit's reasoning in *Hoffmann-La Roche*).

Courts recognize that materiality and intent are distinct elements and that an alleged infringer must prove both elements to prevail on a claim of inequitable conduct.⁶⁹ But alleged infringers can prove intent to deceive the PTO by circumstantial evidence because direct evidence of such intent is rare.⁷⁰ Further, materiality and intent are inversely related, so "[i]f the information involved is highly material to patentability, the level of intent required to sustain an inequitable conduct finding is proportionally less,"⁷¹ and arguments for patentability are presumed material.⁷² Additionally, the PTO cannot run its own tests to verify data from comparative testing—the most commonly advanced evidence of unexpected results submitted in Section 132 affidavits or declarations—so "this area breeds more problems with fraud and inequitable conduct than any other."⁷³ The presumptive materiality of patentability arguments coupled with the inverse relationship of materiality and intent encourages findings of inequitable conduct that are

69. See *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2000) ("[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct." (citations omitted)).

70. See Scott D. Anderson, Comment, *Inequitable Conduct: Persistent Problems and Recommended Resolutions*, 82 MARQ. L. REV. 845, 857–58 (1999) (discussing judicial treatment of the intent prong of inequitable conduct analysis).

71. Mack, *supra* note 3, at 155.

72. See, e.g., *Progressive Games, Inc. v. Shuffle Master, Inc.*, 69 F. Supp. 2d 1276, 1283 (D. Nev. 1999) ("Where false or misleading affidavits or documents are submitted to overcome a prior art rejection by a patent examiner, the requisite materiality may be presumed."); *Upjohn Co. v. MOVA Pharm. Corp.*, 31 F. Supp. 2d 211, 217 (D.P.R. 1998) ("A false or misleading declaration submitted to the PTO is *ipso facto* material."), *rev'd on other grounds*, 225 F.3d 1306 (Fed. Cir. 2000); *Refac Int'l Ltd. v. Lotus Dev. Corp.*, 887 F. Supp. 539, 551 (S.D.N.Y. 1995) ("[M]ateriality is presumed when false affidavits are submitted to the PTO in order to overcome the rejection of a patent application."), *aff'd*, 81 F.3d 1576 (Fed. Cir. 1996). See also 37 C.F.R. § 1.56(b) (2007) (providing the PTO regulation regarding materiality). Section 1.56(b) provides:

[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability

Id.; see also 6 CHISUM ON PATENTS, *supra* note 8, § 19.03[2][d], at 19-210 n.102 (citing many cases supporting the proposition that the materiality of information disclosed in Section 132 affidavits or declarations may be presumed).

73. See 6 CHISUM ON PATENTS, *supra* note 8, § 19.03[2][d], at 19-209–10 (discussing Section 132 affidavits and inequitable conduct).

unsupported by a thorough analysis of whether the requisite intent to deceive exists. *Hoffmann-La Roche* provides an example.

A. Experimental Examples and Verb Tense

In applying for the patent at issue in *Hoffmann-La Roche*, Cetus, the inventors, included Example VI, the description of an experimental procedure.⁷⁴ Cetus wrote Example VI in the past tense, but it never performed the example from start to finish as written.⁷⁵ Although an example written in past tense generally denotes actual performance, a not-yet performed experimental example may be written in the present tense as a prophetic example.⁷⁶ *Hoffmann-La Roche* argued that Cetus included Example VI in the patent application to satisfy the requirement of disclosure of the best mode of practicing the invention.⁷⁷ The majority, however, disagreed: "The best mode requirement . . . does not entitle the inventor to suggest that the best mode has been performed when it has not, and to report results that have not actually been observed."⁷⁸ The majority found use of the past tense to be a material misrepresentation and then found intent to deceive because the inventors attested that all statements in the patent application were true.⁷⁹ Dissenting, Judge Newman pointed out that Example VI was scientifically accurate, was a faithful representation of the experiments actually run, and was indisputably supported by experimental data.⁸⁰

74. See *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1363 (Fed. Cir. 2003) (discussing Example VI, a procedure for refining a bacterial culture of the Taq enzyme).

75. *Id.* at 1364.

76. Hanft & Kerns, *supra* note 57, at 2.

77. *Hoffmann-La Roche*, 323 F.3d at 1367; see generally 35 U.S.C. §112 (2000) ("The specification shall contain a written description of the invention, . . . and shall set forth the best mode contemplated by the inventor of carrying out his invention.").

78. *Hoffmann-La Roche*, 323 F.3d at 1367.

79. *Id.* It is worth noting that declarations filed in the PTO allow inventors to declare that information submitted is true, or *believed to be true*. See generally MPEP, *supra* note 24, at § 602. The MPEP provides an example declaration which requires patent applicants to sign a statement reading, "I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are *believed to be true* . . ." *Id.* (emphasis added).

80. *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1374–75 (Fed. Cir. 2003) (Newman, J., dissenting) (discussing the majority's treatment of Example VI). Judge Newman states:

Example VI as written was a combination of the chromatographic columns of two purification sequences designated as Prep 3 and Prep 4. . . . The fatal flaw,

Initially, the use of the past tense for an example that was not actually performed exactly as written might appear to provide valid grounds for inferring intent to deceive. Instinctively, most people do not hesitate long before attributing intent to deceive to a person who claims to have done something which that person never did. However, in patent law, the issue of tense is not as crystal clear.

The Manual of Patent Examining Procedure (MPEP) permits the use of prophetic or paper examples, in which an example is written in the present tense,⁸¹ and actually cites *Hoffmann-La Roche* for the proposition that prophetic examples should never be written in the past tense.⁸² Determinations of inequitable conduct, however, should turn on more than just improper tense choice; intent to deceive must be shown.⁸³ Even if a patent applicant was negligent, or grossly negligent, in submitting prophetic examples in the past tense, such negligence alone does not provide a sufficient basis for inferring an intent to deceive the PTO.⁸⁴

In *Regents of University of California v. Eli Lilly & Co.*,⁸⁵ only four years prior to *Hoffmann-La Roche*, the Federal Circuit found no inequitable conduct despite experimental examples written in the past tense that

according to the panel majority, is that the entire Example VI was not written in the present tense The inventors believed, and so testified, that the combination of Preps 3 and 4 would be an optimum procedure, and added it to the disclosure because it was their best mode. . . . The ascribed material misrepresentation is not the data in the example, but only the use of the past tense. It was not disputed that the procedure and results of Example VI were supported by Roche's experimental data. There was no proffered evidence of deceptive intent, or basis for such an inference, and no contradiction to the evidence that Example VI was added because the inventors believed it to be the best mode.

Id.

81. See generally MPEP, *supra* note 24, at § 608.01(q).

82. See *id.* ("No results should be represented as actual results unless they have actually been achieved. Paper examples should not be described using the past tense.") (citing *Hoffmann-La Roche*, 323 F.3d at 1367).

83. See *Hoffmann-La Roche*, 323 F.3d at 1377 (Newman, J., dissenting) (discussing the majority's analysis of Example VI). "[P]atentability does not depend on whether [an] example was actually conducted. The presentation of accurate 'constructive' descriptive and enabling information in the specification, whether or not marked as 'prophetic,' is not material misrepresentation with culpable intent." *Id.*

84. See *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) ("[A] finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive.").

85. *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1570 (Fed. Cir. 1999) (concluding that the patent applicant did not engage in inequitable conduct by misrepresenting type of plasmid used in examples of patent application).

differed from the experiments actually performed.⁸⁶ In *Regents*, Eli Lilly, challenging the patent at issue, did not claim that the written examples were inoperative, only that they should not have been written in the past tense.⁸⁷ The court held that no inequitable conduct occurred because "[t]here [was] no reason to believe that a reasonable examiner would have made any different decision if [the University of California] had framed Examples 4 and 5 as constructive examples."⁸⁸

Whereas the court in *Regents* based its decision on a lack of materiality, the court in *Hoffmann-La Roche* addressed intent to deceive instead because Cetus cited Example VI in asserting differences between its claimed enzyme and the prior art in an argument for patentability.⁸⁹ Such arguments for patentability may be presumed to be material.⁹⁰ Thus, Cetus cited information that was arguably misrepresented but likely not material outside of an argument for patentability, in accord with *Regents*. The panel majority in *Hoffmann-La Roche* concluded, however, that such action constituted clear and convincing evidence of an intent to deceive the PTO. By writing all the examples in the present tense, Cetus would have avoided a finding of intent to deceive and inequitable conduct.⁹¹

A patent's enforceability should not turn so quickly on tense choice. It is difficult to support the *Hoffmann-La Roche* decision concerning

86. See *id.* at 1571 ("The misidentification of the plasmid was . . . not material to patentability. Thus, no inequitable conduct occurred in the procurement of the patent.").

87. See *id.* at 1570 ("Lilly does not argue that the pMB9 plasmid was inoperable in the stated examples, only that Examples 4 and 5 should not have been stated as actual examples (even though they presumably could have been stated as constructive, *i.e.*, hypothetical, examples).").

88. *Id.*

89. See *Hoffmann-La Roche, Inc., v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed. Cir. 2003) (discussing Cetus's two-part argument for patentability).

90. See *supra* note 72 and accompanying text (discussing the presumption of materiality for information advanced in arguments for patentability).

91. See *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1578 (Fed. Cir. 1984) (rejecting Du Pont's allegation of inequitable conduct). There, the court stated:

Du Pont argues that Atlas committed inequitable conduct by failing to tell the examiner that the examples were "prophetic" and, hence, in misleading the examiner into believing that the examples were actually performed. However, the district court found that the examples were written in the present tense to conform with the PTO requirements on prophetic examples. Moreover, the district court found that all but one of the examples were based on actual experiments and only slightly modified to reflect the inventor's notion of the most effective formulation. Consequently, the district court found, there was no intent on the part of Atlas to mislead the PTO.

Example VI, where the past tense example cited is operable⁹² and "only slightly modified to reflect the inventor's notion of the most effective formulation."⁹³ The district court in *Hoffmann-La Roche* stated: "The fact that Example VI may have been a superior method of purification is irrelevant: It had not been performed as written, the inventors knew that it had not been performed as written Under these circumstances . . . the inventors' misrepresentation was intentional."⁹⁴ Such an approach ignores the requirement that allegedly inequitable conduct must be "viewed in light of all the evidence, including evidence indicative of good faith, [and] must indicate sufficient culpability to require a finding of intent to deceive."⁹⁵

Further, the district court's approach implies that trivial attacks on experimental procedures written in the past tense are acceptable bases for inequitable conduct allegations.⁹⁶ "Example VI was . . . written for use by manufacturers, and had been given to those manufacturers as instructions for commercial scale purification of [the invention]."⁹⁷ Further, Example VI was not the only example written in the past tense in the patent application.⁹⁸ Cetus wrote all of the examples described in the specification in the past tense.⁹⁹ If Example VI was the only example written in the past tense, then such a unique tense choice might provide supportable grounds for inferring intent to deceive.

Id. The court also exhibited no hesitation affirming the district court's finding of nonobviousness, which relied on the prophetic examples in the patent specification as evidence of differences between the claimed invention and the prior art. *See id.* at 1576 (providing the court's conclusion on nonobviousness).

92. *See Hoffmann-La Roche*, 323 F.3d at 1379 (Newman, J., dissenting) ("The district court agreed that the properties of the Taq polymerase described in Example VI were not significantly different from the properties of the products of Prep 3 or Prep 4."); *see also Hoffmann-La Roche, Inc. v. Promega Corp.*, No. C-93-1748 VRW, 1999 WL 1797330, at *14 (N.D. Cal. Dec. 7, 1999) (discussing the results of Prep 3 and Prep 4).

93. *Atlas Powder Co.*, 750 F.2d at 1578.

94. *Hoffmann-La Roche*, 1999 WL 1797330, at *9.

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

96. *See Hoffmann-La Roche*, 323 F.3d at 1375–76 (Newman, J., dissenting) (discussing the experiment VI details which the panel majority described as misrepresentations). The panel majority designated a number of steps described in Example VI, in the past tense, as misrepresentations because they had not been run as written. *Id.* Judge Newman described the majority's criticisms as "trivial" and "devoid of even the accusation, much less proof, of deceptive intent" because the experimental steps designated as misrepresentations *were* actually run; they were just run in Prep 3, not in a conducted-as-written Example VI. *Id.*

97. *See id.* at 1376.

98. *See generally* U.S. Patent No. 4,889,818 (filed June 17, 1987), available at <http://www.uspto.gov> (providing the text of the example procedures).

99. *Id.*

The analysis of Example VI's tense in *Hoffmann-La Roche* illustrates a lowering of traditional standards for finding intent, which will "result[] in more findings of inequitable conduct ostensibly without the requisite scienter."¹⁰⁰ The treatment of Cetus's representations concerning differences between the claimed invention and the inventions described in the prior art is also problematic because the arguments for patentability advanced by Cetus are similar to arguments that patent applicants will frequently need to advance to meet *KSR*'s heightened standards for patentability.¹⁰¹

B. Comparative Differences Between the Invention and the Prior Art

In arguing for patentability, Cetus asserted that actual differences existed between its invention and the invention described in two prior art journal articles.¹⁰² The panel majority conceded that Cetus's statements about its invention were accurate;¹⁰³ however, it accepted the district court's finding that Cetus's statements comparing its invention to the prior art were inaccurate.¹⁰⁴ *Hoffmann-La Roche* argued that the inventors characterized the prior art based on their interpretation of results of experiments involving the prior art and the claimed invention and that no finding of inequitable conduct could be supported solely on the basis of expert testimony that advanced a contradictory interpretation.¹⁰⁵ Rejecting this, the majority upheld the district court and concluded that Cetus misrepresented the prior art invention as compared with Cetus's invention.¹⁰⁶

100. Hanft & Kerns, *supra* note 57, at 1.

101. See *supra* Part II (discussing *KSR* and its effect on patent examinations).

102. See *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368–69 (Fed. Cir. 2003) (discussing the inventors' comparison of the fidelity and template dependency of the claimed enzyme and the prior art enzymes). Both prior art journals described a DNA polymerase derived from the Taq bacterium. *Id.* Cetus claimed that its Taq enzyme exhibited higher fidelity and template dependence than the prior art enzymes, which experienced misincorporation. *Id.* at 1369.

103. See *id.* at 1369 ("[T]he applicants' statements about the fidelity of their own enzyme were accurate . . .").

104. See *id.* ("[T]he statements characterizing the activity of the prior art enzymes and comparing it to that of the claimed enzyme were inaccurate.").

105. See *id.* at 1370 (rejecting *Hoffmann-La Roche*'s argument that the inventors and Promega's expert witness simply differed over how to interpret experimental results involving the prior art and claimed enzymes).

106. See *id.* at 1371 ("[T]he inventors misrepresented the prior art enzyme and its activity as compared to that of the claimed enzyme.").

The district court stated that Cetus could have replicated the experiments of the two prior art journals and found the failure to do so to be "persuasive evidence" of intent to deceive the PTO.¹⁰⁷ The Federal Circuit did not expressly endorse the district court's imposition of a duty to replicate, stating, in a footnote, "[w]e do not suggest that an applicant is required to repeat the experiments of the prior art; an applicant, however, may not knowingly misrepresent those experiments or their results."¹⁰⁸ In upholding the district court's finding of inequitable conduct, however, the majority gave great weight to Promega's expert witness, Dr. Kunkel.¹⁰⁹ Dr. Kunkel stated that "[Cetus] should have duplicated the prior art in order to conduct a side-by-side comparison."¹¹⁰ Additionally, he called Cetus a fraud, and he described Cetus's activities as "scientific misconduct" and "intentional misrepresentations."¹¹¹

In disagreeing with the panel majority's reliance on Dr. Kunkel's testimony, Judge Newman noted that it was undisputed that the inventors accurately presented their data¹¹² and that there was no evidence that the data in the prior art publications was incorrect.¹¹³ Specifically, Judge Newman stated: "It is not a material misrepresentation with intent to deceive, for an inventor to use his/her knowledge and experience to reach a reasonable conclusion,"¹¹⁴ and "[a] hostile witness' flashy challenge to the inventor's integrity is not probative of anything."¹¹⁵

C. Deciphering Hoffmann-La Roche

Perhaps the split panel Federal Circuit decision in *Hoffmann-La Roche* can best be attributed to the clearly erroneous standard of review the Federal Circuit applies to lower court determinations of materiality and intent.¹¹⁶ The

107. See *Hoffmann-La Roche, Inc. v. Promega Corp.*, No. C-93-1748 VRW, 1999 WL 1797330, at *13 (N.D. Cal. Dec. 7, 1999) (focusing on Cetus's failure to conduct experiments which would provide a "side-by-side comparison" between Cetus's invention and that of the prior art).

108. *Hoffmann-La Roche*, 323 F.3d at 1371 n.4.

109. *Id.* at 1369-72 (discussing Dr. Kunkel's testimony and noting that the district court found intentional deception based primarily on testimony from Dr. Kunkel).

110. *Id.* at 1380 (Newman, J., dissenting).

111. *Id.*

112. *Id.* at 1381.

113. *Id.* at 1379.

114. *Id.* at 1380.

115. *Id.* at 1381.

116. See 6 CHISUM ON PATENTS, *supra* note 8, § 19.03[5][c], at 19-333 ("Because most

panel majority repeatedly cited the clearly erroneous standard of review throughout its opinion.¹¹⁷ Pursuant to such a standard, Federal Circuit reviews of lower court decisions of fact are deferential. Whether the split panel decision should be impugned or may be explained away on standard of review grounds, *Hoffmann-La Roche* evidences an undesirably low standard for inferences of intent to deceive. After *Hoffmann-La Roche*, a patent applicant who relies on prior art representations, experiments, or results without duplicating the prior art experiments, or who describes examples in the specification in the past tense, leaves himself vulnerable to allegations that he "knew better,"¹¹⁸ and "inequitable conduct can be found by using an expert and 20-20 hindsight in questioning an inventor's use of his [] knowledge and experience in reaching a conclusion about the prior art."¹¹⁹

Regarding experiment replication, a patent applicant will find it difficult to effectively replicate the prior art because accused infringers will always be able to point to differences between a prior art experiment and the experiment run by the patent applicant. For example, in *Cetus's* case, there were differences in laboratory equipment, initial salt concentrations, and type of matrix used in size exclusion chromatography.¹²⁰ An accused infringer's ability "to ascertain what experiments were not done, and then to argue that they should have been done,"¹²¹ should not subject patents to a risk of invalidation for inequitable conduct. Nor should tense choice be determinative in establishing the requisite intent to deceive for findings of inequitable conduct.

The requirement of a higher, objective recklessness standard for inferring intent to deceive would likely produce a different result in *Hoffmann-La Roche* at the district court level. A court, faced with the circumstances in *Hoffmann-La Roche*, would likely reject the argument that there was clear and convincing

issues relating to fraud and inequitable conduct are essentially questions of fact, appellate courts will not disturb findings by the trial court unless clearly erroneous." (citations omitted)).

117. See *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1360 (Fed. Cir. 2003) ("With [the clearly erroneous] standard of review in mind, we turn to each of the grounds on which the district court based its ruling."). "There is no clear error in that determination." *Id.* at 1366. "The court's determination [of materiality] is not clearly erroneous." *Id.* at 1368. "The district court did not clearly err in finding the requisite intent." *Id.* at 1372.

118. See *id.* at 1381 (Newman, J., dissenting) ("Dr. Kunkel's charge that [the lead *Cetus* inventor] 'knew better' is mysterious indeed."). The district court found as fact that the inventors believed that the prior art and the claimed enzyme were different, and no error was asserted in that finding. *Id.*

119. Hanft & Kerns, *supra* note 57, at 2.

120. See *Hoffmann-La Roche*, 323 F.3d at 1360-62 (discussing the differences between the *Cetus* and prior art experiments).

121. *Id.* at 1379 (Newman, J., dissenting).

evidence that, in arguing for patentability, Cetus acted objectively recklessly—that Cetus acted in the face of what the PHOSITA would recognize as an objectively high likelihood that such argument constituted either a failure to disclose material information, or a submission of false material information. Cetus did improperly choose to submit a prophetic example in the past tense, but the example was scientifically accurate.¹²² Cetus also relied on representations in prior art journal articles without experimental replication, but there is no duty to replicate prior art experiments.¹²³ Finally, the only evidence that Cetus's interpretation of the prior art reference was inappropriate was Dr. Kunkel's testimony that Cetus "knew better."¹²⁴

The result in *Hoffmann-La Roche* is partly attributable to Hoffmann-La Roche's failure to put forward evidence rebutting Dr. Kunkel's testimony.¹²⁵ Dr. Kunkel's testimony qualified as that of a PHOSITA. But an objective recklessness standard calls for a thorough analysis of the PHOSITA's understanding, one in which testimony that the inventor "knew better" fails to clearly and convincingly prove that the inventor acted despite an objectively high likelihood that his actions constituted failure to disclose material information, or a submission of false material information. An objective recklessness standard would produce a more equitable result in *Hoffmann-La Roche*. If it failed to do so at the lower court level, such a standard would allow a reviewing Federal Circuit panel to reverse a finding of inequitable conduct, even operating under a deferential clearly erroneous standard of review.

D. Hoffmann-La Roche and KSR

After *KSR*, patent applicants face increased standards for nonobviousness and will face an inevitable increase in examiner rejections.¹²⁶ Therefore patent applicants will more frequently find themselves obligated to advance arguments for patentability, similar to those advanced by Cetus in arguing for the

122. See *supra* note 92 and accompanying text (discussing the district court's analysis of Example VI's accuracy).

123. See *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1371 n.4 (Fed. Cir. 2003) (denying any affirmative duty to replicate prior art experiments).

124. See *supra* note 118 and accompanying text (discussing Dr. Kunkel's testimony that the Cetus inventor "knew better").

125. See *Hoffmann-La Roche*, 323 F.3d at 1372 ("[Hoffmann-La Roche] did not put forward evidence to contradict Dr. Kunkel We therefore have no evidentiary basis from which to conclude that it was clearly erroneous for the district court to find that . . . the inventors [] intentionally sought to deceive the PTO.").

126. See *supra* Part II (discussing *KSR* and its effect on patent prosecution).

patentability of its invention in *Hoffmann-La Roche*.¹²⁷ This Note recognizes that the patent rejected on obviousness grounds in *Hoffmann-La Roche* was a biotech patent and that the effects of *KSR* may be felt more strongly in other arts.¹²⁸ But the broader inequitable conduct issue at play in *Hoffmann-La Roche* is relevant regardless of the art in question. Increased nonobviousness standards mean more obviousness rejections, which in turn mean more arguments for patentability.¹²⁹ And all arguments for patentability are susceptible to hindsight criticism.¹³⁰ The *Hoffmann-La Roche* decision encourages this Note to advocate the adoption of an objective recklessness standard for inferences of intent to deceive not just for biotech patent applications, but for patent applications in all the useful arts.

This Note further acknowledges that invoking *KSR* as justification for adopting a higher standard for inferences of intent to deceive opens the door to criticism claiming that this Note is inconsistent. *KSR*'s increased standards of nonobviousness are decidedly anti-inventor, and the standard espoused in this Note is decidedly pro-inventor; however, this apparent inconsistency is without substance. When a patent applicant crosses each patent law hurdle and meets every patentability requirement, that patent applicant presumably has satisfied *KSR*'s anti-inventor standards and is therefore entitled to benefit from this Note's pro-inventor standard. Patentees should not be deprived of their well-earned rights by "[I]tigation-induced assaults on the conduct of science and scientists . . . intent on destruction of reputation and property for private gain."¹³¹ The patent system better protects the incentives to invent and to commercialize when it "promote[s] and protect[s] a structure that fosters a strong and vibrant environment for innovators,"¹³² and an objective

127. See *supra* Part III.A–B (discussing Cetus's argument for patentability).

128. See MacKenzie, *supra* note 23 ("[*KSR*'s] effect on litigation will vary depending on the technology at issue."). "In mechanical cases . . . the claimed technology is easier to understand and usually involves combinations of known prior art elements. . . . In chemical, electrical, and biotechnology cases, a more in depth obviousness analysis may be needed since predictability of results may not be easily apparent . . ." *Id.*

129. See *id.* ("[N]o matter what technology is at issue, the Supreme Court made it easier . . . to prove obviousness To overcome these rejections, [an] applicant will have to . . . rely on declarations from the inventor or a person of ordinary skill in the art.").

130. See Wegner, *supra* note 23, at 6 n.13 ("[I]n hindsight, there can almost *always* be some fact that can be portrayed as 'material' where minds could differ on what evidence *should* have been included.").

131. *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1372 (Fed. Cir. 2003) (Newman, J., dissenting).

132. 153 CONG. REC. S15899 (daily ed. Dec. 18, 2007) (statements of Sen. Hatch), reprinted in *Leahy and Hatch Agree Patent Reform Must Come in Early 2008*, AIPLA REP. (Am. Intellectual Property Law Ass'n, Arlington, Va.), Dec. 21, 2007 (on file with the

recklessness standard offers appropriate protection from opportunistic inequitable conduct claims. Moreover, such a standard is in harmony with recent developments in the Federal Circuit's willful infringement jurisprudence.¹³³

IV. Lessons Learned from Willful Infringement Jurisprudence and Suggested Patent Reforms

The Federal Circuit's *In re Seagate*¹³⁴ decision is relevant to this Note's analysis of inequitable conduct in two respects: (1) the Federal Circuit held that "proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness";¹³⁵ and (2) the Federal Circuit "reemphasize[d] that there is no affirmative obligation to obtain opinion of counsel" to avoid an adverse inference with respect to willfulness.¹³⁶ The first point, above, is relevant because the intent required for a finding of inequitable conduct is analogous to the requisite finding of willfulness in willful infringement suits.¹³⁷ The second point is relevant because it illustrates why one commentator's suggested approach for avoiding inequitable conduct allegations based on arguments for patentability is not advantageous.¹³⁸

A. Adopting Objective Recklessness

Both determinations of willfulness and determinations of intent involve searching for evidence of scienter. The Federal Circuit's decision to adopt an objective recklessness standard for inferring willfulness should motivate the

Washington and Lee Law Review).

133. See *infra* Part IV (discussing recent developments in the Federal Circuit's willful infringement jurisprudence).

134. *In re Seagate Tech.*, 497 F.3d 1360, 1365 (Fed. Cir. 2007) (overruling the standard for determining willfulness set forth in *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (Fed. Cir. 1983), and clarifying "the scope of the waiver of attorney-client privilege and work product protection that results when an accused infringer asserts an advice of counsel defense to a charge of willful infringement"). "*Underwater Devices* sets a lower threshold for willful infringement that is more akin to negligence." *Id.* at 1371.

135. *Id.* at 1371.

136. *Id.*

137. See *infra* Part IV.A (discussing willfulness, intent, and the Federal Circuit's adoption of an objective recklessness standard for inferences of willful infringement).

138. See *infra* Part IV.B (discussing the disadvantages in focusing on a patent attorney obtaining a second opinion from a supervising, senior patent attorney).

adoption of the same standard for inferring intent in inequitable conduct analyses because asking whether an action was taken willfully is substantively the same as asking whether the party in question intended to take such action. "'Intent' commonly means: 'Design, resolve, or determination with which [a] person acts[; a] state of mind in which a person seeks to accomplish a given result through a course of action.'"¹³⁹ Willful is often defined as deliberate, voluntary, or intentional.¹⁴⁰

In adopting an objective recklessness standard for willfulness, the Federal Circuit recognized that the Supreme Court has concluded that "standard civil usage of 'willful' includes reckless behavior."¹⁴¹ The Federal Circuit recognized that "the term reckless is not self defining," but the court noted that a person is generally considered reckless when he acts in the face of an unjustifiably high risk.¹⁴² Therefore, the Federal Circuit stated: "[T]o establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent."¹⁴³

The Federal Circuit should adopt an analogous standard in the inequitable conduct context. Doing so would provide that to establish intent to deceive the PTO, in the absence of direct evidence of such intent, an accused infringer must show by clear and convincing evidence that the patentee acted despite an objectively high likelihood that his actions constituted either a failure to disclose material information, or a submission of false material information. Such a standard would discourage frivolous claims of inequitable conduct and would help swing the Federal Circuit's inequitable conduct pendulum back toward a truthful requirement of scienter and deceitful intent.¹⁴⁴ Further, the Federal Circuit can tailor the objective recklessness standard to be in harmony

139. 6 CHISUM ON PATENTS, *supra* note 8, § 19.03[4][g], at 19-318-19 (quoting *Black's Law Dictionary* 810 (6th ed. 1990)).

140. OXFORD ENGLISH DICTIONARY 339 (2d ed. 1989).

141. *In re Seagate Tech.*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (citations omitted).

142. *See id.* ("The civil law generally calls a person reckless who acts in the face of an unjustifiably high risk of harm that is either known or so obvious that it should be known." (citations omitted)).

143. *Id.*

144. *See Hanft & Kerns, supra* note 57, at 1 (discussing a "disturbing" trend in the Federal Circuit's decisions indicating a decreasing standard for inferences of intent and a consequent increasing readiness to find inequitable conduct). "When viewed over a period of decades, the pendulum swings back and forth regarding the ease with which a finding can be made of inequitable conduct. . . . The trend in recent decisions suggests that the pendulum is swinging back" toward low standards for findings of inequitable conduct. *Id.*

with patent law's frequently used PHOSITA standard.¹⁴⁵ This conservative standard for finding inequitable conduct is consistent with recent congressional suggestions for patent reform.

The Patent Reform Act of 2007¹⁴⁶ passed the House of Representatives in 2007, but failed to pass the Senate by the year's end.¹⁴⁷ Passage of substantially the same bill stalled in the Senate once again in 2008.¹⁴⁸ The Patent Reform Act of 2007 added inequitable conduct as a defense to infringement, amending the "Presumption of validity; defenses" section of the Patent Act.¹⁴⁹ The bill increased the standard of proof for materiality by providing that information is material if "a reasonable examiner would have made a prima facie finding of unpatentability, or maintained a finding of unpatentability, of one or more of the patent claims based on the information, and the information is not cumulative to information already of record or previously considered by the [PTO]."¹⁵⁰

The suggested new standard requiring proof of a reasonable examiner's prima facie finding of unpatentability represents a higher standard for materiality than that of 37 C.F.R. § 1.56(b),¹⁵¹ but the standard is easily met and does little to raise the bar for findings of inequitable conduct post-*KSR*, when the information at issue is likely to be advanced in arguments for patentability

145. An objective recklessness standard infused with an understanding of the PHOSITA standard might be enunciated as follows: To establish intent to deceive the PTO, in the absence of subjective evidence of such intent, an accused infringer must show by clear and convincing evidence that the patentee acted in the face of what a PHOSITA would recognize as an objectively high likelihood that the patentee's actions constituted either a failure to disclose material information, or submission of false material information.

146. Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007) (as passed by House, Sept. 7, 2007) [hereinafter H.R. 1908] (on file with the Washington and Lee Law Review).

147. 153 CONG. REC. S15899 (daily ed. Dec. 18, 2007) (statements of Sen. Leahy and Sen. Hatch) (agreeing that patent reform should be introduced early in 2008 and recognizing that, in 2007, a number of Senate members were of the view that the Patent Reform Act of 2007 needed to be perfected before it came to a vote), reprinted in *Leahy and Hatch Agree Patent Reform Must Come in Early 2008*, AIPLA REP. (Am. Intellectual Property Law Ass'n, Arlington, Va.), Dec. 21, 2007 (on file with the Washington and Lee Law Review).

148. See generally Dugie Standeford, *US Patent Reform Stalls as Senate Negotiations Break Down*, INTELLECTUAL PROPERTY WATCH, Apr. 15, 2008, <http://www.ip-watch.org/weblog/index.php?p=1007> (last visited Sept. 14, 2008) (on file with the Washington and Lee Law Review).

149. See generally H.R. 1908, *supra* note 146, at 64–69; see also generally 35 U.S.C. § 282 (2000) (providing the Patent Act's "Presumption of validity; defenses" section).

150. H.R. 1908, *supra* note 146, at 66.

151. See *supra* note 72 and accompanying text (providing the PTO regulation for materiality).

following examiner obviousness rejections.¹⁵² The bill also explicitly addressed the intent to deceive requirement for a finding of inequitable conduct. The bill provided:

To prove a person with a duty of disclosure to the [PTO] intended to mislead or deceive the examiner . . . specific facts beyond materiality of the information misrepresented or not disclosed must be proven that establish the intent of the person to mislead or deceive the examiner by the actions of the person. Facts support an intent to mislead or deceive if they show circumstances that indicate *conscious or deliberate behavior* on the part of the person to not disclose material information or to submit false material information in order to mislead or deceive the examiner.¹⁵³

The introduction of a conscious and deliberate behavior requirement reflects a congressional intent to achieve a standard for intent to deceive that is analogous to willfulness. Both "conscious" and "deliberate" are synonymous with "willful,"¹⁵⁴ and the Patent Reform Act of 2007 included the conscious and deliberate behavior requirement only after the American Intellectual Property Law Association (AIPLA) criticized both the initial Senate and House patent reform suggestions for failing to advance a "knowing and willful deception" standard for intent to deceive the PTO.¹⁵⁵ Following passage of the Patent Reform Act of 2007 by the House, AIPLA did not object to the inclusion of the conscious and deliberate behavior standard.¹⁵⁶ Presumably, that commentator viewed the conscious and deliberate behavior to deceive standard as equivalent to a "knowing and willful deception" standard.

While a standard requiring proof of "conscious and deliberate behavior" certainly swings the Federal Circuit's inequitable conduct pendulum¹⁵⁷ back toward higher standards for findings of inequitable conduct, it fails to achieve a high enough standard. "[M]ore must be done to change the use of this defense

152. See *id.*; see also *supra* Part II (discussing increased obviousness standards post-*KSR*).

153. See H.R. 1908, at 67 (emphasis added).

154. See ROGET'S INT'L THESAURUS § 380.08 (6th ed. 2001) (providing "deliberate," "conscious," and "willful" as synonyms for "intentional").

155. See *Patent Reform Bills Await Action as Congress Recesses*, AIPLA REP. (Am. Intellectual Property Law Ass'n, Arlington, Va.), Aug. 7, 2007 ("The state of mind element for both bills should be 'knowing and willful deception' rather than simply 'intentional deception.'") (on file with the Washington and Lee Law Review).

156. See *generally House Passes Patent Bill with Modifications*, AIPLA REP. (Am. Intellectual Property Law Ass'n, Arlington, Va.), Sept. 12, 2007 (on file with the Washington and Lee Law Review).

157. See *supra* note 144 and accompanying text (discussing the Federal Circuit's inequitable conduct pendulum).

as an unfair litigation tactic."¹⁵⁸ Under the "conscious and deliberate behavior" standard, arguments for patentability that arguably mislead examiners will meet both the materiality and intent prongs of an inequitable conduct analysis. Materiality may be presumed,¹⁵⁹ and arguing for patentability can only be done consciously and deliberately. Such a standard fails to direct courts' attention to finding either direct evidence of a subjective intent to deceive or the recklessness from which such an intent may properly be inferred.

An objective recklessness standard for inferring intent would better reflect the intentions behind the suggested inequitable conduct reforms and would be recognizably analogous to the Federal Circuit's willful infringement jurisprudence.¹⁶⁰ Moreover, an objective recklessness standard addresses inequitable conduct, post-KSR, in a manner that avoids repeating mistakes that the Federal Circuit's willful infringement jurisprudence has already struggled with and overcome. One commentator has suggested that inequitable conduct concerns surrounding the submission of patentability arguments can be satisfactorily addressed by securing the opinion and approval of second, senior patent attorneys.¹⁶¹ However, by placing significant emphasis on obtaining second opinions, this suggestion risks imposing an obligation on patent applicants, in the inequitable conduct context, that *In re Seagate* reemphasized has been eliminated from the Federal Circuit's willful infringement jurisprudence.¹⁶²

B. No Affirmative Obligation to Obtain Opinions of Counsel

After recognizing that, post-KSR, arguments for patentability advanced in Section 132 affidavits or declarations will be used frequently to overcome obviousness rejections and that such declarations provide fertile ground for spurious claims of inequitable conduct, Professor Wegner suggests that patent attorneys and agents prepare such declarations with the involvement of a

158. 153 CONG. REC. S15899 (daily ed. Dec. 18, 2007) (statement of Sen. Hatch) (commenting on inequitable conduct reform), reprinted in *Leahy and Hatch Agree Patent Reform Must Come in Early 2008*, AIPLA REP. (Am. Intellectual Property Law Ass'n, Arlington, Va.), Dec. 21, 2007 (on file with the Washington and Lee Law Review).

159. See *supra* note 72 and accompanying text (discussing the presumption of materiality for information advanced in arguments for patentability).

160. See generally *In re Seagate Tech.*, 497 F.3d 1360 (Fed. Cir. 2007).

161. See Wegner, *supra* note 23, at 6 n.13 (advocating the acquisition of second, senior patent attorney review).

162. See *In re Seagate*, 497 F.3d at 1369–70 (reemphasizing that no adverse inference should attach to a patent applicant's failure to obtain opinion of counsel).

second, senior patent attorney.¹⁶³ Specifically, Professor Wegner suggests, "the good faith effort involving multiple attorneys checking each other should preclude a finding of *mens rea*—a necessary element to establish inequitable conduct."¹⁶⁴ But the adoption of such an approach to patentability arguments risks leading inequitable conduct jurisprudence into a situation where a patent applicant, patent practitioner, or patent agent's failure to obtain a secondary expert opinion concerning information submitted to the PTO is viewed as grounds for drawing an adverse inference with respect to intent to deceive the PTO.

In the context of willful infringement, the *In re Seagate* decision reemphasized that "an accused infringer's failure to obtain legal advice does not give rise to an adverse inference with respect to willfulness."¹⁶⁵ Before 2004, the Federal Circuit "had held that an accused infringer's failure to produce advice from counsel 'would warrant the conclusion that it either obtained no advice of counsel or did so and was advised that its [activities] would be an infringement of valid U.S. Patents.'"¹⁶⁶ Deciding that such an adverse inference was too burdensome on patent applicants and attorneys, the Federal Circuit, in 2004, held that the failure to obtain opinion of counsel did not give rise to an adverse inference with respect to willfulness.¹⁶⁷

In the inequitable conduct context, resorting to a system where arguments for patentability must be checked by second, senior patent attorneys threatens to push inequitable conduct jurisprudence into the morass from which the Federal Circuit's willful infringement jurisprudence just emerged. A required second level check on patentability arguments would likely foster extensive satellite

163. See Wegner, *supra* note 23, at 6 n.13 ("Optimum declaration presentation should involve a second, senior patent attorney to carefully make his own review . . . to play devil's advocate . . . and so forth.").

164. *Id.*

165. *In re Seagate*, 497 F.3d at 1370; see also *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1341 (Fed. Cir. 2004) (finding "that no adverse inference that an opinion of counsel was or would have been unfavorable flows from an alleged infringer's failure to obtain or produce an exculpatory opinion of counsel").

166. *In re Seagate Tech.*, 497 F.3d 1360, 1369 (Fed. Cir. 2007) (quoting *Knorr-Bremse*, 383 F.3d at 1343).

167. See *Knorr-Bremse*, 383 F.3d at 1345–46 ("Although there continues to be 'an affirmative duty of due care to avoid infringement of the known patent rights of others,' the failure to obtain an exculpatory opinion of counsel shall no longer provide an adverse inference or evidentiary presumption that such an opinion would have been unfavorable." (citations omitted)). In *Knorr-Bremse* the Federal Circuit cited *Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342, 1364 (Fed. Cir. 1998), "wherein the court held that to avoid liability for willful infringement in that case, an exculpatory opinion of counsel must fully address all potential infringement and validity issues." *Id.* at 1345.

litigation concerning whether the failure to obtain a superior's review is proper grounds for inferring intent to deceive the PTO.¹⁶⁸ Such a system would be unduly burdensome on the patent application process and should be avoided to steer clear of the same problems the Federal Circuit addressed in its willful infringement jurisprudence.¹⁶⁹

V. Applying an Objective Recklessness Standard

Two commentators cite *Hoffmann-La Roche* as evidence of a trend in the Federal Circuit's jurisprudence toward a standard for inequitable conduct determinations which "flies in the face of the clear-and-convincing standard reiterated in *Kingsdown* and resurrects the inequitable conduct plague that existed pre-*Kingsdown*."¹⁷⁰ The fact that the Federal Circuit affirmed lower court findings of inequitable conduct in *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*¹⁷¹ and *Ferring B.V. v. Barr Laboratories, Inc.*¹⁷² is further evidence of such a trend.¹⁷³ Under an objective recklessness

168. Cf. *Knorr-Bremse*, 383 F.3d at 1345 (noting that an adverse inference from failure to obtain opinions of counsel in the willful infringement context led to extensive satellite litigation).

169. Cf. *id.* (discussing the burdens of such a system and citing *Johns Hopkins Univ.*, 152 F.3d at 1364, "wherein the court held that to avoid liability for willful infringement . . . an exculpatory opinion of counsel must fully address all potential infringement and validity issues").

170. Hanft & Kerns, *supra* note 57, at 5. "The trend is away from the stricter standard of *Kingsdown*, which required proof of scienter . . . and more toward a strict liability standard." *Id.*

171. *Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1362–63 (Fed. Cir. 2005) (affirming the district court's holding that the patent at issue was unenforceable due to inequitable conduct).

172. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1194–95 (Fed. Cir. 2006) (affirming the district court's holding that the patent at issue was unenforceable due to inequitable conduct).

173. See Hanft & Kerns, *supra* note 57, at 5 ("The theme of these decisions is that, once materiality of information is found, the Federal Circuit is far more likely to infer an intent to deceive . . . than it has in the past."). Hanft and Kerns also cite *Kao v. Unilever*, as evidence of a trend away from *Kingsdown*. *Id.* at 4–5. In *Kao*, the Federal Circuit affirmed a lower court determination that no inequitable conduct had occurred, but stated, "Given a blank slate, we might weigh the evidence differently. Given the limited scope of our review, however, we cannot second-guess the trial court's decision," implying that such a ruling was reached only as a result of the Federal Circuit's applicable clear error standard of review. *Kao v. Unilever*, 441 F.3d 963, 972 (Fed. Cir. 2006). Hanft and Kerns call the above language from the *Kao* decision "ominous," and assert that it shows that "[w]hereas in the past, the lower courts were encouraged to fight against the 'plague' of inequitable conduct charges . . . now the Federal Circuit seems more eager to embrace anything that could resemble a mistake in prosecution."

standard for inferences of intent to deceive, *Novo Nordisk* would be more supportable and *Ferring B.V.* would be decided differently.¹⁷⁴

A. *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*

In *Novo Nordisk*, *Novo Nordisk* claimed priority for its invention based on a patent application filed in 1983,¹⁷⁵ which contained a prophetic example that was written in the past tense.¹⁷⁶ Initially tense choice was not determinative in this case. The district court found that the Danish inventor's 1983 submission of the prophetic example partially written in the past tense "did not intentionally breach his duty of candor and good faith" because his "use of past tense was merely an oversight . . . likely due to the fact that [he was] trained as a scientist, not as a patent attorney familiar with the teachings of the MPEP."¹⁷⁷

But, in 1994, in attempting to establish priority during an interview with a patent examiner, the Danish inventor and other representatives of *Novo Nordisk* failed to disclose the true prophetic nature of the example from 1983.¹⁷⁸ This nondisclosure was held to be grounds for a finding of inequitable conduct. The Danish inventor was charged with knowledge of the law,¹⁷⁹ meaning he knew that prophetic examples should not be submitted in the past tense, and, from this presumed knowledge of the law, both intent to deceive the PTO and knowledge that the true prophetic nature of the example was material were inferred.¹⁸⁰

Hanft & Kerns, *supra* note 57, at 5.

174. See *infra* Part V.A–B (applying an objective recklessness standard to *Novo Nordisk* and *Ferring B.V.*).

175. See 35 U.S.C. § 120 (2000) (providing the rule for claiming the benefit of an earlier filing date).

176. *Novo Nordisk*, 424 F.3d at 1357.

177. *Id.* at 1361 n.12.

178. *Id.* at 1361.

179. See *id.* ("[The Danish inventor] was aware that Example 1 was prophetic, and because 'knowledge of the law is chargeable to the inventor,' and 'inventors represented by counsel are presumed to know the law,' the district court's inference of deceptive intent was not clearly erroneous." (citations omitted)).

180. See Hanft & Kerns, *supra* note 57, at 3 (explaining why they disagree with the Federal Circuit's reasoning in *Novo Nordisk*). Hanft and Kerns state:

What the Federal Circuit did was to charge knowledge of the law . . . from the attorney to the inventor, infer that the applicant "should have known" about the materiality of the information, and then infer deceptive intent from that presumed knowledge, in total disregard for the district court finding that the inventor had acted innocently 10 years earlier in drafting the application.

Id.

Bio-Technology General Corp. (Bio-Tech) would likely be hard-pressed to show that the Novo Nordisk prosecuting attorneys were objectively reckless. Under an objective recklessness standard for inferences of intent, Bio-Tech must clearly and convincingly prove that, in failing to disclose the true prophetic nature of the 1983 example in its priority-related interview, the Novo Nordisk prosecuting attorneys acted despite what a PHOSITA would recognize as an objectively high likelihood that such action constituted a failure to disclose material information. In *Novo Nordisk*, "there was never a finding that the inventor ever learned that tense could change the meaning of an example or that the inventor ever disclosed the prophetic nature of the example to the [Novo Nordisk] prosecuting attorneys."¹⁸¹ Without any evidence that the Novo Nordisk prosecuting attorneys knew that the example was prophetic, Bio-Tech will not be able to clearly and convincingly prove that those attorneys argued for priority despite an objectively high likelihood that such action constituted a failure to disclose material information. It is not objectively reckless for prosecuting attorneys to rely on a past-tense example that they have no reason to believe is actually a prophetic example. Such reliance does not provide sufficient grounds for inferring an intent to deceive the PTO. To decide otherwise would be to entirely remove the ability of prosecuting attorneys to rely on past-tense examples.

Bio-Tech's case against the Danish inventor is stronger, but use of an objective recklessness standard for inferring intent to deceive would result in a more appropriate determination of intent than that which took place in *Novo Nordisk*. The Federal Circuit noted, without disapproval, that the district court found "the inequitable conduct intent requirement satisfied because 'Novo, nine years after it first submitted [the example] to the PTO, knew or should have known that the examiner would have considered the fact that [the example] contained prophetic data important in evaluating whether [priority could be claimed].'"¹⁸² Such reasoning fails to properly treat materiality and intent as separate elements of an inequitable conduct claim. Under an objective recklessness standard, Bio-Tech would need to advance proof, most likely in the form of expert testimony, that a PHOSITA would recognize that the inventor's reliance on the example took place in the face of an objectively high likelihood that such reliance constituted a failure to disclose material information. Bio-Tech may have been able to carry this burden on the facts of *Novo Nordisk*,¹⁸³ but an

181. *Id.*

182. *Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1360 (Fed. Cir. 2005).

183. *See id.* (emphasizing that the example at issue was not enabling). "We are not prepared to accept the proposition that simply because fate interceded and Novo scientists unintentionally [conducted the steps in the example after the example's submission], Novo

objective recklessness standard would necessitate a thorough examination of both the scientific accuracy of the example and the knowledge of a PHOSITA. Thus, an objective recklessness standard would remain more loyal to the requirement for scienter from which the reasoning in *Novo Nordisk* departs¹⁸⁴ and would result in a more supportable inference of intent to deceive.

B. *Ferring B.V. v. Barr Laboratories, Inc.*

In *Ferring B.V.*, in response to an obviousness rejection and following an examiner suggestion that "applicants obtain evidence from a *non-inventor*,"¹⁸⁵ the inventor submitted five Section 132 declarations arguing for patentability.¹⁸⁶ The Federal Circuit held that the submission of the declarations constituted intent to deceive the PTO because four of the five declarations were written by scientists with "intimate ties to the inventors of Ferring itself,"¹⁸⁷ and "it must have been clear to [the inventor] . . . that a non-inventor affidavit was sought for purposes of obtaining *objective evidence*" of nonobviousness.¹⁸⁸ As in *Hoffmann-La Roche*, Judge Newman vigorously dissented from the panel majority's decision.¹⁸⁹ In inferring an intent to deceive from nondisclosure of the affiant scientists' Ferring affiliations, the court stated that the inventor "should have known" that such affiliations were material because he was "on notice that disinterested affidavits were necessary."¹⁹⁰ Judge Newman attacked the majority's reliance on a "should have known" standard as "bad law" contrary to *Kingsdown*.¹⁹¹ She rebuked the

produced [the invention] according to the methodology of Example 1." *Id.*

184. See Hanft & Kerns, *supra* note 57, at 3 (noting that in *Novo Nordisk* "the court found deceptive intent based on presumed knowledge of the law"). "[A]n inference [of intent to deceive] based on a should-have-known standard . . . is not an inference based on circumstantial evidence. . . . and does not meet the scienter requirement emphasized in *Kingsdown*." *Id.*

185. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1184 (Fed. Cir. 2006).

186. *Id.* at 1185.

187. See *id.* at 1190 ("[T]he district court was correct to conclude as a matter of law that the examiners' request for non-inventor declarations was for declarations from individuals without intimate ties to the inventors or Ferring itself."). "In sum, four of the five declarations submitted to the PTO . . . were written by scientists who had been employed or had received research funds from Ferring." *Id.* at 1185.

188. *Id.* at 1186.

189. Hanft & Kerns, *supra* note 57, at 3. See generally *Ferring B.V.*, 437 F.3d at 1195-1205 (Newman, J., dissenting).

190. See *Ferring B.V.*, 437 F.3d at 1192 (upholding the district court's determination of intent).

191. See *id.* at 1202 (Newman, J., dissenting) (discussing why it is inappropriate to rely on precedent espousing a "should have known" standard).

majority's reliance on a case overruled by *Kingsdown* and called it a "resurgence of the plague that *Kingsdown* had intended to cure."¹⁹² Summarizing the work experience of the affiant scientists, Judge Newman believed that the panel majority mischaracterized their connections with Ferring as "intimate ties," and stated that the "inference that their scientific opinions may be biased and were submitted with deceptive intent [was] a travesty."¹⁹³

An objective recklessness standard for inferring intent to deceive would likely lead to a finding that no inequitable conduct occurred in *Ferring B.V.* For Barr Laboratories to prove that the inventor in *Ferring B.V.* was objectively reckless, Barr Laboratories would have to show that, in failing to disclose the affiant scientist's affiliations with Ferring, the inventor acted in the face of what a PHOSITA would recognize as an objectively high likelihood that such action constituted failure to disclose material information or a submission of false information. The affiant scientists in *Ferring B.V.* were well reputed professors. It is unlikely that such distinguished affiants would deliberately conceal or submit false information.¹⁹⁴ Moreover, as Judge Newman points out, "it is rare that any scientist working in a specialized field would not have interacted professionally with other scientists and with the industries in that field,"¹⁹⁵ and "[t]here [was] simply no evidence of any intention to withhold [the affiant scientists' affiliations]; in fact, there [was] no evidence that [the inventor] even thought about whether or not to disclose these affiliations, much less that he made the deliberate decision to withhold material information from the PTO."¹⁹⁶ The facts of *Ferring B.V.* do not clearly and convincingly establish that there is an objectively high likelihood that the inventor's submission of distinguished scientists' affidavits, in response to a request for *non-inventor* affidavits, ran the risk of constituting a failure to disclose, or a submission of false, material information. Thus, an objective recklessness standard applied to the facts of *Ferring B.V.* produces a more palatable and equitable result and avoids the danger of inferring both a patentee's knowledge of materiality and intent to deceive from evidence the court decides the patentee "should have known."¹⁹⁷

192. *Id.*

193. *Id.* at 1197-98.

194. *See id.* ("[T]he professors' reputations are enough, on the face of their scholarship, to put into dispute the panel majority's summary judgment that they deliberately concealed information that was important to the credibility of their affidavits.")

195. *Id.* at 1200. "Such relationships do not warrant an inference of bias and deception. There must be evidence and analysis, not innuendo." *Id.*

196. *Id.* at 1198. The inventor only had knowledge of one of the affiant scientists' affiliations, and this affiliation "was omitted from a declaration submitted after the relationship ended and four years after the examiner's request for 'non-inventor' testimony." *Id.*

197. *See Hanft & Kerns, supra* note 57, at 4 (discussing the *Ferring B.V.* decision). "[In

VI. Conclusion

Allegations of inequitable conduct require close monitoring and scrutiny because the "uncertainties," "vagaries," and "complexities" of the scientific process and patent procedure combined with "the twists of hindsight" provide fertile ground for such allegations¹⁹⁸ and because "[a] successful attack on the inventor or his lawyer will destroy the patent, no matter how valid the patent and how sound the invention."¹⁹⁹ The *Hoffmann-La Roche* case illustrates that the current state of the Federal Circuit's inequitable conduct jurisprudence fails to provide inventors arguing for patentability with proper protection from opportunistic, litigation-induced claims of inequitable conduct. After *KSR*, patent applicants will argue for patentability more frequently than ever, leaving the door wide open for allegations of inequitable conduct. Thus, the Federal Circuit must adopt a higher standard for inferences of intent to deceive the PTO.

To establish inequitable conduct in the absence of direct evidence of a subjective intent to deceive, an accused infringer must be required to prove, by clear and convincing evidence, that a patentee acted objectively recklessly—that the patentee acted despite what the person having ordinary skill in the art would recognize as an objectively high likelihood that the patentee's actions constituted either a failure to disclose material information, or a submission of false material information. Such a standard is in harmony with Federal Circuit willful infringement jurisprudence and consistent with recent congressional suggestions for patent reform. Further, with this standard, the Federal Circuit can constrain unwarranted findings of inequitable conduct, secure inventors' well-earned property rights, effectuate patent incentive, strengthen technology-based investment,²⁰⁰ and successfully give force to the constitutional command to promote the progress of the useful arts.²⁰¹

Ferring B.V.], the court used a should-have-known materiality standard and then further inferred a specific intent to deceive from it. . . . When the inventor should have known, but did not, the court inferred an intent to deliberately deceive the [PTO]" *Id.*

198. *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1372 (Fed. Cir. 2003) (Newman, J., dissenting).

199. *Id.*

200. See *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1195–96 (Fed. Cir. 2006) (Newman, J., dissenting) (discussing the unreliability of patents, pre-*Kingsdown*, and noting that "the contribution of a diminished patent incentive to the weakening of technology-based investment was a serious national concern").

201. U.S. CONST. art. I, § 8, cl. 8.

