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APPLICATION OF THE INEQUITABLE CONDUCT DOCTRINE AFTER KINGSDOWN

Erik R. Puknys† & Jared D. Schuettenhelm††

Abstract

All individuals associated with prosecuting and filing patent applications owe a duty of candor to the U.S. Patent Office, including the obligation to disclose all information that is material to the patentability of an invention. Where an applicant fails to comply with this duty, challengers may seek to render the patent unenforceable by charging the applicant with inequitable conduct. Responding to a vast increase in inequitable conduct claims, the Federal Circuit in 1988 decided Kingsdown Medical Consultants, Ltd. v. Hollister, Inc., enumerating clear requirements for an inequitable conduct ruling. The Kingsdown court held that inequitable conduct requires a showing of both materiality and intent to deceive by clear and convincing evidence. Nevertheless, since Kingsdown, judges and commentators have criticized the perceived erosion of the intent element of inequitable conduct. Although Kingsdown requires a finding of a specific intent to deceive, subsequent decisions have been criticized for establishing a “should have known” standard for intent, thus lowering the requirements specified in Kingsdown. This article traces the development of the inequitable conduct doctrine leading up the Kingsdown decision. It also summarizes a number of criticized cases decided after Kingsdown, noting the perceived shift in the intent analysis. Finally, this article discusses several recent cases that may symbolize a shift to more rigorous requirements for intent to deceive.

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I. Introduction

The purpose of the patent system is to foster innovation and progress by promoting the free flow of information to the public. In order to achieve this purpose, the patent system provides a *quid pro quo*, conferring a limited right to prevent others from making, using, selling, or offering to sell an invention in exchange for full public disclosure.¹ Thus, by conferring this limited right of exclusivity, patents provide a valuable incentive for innovation. To obtain this right, however, patentees must comply with numerous requirements. Among these requirements, individuals associated with the filing or prosecution of patent applications owe a duty of candor and good faith to the United States Patent and Trademark Office (PTO).² This duty includes an obligation to disclose any known information that is material to patentability.³ By imposing this obligation, the PTO seeks to ensure that individuals bring any references that may be relevant for establishing patentability to an examiner’s attention. Courts have recognized the need to enforce this obligation to the PTO.

Developed from the equitable principle of unclean hands,⁴ inequitable conduct originated as a mechanism to punish applicants that committed willful fraud on the Patent Office. Courts understood that a harsh remedy was necessary, both to penalize offenders and to serve as a deterrent to future abuse of the patent system. Thus, the “atomic bomb” remedy of unenforceability was intended to mitigate the risk that applicants would knowingly mislead the Patent Office.⁵

Despite its original application to willful and intentional actions, inequitable conduct was gradually expanded to include negligent actions as well.⁶ Due to this expansion, it became commonplace to charge inequitable conduct in virtually every litigated case,⁷ which was not the original intent of the inequitable conduct defense. Indeed, observers have opined that it was intended to punish "only the most

². 37 C.F.R. § 1.56(a) (2008).
³. Id.
extreme cases of fraud and deception. Nevertheless, alleged infringers began pleading inequitable conduct so frequently that the Federal Circuit eventually declared it a "plague" on the patent system.

In the seminal case of *Kingsdown Medical Consultants Ltd. v. Hollister, Inc.*, the Federal Circuit moved to quarantine this plague. In *Kingsdown*, the court clarified the requirements for inequitable conduct. In order to satisfy these requirements, the court held that an omission or misrepresentation must be material to patentability and must be made with the intent to deceive the Patent Office. The court also required that both materiality and deceitful intent be proven separately by clear and convincing evidence. At the same time, the court expressly rejected the notion that negligent or even grossly negligent conduct alone could serve as the basis for an inequitable conduct finding. Instead, a party "must have intended to act inequitably" in order to be guilty of committing inequitable conduct.

Despite the standards enunciated in *Kingsdown*, an increasing number of commentators and judges have noted an apparent return to the "plague" of inequitable conduct charges. In particular, recent decisions have been criticized for relaxing the intent element to encompass actions that fall short of the substantial intent requirements established by *Kingsdown*. A majority of criticism has been focused on cases holding that specific intent to mislead the Patent Office may be inferred from the materiality of an act or omission. Even more controversial is the proposition that intent may be established when an applicant knew, or should have known, of the materiality of an act or omission. As a result of these decisions, some commentators have

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8. *Aventis*, 525 F.3d at 1349 (Rader, J., dissenting).
11. *Id.* at 872.
12. *Id.*
13. *Id.* at 876.
14. *Id.* at 872 (emphasis added) (quoting *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987)).
16. *See Aventis*, 525 F.3d at 1350 (Rader, J., dissenting).
warned of a trend towards a strict liability standard for inequitable conduct.\textsuperscript{17}

This article traces the early development of the inequitable conduct doctrine, culminating in the seminal \textit{Kingsdown} decision. Further, it analyzes the subsequent application of the inequitable conduct analysis. In the course of this overview, the article notes with concern the seeming relaxation of the inequitable conduct analysis. Of particular concern is the perceived lowering of the standard to prove deceitful intent. By inferring intent from materiality, the two elements of the inequitable conduct analysis appear to have merged. This is difficult to reconcile with \textit{Kingsdown}, which requires that both elements be independently proven by clear and convincing evidence. Thus, this paper agrees with those judges and commentators that urge a strict application of \textit{Kingsdown}'s standards.\textsuperscript{18} Absent such an application, we risk a return to the pre-\textit{Kingsdown} "plague" of inequitable conduct charges.

II. DEVELOPMENT OF INEQUITABLE CONDUCT

\textbf{A. Buildup to the "Plague"}

The doctrine of inequitable conduct can be traced to the Supreme Court's 1945 decision in \textit{Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.}\textsuperscript{19} The facts of \textit{Precision} involved a patentee's particularly egregious and fraudulent conduct. In this case, George Thomasma, an employee of Automotive Performance Machinery (Automotive), misappropriated information relating to the design of torque wrenches.\textsuperscript{20} Thomasma passed this information to a partner, Kenneth Larson, and together they developed plans for a new wrench.\textsuperscript{21} After attempts to interest other distributors failed, Larson entered into an agreement to provide Snap-On tools with the new wrench.\textsuperscript{22} Larson prepared a patent application for the wrench, but since he did not have the necessary funds to file

\begin{thebibliography}{9}
\bibitem{17} James E. Hanft \& Stacey S. Kerns, \textit{The Return of the Inequitable Conduct Plague: When "I Did Not Know" Unexpectedly Becomes "You Should Have Known,"} INTELL. PROP. \& TECH. LAW J., Feb. 2007, at 5.
\bibitem{18} See generally \textit{id.} See also \textit{Aventis}, 525 F.3d at 1350 (Rader, J., dissenting); \textit{Ferring}, 437 F.3d at 1195 (Newman, J., dissenting).
\bibitem{20} \textit{id.} at 808.
\bibitem{21} \textit{id.}
\bibitem{22} \textit{id.} at 808-09.
\end{thebibliography}
the application, he assigned it to Snap-On.\textsuperscript{23} Snap-On filed the application and took the assignment as security for performance of the agreement to manufacture the wrenches.\textsuperscript{24} Subsequently, Larson, Thomasma, and another partner, Walter Carlsen, formed Precision Instrument Manufacturing (Precision) for the purpose of manufacturing the wrench design.\textsuperscript{25} Meanwhile, Automotive filed a patent application for a similar wrench.\textsuperscript{26} After receiving both applications, the PTO declared an interference between Larson’s patent and Automotive’s patent.\textsuperscript{27}

Due to the misappropriation, Larson had no legitimate basis on which to pursue the patent application. Rather than admit his misconduct, however, he attempted to show priority of invention by filing a fraudulent statement with the PTO designating false dates for conception, disclosure, drawing, description, and reduction to practice.\textsuperscript{28} In addition, Larson claimed that he was the sole inventor of the wrench.\textsuperscript{29} This did not sit well with Thomasma, who met with representatives from Automotive and declared that he was actually the inventor of Larson’s wrench.\textsuperscript{30} Eventually realizing that he could no longer maintain his position, Larson admitted to Snap-On that the entire case was false.\textsuperscript{31}

In an interesting turn of events, Automotive saw an opportunity to benefit from the situation. Rather than notify the PTO of Larson’s misconduct, Automotive negotiated a settlement which resulted in three separate agreements among the parties.\textsuperscript{32} Under an agreement between Automotive and Snap-On, Snap-On agreed to reassign the Larson application to Precision and acknowledged the validity of the claims on patents to issue from Larson and Automotive’s applications.\textsuperscript{33} In exchange, Automotive gave Snap-On the right to sell 6,000 wrenches previously ordered from Precision and released Snap-On from all past liability or damages.\textsuperscript{34} Under a separate

\begin{itemize}
\item \textsuperscript{23} \textit{Id.} at 809 & n.2.
\item \textsuperscript{24} \textit{Id.}
\item \textsuperscript{25} \textit{Id.} at 809.
\item \textsuperscript{26} \textit{Id.}
\item \textsuperscript{27} \textit{Id.}
\item \textsuperscript{28} \textit{Id.}
\item \textsuperscript{29} \textit{Id.} at 810.
\item \textsuperscript{30} \textit{Id.}
\item \textsuperscript{31} \textit{Id.} at 811.
\item \textsuperscript{32} \textit{Id.} at 813.
\item \textsuperscript{33} \textit{Id.} at 813-14.
\item \textsuperscript{34} \textit{Id.} at 814.
\end{itemize}
agreement between Automotive and Precision-Larson, Larson conceded priority to Automotive’s patent. Larson also agreed to assign his application to Automotive in exchange for a license allowing Precision and Larson to complete the unfulfilled order for 6,000 wrenches. Further, Precision and Larson acknowledged the validity of the claims in both applications. Finally, under an agreement between Snap-On and Precision-Larson, Snap-On reassigned any remaining title in the Larson application to Larson and Precision.

After the settlement, Automotive made a number of changes to both applications and continued to prosecute them, never notifying the PTO of Larson’s fraudulent behavior. Eventually, both applications matured into patents. In a final twist of irony, Automotive accused Precision of patent infringement and breach of contract after Precision began to manufacture, and Snap-On began to sell, a new wrench. The full details of these events were subsequently uncovered during litigation.

At the outset, the court noted that matters concerning patents and patent rights are closely tied to the public interest. Thus, the public has a stake in ensuring that patents are not granted based on fraudulent or misleading conduct by a patentee.

A patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the “Progress of Science and useful Arts.” At the same time, a patent is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds

35. Id. at 813.
36. Id. As part of the settlement, Automotive also released Precision, Larson, and their customers from liability for any past infringement and gave Precision and Larson a general release as to all civil damages. Id.
37. Id. Although the case does not indicate why Precision and Larson acknowledged the validity of the claims, Automotive presumably imposed this requirement as a condition of the settlement.
38. Id. at 814.
39. Id.
40. Id. at 818.
41. Id. at 814.
42. Id.
43. Id. at 816.
free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.\textsuperscript{44}

Analyzing both Larson and Automotive's conduct under the doctrine of unclean hands, the Supreme Court declared that the patents were "steeped in perjury and undisclosed knowledge of perjury."\textsuperscript{45} The Court found that Automotive had a duty to disclose this information, declaring that "Automotive knew and suppressed facts that, at the very least, should have been brought in some way to the attention of the Patent Office."\textsuperscript{46} The Supreme court concluded that Automotive's failure to notify the Patent Office did not "conform to minimum ethical standards."\textsuperscript{47} As a result, "inequitable conduct impregnated Automotive's entire cause of action and justified dismissal by resort to the unclean hands doctrine."\textsuperscript{48} Under these circumstances, the Court determined that Automotive should not be able to enforce the perjury-tainted patents.\textsuperscript{49}

As Precision and other early Supreme Court cases demonstrate, the inequitable conduct doctrine originated in actions involving particularly egregious and fraudulent conduct.\textsuperscript{50} Indeed, the courts originally analyzed such cases under the charge of "fraud on the Patent Office."\textsuperscript{51} The standard for these actions was high, involving intentional conduct meant to mislead or deceive the Patent Office. While courts ultimately expanded the doctrine beyond the classical definition of fraud to include a wide range of inequitable conduct, courts continued to recognize that there must still be some element of willfulness or bad faith.\textsuperscript{52}

Unfortunately, the standard changed over time. Despite the origin of the doctrine in actions for fraud, courts gradually relaxed the lofty requirements for inequitable conduct. In a subsequent line of

\textsuperscript{44} Id.
\textsuperscript{45} Id.
\textsuperscript{46} Id. at 818.
\textsuperscript{47} Id.
\textsuperscript{48} Id. at 819 (citing Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 245 (1933)).
\textsuperscript{49} Precision Instrument, 342 U.S. at 816.
\textsuperscript{50} See id. See also Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238, 245-46 (1944) (condemning "a deliberately planned and carefully executed scheme to defraud not only the Patent Office but the Circuit Court of Appeals"); Keystone, 290 U.S. at 243-44 (condemning a "corrupt transaction" to "keep secret the details of [a] prior use" that would have cast doubt on the patent's validity).
\textsuperscript{51} Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988); Digital Equip. Corp. v. Diamond, 653 F.2d 701, 708 (1st Cir. 1981).
\textsuperscript{52} Digital Equip., 653 F.2d at 709.
cases, the Federal Circuit even suggested that a finding of gross negligence was sufficient to compel a finding of inequitable conduct.\textsuperscript{53} Consequently, the inequitable conduct doctrine expanded far beyond punishing fraudulent practices.\textsuperscript{54}

In the absence of strict standards, the defense was “grossly misused” and “charged in almost every case.”\textsuperscript{55} In fact, “it was irrelevant whether the examiner was in fact deceived, or whether the purported flaw in prosecution affected patentability, or whether the action was an intentional misrepresentation or at worst negligence, or whether the invention met the statutory requirements of patentability.”\textsuperscript{56} Despite a patentee’s best efforts, he or she could be virtually assured of an inequitable conduct charge in subsequent litigation, often placing the patentee in a no-win situation. For example, Judge Newman noted that “if the inventor provided selected references, he was accused of inequitable conduct in the selection; and if he provided an entire search report, he was accused of burying the significant references.”\textsuperscript{57}

In light of this explosion of inequitable conduct charges, “judges came to believe that every inventor and every patent attorney wallowed in sharp practice,”\textsuperscript{58} and “that all scientists [were] knaves and all patent attorneys [were] jackals.”\textsuperscript{59} This led the Federal Circuit to lament that “the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”\textsuperscript{60} Indeed, the court observed that “[r]eputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds.”\textsuperscript{61} Expressing its apparent frustration with the rampant abuse of the doctrine, the Federal Circuit declared that “[a] patent litigant should be made to feel, therefore, that an unsupported charge of

\begin{itemize}
\item \textsuperscript{53} Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) (citing \textit{In re Jerabek}, 789 F.2d 886, 891 (Fed. Cir. 1986); Driscoll v. Cebalo, 731 F.2d 878, 885 (Fed. Cir. 1984)).
\item \textsuperscript{54} \textit{See} Ferring B.V. v. Barr Labs, Inc., 437 F.3d 1181, 1195 (Fed. Cir. 2006) (Newman, J., dissenting).
\item \textsuperscript{55} Id.
\item \textsuperscript{56} Id. at 1196.
\item \textsuperscript{57} Id. at 1196 n.1.
\item \textsuperscript{58} Id. at 1195.
\item \textsuperscript{59} Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1372 (Fed. Cir. 2003) (Newman, J., dissenting).
\item \textsuperscript{60} Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988).
\item \textsuperscript{61} Id.
\end{itemize}
'inequitable conduct on the Patent Office' is a negative contribution to the rightful administration of justice."^62

In the end, rather than focusing on patentability or validity, litigants began to sift through every detail in the prosecution history, trying to find some fact on which to base an inequitable conduct charge. Armed with a "20-20 vision of hindsight," deep pockets, and the benefits of long and detailed discovery, litigants would attempt to uncover some act or omission to use as a basis for finding inequitable conduct.^^3 Eventually, this "plague" prompted the Federal Circuit to decide *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, in an effort "to bring objective standards and reasoned perspective to the charge of inequitable conduct."^65

**B. Kingsdown: The Attempt to Eradicate the Plague**

In *Kingsdown*, the Federal Circuit sought to mitigate the proliferation of inequitable conduct charges and to set the standard for an inequitable conduct finding. The case involved a mistake made by an attorney during a complex patent prosecution for an ostomy appliance that spanned a six and a half year period. The prosecution involved "submission, rejection, amendment, and renumbering [] of 118 claims, a continuation application, an appeal, a petition to make special, and citation and discussion of 44 references." After a succession of Office Actions and amendments, the patentee submitted claim 50 of the parent application. The examiner initially rejected this claim for indefiniteness but, after the patentee amended the claim, the examiner eventually allowed it.^^70

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62. *Id.*

63. *Id.* at 1420 (noting that the trial court "with the '20-20 vision of hindsight,' read the patent entirely differently than did those concerned with its issue"). *See N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990) (discussing "the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive"); *Hoffmann-La Roche*, 323 F.3d at 1381 (Newman, J., dissenting) (noting that with a decreased standard "every experiment done and not done, every scientific inference, every judgment or belief, is fair game for opportunist attack").


66. An ostomy appliance is a device for use by patients with openings in their abdominal walls to release waste. *Kingsdown*, 863 F.2d at 869.

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.* at 870.
Subsequently, the patentee filed a continuation application.\textsuperscript{71} In the continuation application, the patent attorney filed both new claims and claims that had previously been allowed in the parent application.\textsuperscript{72} He also created a table detailing the relationship between the claims in the continuation application and the previously allowed claims.\textsuperscript{73} In this table, the patent attorney indicated that claim 43 of the continuation corresponded to the amended claim 50 from the parent application.\textsuperscript{74} In reality, claim 43 in the patent attorney’s table actually corresponded to the unamended claim 50, which had been rejected by the examiner for indefiniteness.\textsuperscript{75} Neither the attorney nor the examiner noticed the mistake and the patent ultimately issued with the original claim 50.\textsuperscript{76} During subsequent litigation, the district court found that the attorney was grossly negligent in failing to catch the mistake\textsuperscript{77} and declared the patent unenforceable due to inequitable conduct.\textsuperscript{78} The district court came to this conclusion without any evidence suggesting deceptive intent.\textsuperscript{79}

Reversing the district court’s ruling, the Federal Circuit delineated the requirements for inequitable conduct. The court observed that “[t]o be guilty of inequitable conduct, one must have \textit{intended} to act inequitably.”\textsuperscript{80} Thus, the court separated the inequitable conduct analysis into two distinct elements, requiring the challenger to prove:

1) The patentee failed to submit material information to the PTO, or submitted false information; and

2) The material information was withheld or advanced with the intent to deceive.\textsuperscript{81}

In addition, the court declared that both elements must be proven separately by clear and convincing evidence and required that any

\begin{itemize}
  \item \textsuperscript{71} Id.
  \item \textsuperscript{72} Id.
  \item \textsuperscript{73} Id.
  \item \textsuperscript{74} Id.
  \item \textsuperscript{75} Id. at 871.
  \item \textsuperscript{76} Id. at 873.
  \item \textsuperscript{77} Id. at 871-72.
  \item \textsuperscript{78} Id. at 869.
  \item \textsuperscript{79} Id. at 872.
  \item \textsuperscript{80} Id. (emphasis added) (quoting FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987)).
  \item \textsuperscript{81} Id. (citing J.P. Stevens & Co., Inc. v. Lex Tex Ltd., 747 F.2d 1553, 1559 (Fed. Cir. 1984)).
\end{itemize}
evidence of good faith be considered in the inequitable conduct calculus.82

Addressing the intent element as it pertained to the facts of the case, the court found that there was no evidence that the patent attorney intended to act inequitably or that he intended to deceive the Patent Office.83 The transfer of claims en masse was a ministerial act.84 As such, the court acknowledged that it was prone to errors resulting from mere inattention rather than intentional omission.85 In short, there was nothing to suggest that this was anything more than an inadvertent mistake.

More importantly, the en banc portion of the Kingsdown decision expressly rejected the proposition that gross negligence may be used to infer inequitable conduct.86 It acknowledged that “[s]ome of [its] opinions have suggested that a finding of gross negligence compels a finding of intent to deceive.”87 But the court went on to expressly overrule such cases, declaring that “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive.”88 Rather, the patentee’s “conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.”89

Further, as discussed in greater detail below, Kingsdown did not hold that intent may be inferred from materiality. Kingsdown explicitly notes that materiality and intent are distinct elements that must be proven by clear and convincing evidence.90 Nothing in the opinion intimates that evidence of one element may be inferred based on the existence of the other. On the contrary, the court seemingly suggested the opposite, noting that since intent was not present “it is unnecessary to discuss materiality.”91

82. Id.
83. Id. at 873.
84. Id. at 875.
85. Id.
86. Id. at 876 (en banc).
87. Id. (citing In re Jerabek, 789 F.2d 886, 891 (Fed. Cir. 1986); Driscoll v. Cebalo, 731 F.2d 878, 885 (Fed. Cir. 1984)).
88. Id.
89. Id. (emphasis added).
90. Id. at 872.
91. Id. at 872 n.5 (citing Allen Archery, Inc. v. Browning Mfg. Co., 819 F.2d 1087, 1094 (Fed. Cir. 1987)).
III. THE POST *KINGSDOWN* ERA

While *Kingsdown* remains the leading case for inequitable conduct, some commentators and Federal Circuit judges maintain that subsequent decisions have eroded "the lofty intent requirement for inequitable conduct." As a result, they contend that intent and materiality have been presumed "at levels far below the *Kingsdown* rule," thus "reviv[ing] the inequitable conduct tactic." This section focuses on several cases since *Kingsdown* that have been criticized for reverting to lower thresholds for inequitable conduct.

A. Critikon

1. Inferring Intent From Materiality

*Critikon, Inc. v Becton Dickinson* was one of the first post-*Kingsdown* cases to generate controversy. In *Critikon*, the Federal Circuit charged a plaintiff with inequitable conduct for failing to disclose two pieces of information to the PTO in a patent infringement suit. First, the patentee failed to disclose a prior art patent during prosecution. Second, the plaintiff commenced reissue proceedings after litigation had been initiated, but did not notify the PTO that the patent was involved in litigation and that claims of invalidity and inequitable conduct had been asserted against it. The district court failed to find the requisite intent to deceive the PTO and held the patents enforceable. Upon review, however, the Federal Circuit reversed the district court’s decision.

Some commentators’ objections to *Critikon* stem from the court’s statement that "intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO’s consideration of the patent application." At the outset, it is important to note that the court relied on *Driscoll v. Cebalo*, a case decided prior to *Kingsdown*, to support this proposition. Several commentators have noted, however, that

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93. *Id.*
95. *Id.* at 1255.
96. *Id.*
97. *Id.*
98. *Id.* at 1259.
99. *Id.* at 1256 (citing *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984)).
Kingsdown specifically overruled Driscoll on this precise issue.100 Discussing several cases under the heading “Resolution of Conflicting Precedent,” the Kingsdown court cited Driscoll as “suggest[ing] that a finding of gross negligence compels a finding of intent to deceive.”101 Yet in the very next paragraph, the en banc court rejected this suggestion, finding that “‘gross negligence’ does not of itself justify an inference of intent to deceive.”102 Accordingly, some judges and observers have urged that Critikon’s proposition that intent may be inferred where the applicant knew, or should have known of materiality, is ultimately based on bad law.103 This is important because a number of subsequent cases draw support for this proposition from either Critikon directly, or from other cases that rely on Critikon.104

Aside from Critikon’s reliance on Driscoll, language from other Federal Circuit majority opinions suggest that this proposition (inferred intent) does not conform to the requirements articulated in Kingsdown.105 These cases emphasize that materiality and intent are

100. Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1202 (Fed. Cir. 2006) (Newman, J., dissenting) (noting that this proposition from Critikon was supported solely by reference to Driscoll, “a case that was overruled en banc by Kingsdown on this very point”). See also, Lynn C. Tyler, Kingsdown Fifteen Years Later: What Does It Take to Prove Inequitable Conduct?, 13 FED. CIR. B.J. 267, 276 (2003-2004) (noting that, to the extent cases such as Critikon stand for the proposition that intent may be inferred from materiality, “they are bad law because ultimately they all rest on a decision that the Federal Circuit expressly overruled in Kingsdown.”).


102. Id.

103. Ferring, 437 F.3d at 1202 (Newman, J., dissenting) (“Thus, this aspect of Critikon, Inc. has been correctly identified by practitioners as ‘bad law,’ both because it relies on the overruled Driscoll decision and because it is representative of a recent resurgence of the plague that Kingsdown had intended to cure.”). See also Tyler, supra note 100 at 276.

104. See, e.g., Ferring, 437 F.3d at 1191.

105. Indeed, a number of cases decided by various Federal Circuit panels have emphasized that materiality and intent are distinct factors to be proven separately. See, e.g., Allen Eng’g Corp. v. Bartell Indus., 299 F.3d 1336, 1352 (Fed. Cir. 2002) (“[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.”’ (quoting Allen Organ Co. v. Kimball Int’l, Inc. 839 F.2d 1556, 1567 (Fed. Cir. 1988))); Kao Corp. v. Unilever U.S., Inc., 441 F.3d 963, 972 (Fed. Cir. 2006) (holding that intent to deceive could not be inferred from materiality, despite a “rather glaring failure of the inventors to offer any rationale for the omission”); Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365-66 (Fed. Cir. 2008) (“[A]t least a threshold level of each element—i.e., both materiality and intent to deceive—must be proven by clear and convincing evidence” and “‘materiality’ does not presume intent, which is a separate and essential component of inequitable conduct” (quoting GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001)); Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1356 (Fed. Cir. 2008) (“Materiality is not evidence of intent, which must be established as a separate factual element”). Despite these cases, some judges on the Federal Circuit have
separate factors that must be independently proven by clear and convincing evidence. To be sure, since there is rarely direct evidence of intent to deceive, the cases accepted that intent may be proven from indirect evidence and the surrounding circumstances. But commentators posit that inferring intent from circumstantial evidence indicating deceitfulness is fundamentally different from inferring intent based on a "should have known" standard of materiality. While certain facts may be relevant to both inquiries, inferring intent directly from materiality would appear to reduce the inequitable conduct analysis to a single element test. Further, other cases have explicitly noted that indirect evidence used to infer intent must still be clear and convincing and "inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement."

Moreover, there is another argument suggesting that the notion that intent can be inferred from materiality conflicts with *Kingsdown*. In this case, the *Kingsdown* decision may be notable for what it did not analyze. Specifically, the *Kingsdown* court did not reach the issue of materiality, determining that such an inquiry was unnecessary in light of its holding on intent. But if the *Kingsdown* court declared that other cases continue to incorrectly infer intent from materiality in violation of *Kingsdown*. See *Ferring*, 437 F.3d at 1201, 1203 (Fed. Cir. 2006) (Newman, J., dissenting) (opining that the majority's finding of deceptive intent where an applicant knew or should have known that omitted information was material was "directly contrary to *Kingsdown*" and "further revives the 'plague' of the past, with burdens that far outweigh any conceivable benefits"); *Hoffmann-La Roche*, Inc. v. Promega Corp., 323 F.3d 1354, 1373 (Fed. Cir. 2003) (Newman, J., dissenting) (stating that by inferring intent, the majority cast the safeguards of *Kingsdown* aside and "finds misrepresentation in correct science, infers malevolence from verb tense, and grounds intent to deceive on personal slurs by a hostile witness"); *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1350 (Fed. Cir. 2008) (Rader, J., dissenting) (noting that "the judicial process has too often emphasized materiality almost to the exclusion of any analysis of the lofty intent requirement" and, in so doing, has "[m]erg[ed] intent and materiality at levels far below the *Kingsdown* rule").

106. *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997); *Star Scientific*, 537 F.3d at 1366 ("We have also held that because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence.").

107. Hanft & Kerns, *supra* note 17, at 3 ("While inferences may be drawn from circumstantial evidence, an inference based on a should-have-known standard [of materiality] . . . is not an inference based on circumstantial evidence. It is an inference based on something more nebulous and does not meet the *scienter requirements of Kingsdown*.")

108. *Abbott*, 544 F.3d at 1356 ("Materiality is not evidence of intent, which must be established as a separate factual element").


110. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 n.5 (Fed. Cir. 1988) ("Because of our decision on intent, it is unnecessary to discuss materiality"). See also *Star Scientific*, 537 F.3d at 1367 ("If a threshold level of intent to deceive or materiality is not established by clear and convincing evidence, the district court does not have any discretion to
contemplated that intent could be inferred from materiality, it would seem that its analysis was incomplete. In that event, the court should have addressed the materiality element to determine whether it rose to a level sufficient to infer intent. The court’s silence in this regard thus seems to conflict with the proposition that intent could be inferred from materiality.

Finally, the idea that intent may be inferred based on a "should have known" standard has been criticized as invoking negligence principles. Kingsdown states that the accused conduct must be sufficiently blameworthy to require a finding of deceitful intent and holds that even gross negligence is not sufficient for an inequitable conduct finding. Thus, while Kingsdown rejects the notion that inequitable conduct can be based on mere negligence, Critikon’s inference of intent based on what a person "should have known" has been criticized for injecting negligence principles into the analysis.

2. Balance and Burden

A separate question raised is whether Critikon balanced materiality and intent prematurely. It is accepted that "[o]nce thresholds of materiality and intent have been established, the court conducts a balancing test and determines whether the scales tilt to a conclusion that ‘inequitable conduct’ occurred." The threshold levels of each element, however, must still be established by clear and convincing evidence prior to balancing; inferences drawn from lesser evidence cannot satisfy these requirements. To establish a threshold exercise and cannot hold the patent unenforceable regardless of the relative equities or how it might balance them.

111. Furthermore, had the court analyzed materiality according to Critikon, it is likely that it would have risen to a sufficient level to infer intent. See Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334, 1350 (Fed. Cir. 2008) (Rader, J., dissenting) (referring to Kingsdown, Judge Rader notes that "it is hard to imagine a more material mistake than reasserting claims to rejected subject matter").

112. David Hricik, Where The Bodies Are: Current Exemplars of Inequitable Conduct and How to Avoid Them, 12 TEX. INTELL. PROP. L.J. 287, 295 (2004) ("The issue of whether a person ‘should have known’ of the materiality of information obviously turns on negligence principles."); Shashank Upadhye, Liar Liar Pants on Fire: Towards a Narrow Construction for Inequitable Conduct as Applied to the Prosecution of Medical Device and Drug Patent Applications, 72 U. MO. KAN. CITY L. REV. 669, 697 (2003-2004) ("Gross negligence though, which generally uses the ‘knew or should have known’ standard, is not enough [to find intent to deceive]. . . . Thus, the standard of ‘knew or should have known’ is not the proper standard.").

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


115. Star Scientific, 537 F.3d at 1366.
level of intent, clear and convincing evidence must prove that the
applicant had the specific intent to mislead or deceive the PTO.\textsuperscript{116}

The court in \textit{Critikon} noted the necessity of establishing
"thresholds of materiality and intent,"\textsuperscript{117} but it inferred intent based on
the materiality of the omission. Indeed, the court stated that "a
patentee facing a high level of materiality and clear proof that it knew
or should have known of that materiality can expect to find it
difficult...to prevent the drawing of an inference of intent to
mislead."\textsuperscript{118} Nonetheless, if intent cannot be inferred from materiality,
as posited above, it follows that the threshold level of intent could not
have been established based on this inference. In that event, it would
be premature to balance the elements without analyzing independent
evidence of intent.

This also raises an additional question regarding the shift in the
burden of proof. The \textit{Critikon} court stated that "a patentee facing a
high level of materiality and clear proof that it knew or should have
known of that materiality, can expect to find it difficult to establish
'subjective good faith' sufficient to prevent the drawing of an
inference to mislead."\textsuperscript{119} In essence, this appears to shift the burden to
the patentee to provide a good faith explanation once an accused
infringer has shown materiality. Again, however, if intent cannot be
inferred from materiality, the accused infringer would have only
proven one prong of the inequitable conduct test. In this event, it
would seem that the burden of proof was shifted to the patentee
before the accused infringer met its burden of proof.\textsuperscript{120} Indeed, the
Federal Circuit has noted elsewhere that

\begin{quote}
[the patentee need not offer any good faith explanation unless the
accused infringer first carried his burden to prove a threshold level
of intent to deceive by clear and convincing evidence. Only when
the accused infringer has met this burden is it incumbent upon the
patentee to rebut the evidence of deceptive intent with a good faith
explanation for the alleged misconduct.\textsuperscript{121}
\end{quote}

\begin{itemize}
\item \textsuperscript{116} Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995).
\item \textsuperscript{117} \textit{Critikon}, 120 F.3d at 1256.
\item \textsuperscript{118} \textit{Id.} at 1257.
\item \textsuperscript{119} \textit{Id.}
\item \textsuperscript{120} \textit{Star Scientific}, 537 F.3d at 1368 ("[The accused infringer] cannot carry its burden
simply because [the patentee] failed to prove a credible alternative explanation.").
\item \textsuperscript{121} \textit{Id.} (emphasis added) (citation omitted).
\end{itemize}
Thus, Critikon's holding not only raises questions regarding whether intent may be inferred from materiality, but it also raises questions regarding equitable balancing and the burden of proof.

B. Novo Nordisk

Some commentators opine that the court in Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.122 expanded the "should have known" standard even further. In this case, the controversy centered on an example in a patent application, filed by Danish inventors that were directed to a process for producing human growth hormone (hGH).123 The example described the production, purification, and evaluation of a fusion protein124 as well as the treatment of fusion proteins with an enzyme to produce ripe hGH.125 Nonetheless, while the final step of the example was written in past tense, the inventors had not actually prepared hGH according to the example at the time the application was filed.126 This was clearly not in compliance with PTO regulations, which, while allowing paper or prophetic examples, require them to be written in present tense.127 Notably, the district court acknowledged that during prosecution the inventor was not aware of this requirement and thus "did not intentionally breach his duty of candor and good faith."128 Further, though the patent attorney would have been aware of this requirement, there was no evidence that the patent attorney discovered that the inventor had not actually performed the final step. Despite these facts, the district court found inequitable conduct,

123. Id. at 1349.
124. Id. at 1357.
125. Id.
126. Id. For instance, the example stated that "'[t]he fusion product was purified from this extract," that "'[t]he purified fusion protein was evaluated to be more than 98% pure," and that "'[t]his . . . product was then treated with leucine aminopeptidase." Id.
127. U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2004 (8th ed., rev. 7 2008) ("Paper or prophetic examples should not be described using the past tense.").
128. Novo Nordisk, 424 F.3d at 1361 n.12. The appellate court further elaborated that "the [district] court concluded 'that Mr. Christensen's use of past tense was merely an oversight on his part, likely due to the fact that Dr. Christensen is trained as a scientist, not as a patent attorney familiar with the teachings of the MPEP.'" Id. See also Hanft & Kerns, supra note 17 at 2 ("The district court acknowledged that the Danish inventor did not know that verb tense could change the meaning of an example during patent prosecution and found no intent to deceive based on this mistake at the time of filing.").
holding that knowledge of the law, or in this case an MPEP provision, was chargeable to the inventor.\textsuperscript{129}

The Federal Circuit affirmed the finding of inequitable conduct. Specifically, it agreed that “knowledge of the law is chargeable to the inventor,” and ‘inventors represented by counsel are presumed to know the law.’\textsuperscript{130} Since the inventor knew the example was prophetic, and since the court charged him with knowledge of the MPEP, the court found that he “knew or should have known” that the verb tense was material.\textsuperscript{131} As a result, the court found that the inventor had deceitful intent.\textsuperscript{132} The court dismissed the plaintiff’s defense, stating:

Novo asks us to hold, on the one hand, that the failure of Dr. Christensen and his co-inventors to disclose the truth about Example 1 to Novo’s attorneys absolves them of their duty to disclose this information to the PTO or the Board, because without their attorney’s consultation, they could not have known that this information was material. At the same time, Novo asks us to hold that its counsel’s failure to disclose the truth about Example 1 to the PTO or Board is excused because the inventors failed to fully inform them of the details surrounding Example 1. As we have done in similar situations in the past, we reject the “circular logic” of this request.\textsuperscript{133}

The imputation of knowledge from one party to another has been the target of controversy.\textsuperscript{134} As other decisions have noted, a

\textsuperscript{129} Hanft \& Kerns, supra note 17 at 3.
\textsuperscript{130} Novo Nordisk, 424 F.3d at 1361. Both the defendant and the court based this proposition on the statement in Brasseler, U.S.A. I., L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1385 (Fed. Cir. 2001), that “knowledge of the law is chargeable to the inventor.” Brasseler, in turn, relied on two prior cases for this proposition. See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995); FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 n.8 (Fed. Cir. 1987). However, one commentator has noted:

Neither Molins nor FMC Corp. support the proposition that knowledge of the law is chargeable to applicants in order to determine whether an applicant knew of the materiality of the information. Instead, what each holds is that if a person substantively involved in prosecution of an application commits inequitable conduct, that person’s misconduct is chargeable to the applicant, and thus the applicant’s patent is unenforceable. The Brasseler court’s imputation of information from one person to another is, I believe, unprecedented in inequitable conduct law.

Hricik, supra note 112 at 295 n.39 (citations omitted) (emphasis added).

\textsuperscript{131} Novo Nordisk, 424 F.3d at 1361.
\textsuperscript{132} Id. at 1362.

\textsuperscript{133} Id. at 1361-62.

\textsuperscript{134} See Hanft \& Kerns, supra note 17, at 1 (“A disturbing trend has emerged in recent inequitable conduct decisions from the Court of Appeals for the Federal Circuit. When viewed
defendant must prove that an applicant had "the specific intent to . . . mislead[] or deceiv[e] the PTO." But commentators reason that "[a] person cannot form a specific intent to deceive without having actual knowledge of the materiality of information or at least by intentionally avoiding learning about material information after being put on notice." Thus, the defendant's argument can reasonably be viewed as involving two concepts. First, inventors cannot have a specific intent to deceive if they do not know that something, such as verb tense, is critical. Second, patent attorneys cannot have the specific intent to deceive, absent knowledge that the inventors did not actually perform a step in an example. While miscommunication between an attorney and inventor should not be encouraged, it is difficult to characterize it as constituting a specific intent to deceive.

Consequently, commentators from a firm that represented Novo during its appeal portrayed the decision in the following manner:

What the Federal Circuit did was to charge knowledge of the law (or in this case, a specific provision of the MPEP about the effect of tenses in the English language in a biotechnology patent) 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. These commentators have characterized the court's so-called "double inference" as "disturbing." Further, they contend that such inferences do not meet the requirements of Kingsdown. Indeed, it is difficult to reconcile the notions that an inventor who committed an "oversight" and who "did not intentionally breach his duty of candor" nevertheless had the specific intent to deceive the PTO. Based on the holding in Novo, these commentators have argued that the inventor

over a period of decades, the pendulum swings back and forth regarding the case with which a finding can be made of inequitable conduct."). See also Hricik, supra note 112 at 295 (opining that the Federal Circuit in Brasseler "applied an even more unusual gloss on this issue when it applied what amounts to an almost strict liability standard" by imputing knowledge of what constituted a sale under patent law to inventors). Indeed, "[t]he Brasseler court's imputation of information from one person to another is, I believe, unprecedented in inequitable conduct law." Id. n.39 (emphasis added).

135. Molins, 48 F.3d at 1181.
136. Hanft & Kerns, supra note 17 at 3.
137. Id.
138. Id.
139. Id.
and patent attorney must be virtual "mind-readers" throughout prosecution.\textsuperscript{140}

In sum, the proposition that knowledge can be imputed to the inventor has been criticized as moving away from \textit{Kingdown}'s requirements toward a strict liability standard.\textsuperscript{141} Further, commentators have criticized this shift as imposing harsh requirements on both inventors and patent attorneys.\textsuperscript{142} In light of the intricacies of patent law and practice, inferring intent by imputing knowledge of materiality may indeed be fraught with hazard and uncertainty.

\textbf{C. Ferring}

In \textit{Ferring B.V. v. Barr Laboratories, Inc.},\textsuperscript{143} the court considered a case involving the submission of declarations to the PTO during patent prosecution. The inventors, who had assigned all their rights to their employer Ferring, claimed a medicinal peptide compound and a method of administering the compound whereby it was absorbed in the gastrointestinal tract.\textsuperscript{144} Initially, the examiners were concerned that a prior art reference ('491 patent) discussing the peroral application of a peptide anticipated the invention.\textsuperscript{145} The inventors disagreed that the peroral application in the '491 patent anticipated the invention, so the patent examiners suggested that the inventors submit non-inventor affidavits to support their interpretation of the term "peroral."\textsuperscript{146} The inventors complied, submitting two declarations from non-inventors opining that the peroral application of a peptide, as disclosed in the '491 patent, did not anticipate the patentee's invention.\textsuperscript{147} Nevertheless, the examiners rejected the claims as anticipated or obvious in light of the '491 patent.\textsuperscript{148} After appeal, the Board of Patent Appeals and Interferences (BPAI) found that the invention was not anticipated by the '491 patent, but was

\textsuperscript{140} \textit{Id.} at 5.
\textsuperscript{141} \textit{Id.}
\textsuperscript{142} \textit{Id.}
\textsuperscript{143} \textit{Ferring B.V. v. Barr Labs., Inc.}, 437 F.3d 1181 (Fed. Cir. 2006).
\textsuperscript{144} \textit{Id.} at 1183.
\textsuperscript{145} \textit{Id.} at 1183 (stating the examiners were concerned that the use of the term "peroral" in the prior art reference encompassed oral administration of a peptide for gastrointestinal absorption).
\textsuperscript{146} \textit{Id.} at 1183-84.
\textsuperscript{147} \textit{Id.} at 1184. The affidavits relayed the writer's belief that the term "peroral" in the prior art reference meant that the compound could be administered orally, but could only be absorbed through the cheek or under the tongue rather than through the gastrointestinal tract. \textit{Id.}
\textsuperscript{148} \textit{Id.} at 1184.
rendered obvious by the '491 patent in light of another reference.\textsuperscript{149} To overcome this rejection, the inventors submitted four additional declarations from non-inventors, explaining why the invention was not obvious in light of the cited art.\textsuperscript{150}

The key issue centered on the fact that the inventors failed to disclose that several of the affidavits were written by scientists that had either been previously employed by Ferring or that received funding from Ferring.\textsuperscript{151} Notably, the court found that the inventors only knew of prior relationships between Ferring and two of the four affiants.\textsuperscript{152} Nevertheless, the district court granted the defendant's motion for summary judgment on inequitable conduct based on the omissions of these prior relationships.\textsuperscript{153}

As an initial matter, it is important to note that there was no evidence that any of the affiants presented a false opinion in their affidavits, that the affidavits deceived the examiner, or that the affiants provided misinformation.\textsuperscript{154} Thus, the analysis did not focus on the materiality or accuracy of the scientific information itself, but rather on the materiality of the affiants' relationship to the inventor.\textsuperscript{155} Noting that materiality does not presume intent, the majority went on to state that "in the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information."\textsuperscript{156} Referencing earlier cases, the court stated that summary judgment is appropriate on the issue of intent where an applicant fails to supply highly material information and

1. the applicant knew of the information;
2. the applicant knew or should have known of the materiality of the information; and

\textsuperscript{149} Id.
\textsuperscript{150} Id. at 1185. One of the inventors also submitted a declaration.
\textsuperscript{151} Id. at 1186.
\textsuperscript{152} While three of the scientist had a prior relationship, it was unclear whether the inventor was aware of the relationship between Ferring and the third affiant. Id. at 1191 & n.12. Note, however, that the dissent states that the evidence only showed that the inventor knew of one of these affiliations. Id. at 1198 (Newman, J., dissenting). Further, the dissent declared that the majority's description of "intimate ties" between the affiants and inventor was a "mischaracterization" and described the inference of bias as a "travesty." Id.
\textsuperscript{153} Id. at 1186.
\textsuperscript{154} Id. at 1199 (Newman, J., dissenting).
\textsuperscript{155} Id.
\textsuperscript{156} Id. at 1191 (majority opinion) (quoting Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1354 (Fed. Cir. 2005)).
3. the applicant has not provided a credible explanation for his withholding.\textsuperscript{157}

Addressing the facts of the case, the court first concluded that the undisclosed information was highly material.\textsuperscript{158} Moving to intent, the court analyzed the three factors enumerated above. The court concluded that the inventor knew of past relationships between two of the affiants and Ferring, thus satisfying the first prong of the test.\textsuperscript{159} Next, the court concluded that the examiner’s request for “non-inventor” affidavits put the inventor on notice that “disinterested affidavits” were necessary, and thus the inventor should have known that the past relationships were material.\textsuperscript{160} Finally, the court concluded that the patentee’s various explanations for the omission were inadequate.\textsuperscript{161} Based on these findings, the court found the omission of the relationships sufficient to infer intent to deceive the PTO.

\textsuperscript{157.} Id. (citing Bruno, 394 F.3d at 1354; Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997)).

\textsuperscript{158.} Id. at 1190.

\textsuperscript{159.} Id. at 1191. There appears to be a discrepancy between the majority and dissent regarding the number of affiant relationships the inventor was aware of. While the majority states that the inventor knew of past relationships between Ferring and two of the inventors, the dissent states that the inventor knew of only one such affiliation. Id. at 1198 (Newman, J., dissenting).

\textsuperscript{160.} Ferring, 437 F.3d at 1192. To support this proposition, the majority cited Refac Int’l Ltd. v. Lotus Dev. Corp., 81 F.3d 1576, 1581-82 (Fed. Cir. 1996). But the dissent opined that this case did “not support the sweeping inference now applied.” Ferring, 437 F.3d at 1199. Indeed, the dissent distinguished Refac based on the fact that the declarant in that case had been an employee of the inventor’s company, he “had worked with and reviewed documentation for the commercial embodiment of the invention,” and he “recognized the flow chart [of the computer program invention] as being essentially the same one” shown to him during training. Id. (citations omitted). Thus, “the relevant omitted material information [concerned] the declarant’s prior experience with the invention.” Id.

\textsuperscript{161.} The court characterized the crux of appellants’ explanation as essentially arguing “that there are possible benign explanations for the withholding and that evidence might have been developed at trial to support those theories.” Id. at 1192. The court rejected this argument, noting that on summary judgment appellants bore the burden of submitting an affidavit to contradict the movant’s evidence of intent. Id. Thus, appellants could not create a genuine issue by suggesting that they “might have proffered favorable evidence at trial.” Id.

In addition, appellants offered several specific arguments to explain the omission. First, they argued that the inventor who obtained the affidavits, “as a foreign scientist, was not familiar with patent prosecution, and therefore would not have known of ‘some obligation to disclose declarants’ associations with Ferring.’” Id. The court rejected this argument, asserting that there was no evidence to support the inventor’s lack of knowledge. Id. Further, appellants argued that “there was no reason for Dr. Vilhardt [the inventor], a foreigner and non-lawyer, to have understood the examiner to be requesting declarations from persons with no relationship to Ferring.” Id. at 1193. Again, the court declared that appellants “offered nothing to support such an inference.” Id. In sum, the court concluded that appellants’ “argument concerning credible explanations consists entirely of speculation.” Id.
The *Ferring* ruling is notable because there was no suggestion that the examiner would have weighed the declarations differently.\(^{162}\) Indeed, the majority noted that there was nothing inherently wrong with these types of declarations at all.\(^{163}\) The majority recognized that it may be "completely natural for the inventor to recommend, and even contact, his own colleagues . . . and to submit declarations from such people."\(^{164}\) Further, "[n]othing in this opinion should be read as discouraging such practice."\(^{165}\) Nevertheless, the majority found that the relationships were material, inferring intent to mislead the PTO based on their omission.

In dissent, Judge Newman asserted that the defendant presented no evidence of deceptive intent.\(^{166}\) Judge Newman charged that the majority "infers material misrepresentation, infers malevolent intent, and presumes inequitable conduct . . . on the theory that the inventor 'should have known' that something might be deemed material."\(^{167}\) She contended that the majority, "steeped in adverse inferences, holds that good faith is irrelevant and presumes bad faith."\(^{168}\) While acknowledging that dishonest persons rarely confess to wrongdoing, she declared that "the court goes too far in establishing such deceptive intent as a matter of law based on inference as to what an inventor 'should have known.'"\(^{169}\) Thus, she alleged that the panel majority "not only ignore[d] *Kingsdown* and restore[d] a casually subjective standard, they also impose a positive inference of wrongdoing, replacing the need for evidence with a 'should have known' standard."\(^{170}\)

Judge Newman also noted the impropriety, in her opinion, of making such an inference on summary judgment.\(^{171}\) She characterized the majority's assertion that Ferring offered no evidence to support its position as "untenable."\(^{172}\) Instead, the evidence seemed susceptible to

\(^{162}\) *Id.* at 1199 (Newman, J., dissenting). In fact, an examiner later dismissed the requested declarations defining the term "peroral," finding that they were unnecessary. *Id.* at 1197 n.2.

\(^{163}\) *Id.* at 1194-95.

\(^{164}\) *Id.* at 1195.

\(^{165}\) *Id.*

\(^{166}\) *Ferring*, 437 F.3d at 1201 (Newman, J., dissenting).

\(^{167}\) *Id.* at 1196.

\(^{168}\) *Id.* at 1197.

\(^{169}\) *Id.* at 1201.

\(^{170}\) *Id.* at 1196.

\(^{171}\) *Id.* at 1204.

\(^{172}\) *Id.* at 1205.
different interpretations.\textsuperscript{173} In light of these issues, Judge Newman felt it was inappropriate to decide the issue on summary judgment:

At a minimum, the issue should be remanded, on correct law. It is not the law that a declarant’s past affiliations are always material, and it surely is not the law that “should have known” establishes deceptive intent, which requires scienter and deliberateness. On its face, “the involved conduct viewed in light of all the evidence,” does not “indicate sufficient culpability to require a finding of intent to deceive,” the standard of \textit{Kingsdown}. It is improper to convict this inventor of fraudulent conduct based on inference, on summary judgment. That is not the law, and it is not a just procedure.\textsuperscript{174}

Thus, in holding that deceptive intent may be established as a matter of law where an applicant should have know that information was material, Judge Newman charged that the majority “further revives the ‘plague’ of the past, with burdens that far outweigh any conceivable benefits.”\textsuperscript{175}

In the end, this outcome illustrates the different views of the inequitable conduct test within the Federal Circuit. It also exemplifies the controversy in inferring intent based on a “should have known” standard of materiality. In this case, the inventor strictly complied with the requirement for non-inventor affidavits. Further, there is merit in the contention that a request for non-inventor affidavits is not the same as a request for disinterested affidavits. Thus, without more, it is difficult to construe this omission as containing the requisite \textit{scienter} for a finding of specific intent to deceive the PTO, particularly on summary judgment.

\textsuperscript{173} For instance, in this case the examiner asked for declarations from a “non-inventor.” \textit{Id.} at 1184. The inventor strictly complied with this request, as none of the four remaining affiants were inventors. \textit{Id.} at 1197 (Newman, J., dissenting). Judge Newman distinguished this from the case of \textit{Paragon Podiatry}, relied on by the majority, where the examiner asked for declarations from a “disinterested third party.” \textit{Id.} at 1199. Further, in \textit{Paragon Podiatry} the affiants, who were former consultants that owned stock in the assignee’s company, engaged in deceptive behavior by telling a “half-truth” in their declarations. Specifically, their declarations contained “the carefully worded statement that they were not ‘in the past employed by nor do I intend in the future to be employed by’ the patentee.” \textit{Id.} (citing \textit{Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.}, 984 F.2d 1182, 1191-92 (Fed. Cir. 1993)).

\textsuperscript{174} \textit{Id.} at 1205 (citation omitted).

\textsuperscript{175} \textit{Id.} at 1203.
D. Dippin' Dots

Another recent case in the inequitable conduct arena is Dippin' Dots, Inc. v. Mosey. In this case, Dippin' Dots (DDI) was the exclusive licensee of a patent directed to a method for making ice-cream. DDI brought an infringement suit against former distributors that entered into competition against it. In defense, the distributors claimed inequitable conduct based on the inventor's failure to disclose to the PTO a sale of the ice cream made more than one year prior to its application date. Specifically, the inventor had sold samples of the product at a market over the course of several days to obtain "test-marketing information." The inventor claimed that he only practiced the first three steps of the method and that the method, as practiced at the market, could not be commercially exploited. Considering the sales to fall within the experimental use exception to 35 U.S.C. 102(b), the patent attorney did not disclose them to the PTO. Nevertheless, the district court found that this omission constituted inequitable conduct and the Federal Circuit affirmed.

The concern in the Dippin' Dots case lies in the court's rather broad statements regarding the type of evidence sufficient to satisfy the intent element. At the outset, the court declared that "[s]moking gun' evidence is not required in order to establish an intent to deceive.... Rather, this element of inequitable conduct] must generally be inferred from the facts and circumstances." Analyzing the particular facts of the case, the court acknowledged that "a finding of intent may not be particularly strong here." Indeed, the Federal Circuit rejected the district court's characterization that the intent to

176. Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337 (Fed. Cir. 2007).
177. Id. at 1340.
178. Id. at 1341.
179. Under 35 U.S.C. § 102(b), an inventor shall be entitled to a patent unless the invention was "in public use or on sale in the country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b) (2006). There is a limited experimental use exception to section 102(b) whereby the inventor may use the invention for certain experimental purposes more than one year prior to filing an application. See generally Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. CHI L. REV. 1017 (1989).
180. Dippin' Dots, 476 F.3d. at 1340.
181. Id. at 1341.
182. Id.
183. Id. at 1345 (alterations in original) (quoting Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1189-90 (Fed. Cir. 1993)).
184. Id. at 1346 (emphasis added).
deceive was "of a high nature," concluding instead that "the evidence reveals less than an egregiously willful intent to deceive." Nevertheless, the Federal Circuit declared that "the district court was permitted to balance the relatively weak evidence of intent."

A troubling aspect of these statements is their seemingly expansive reach and potential for broad interpretation. To be sure, the court acknowledged that an applicant must establish threshold levels of materiality and intent. But it is unclear how a threshold level of intent, requiring clear and convincing evidence, can be established by "relatively weak evidence." The opinion offers no guidance to suggest how parties may reconcile these apparently different levels of evidence. Without more, there is a risk that litigants may point to this decision in an effort to lower the threshold for intent as a practical matter.

This case raises additional questions regarding the accused infringer’s showing of intent. Rejecting a Walker Process antitrust claim for insufficient proof of intent, the court recognized that an omission such as this "could happen for any number of nonfraudulent reasons—the applicant could have had a good-faith belief that disclosure was not necessary, or simply have forgotten to make the required disclosure." Further, the court noted that "the defendants submitted no evidence of their own—aside from the absence of the Festival market sales from the prosecution record—which affirmatively shows DDI’s fraudulent intent." Addressing the intent element, the court noted that for a Walker Process antitrust claim, "there must be evidence of intent separable from the simple fact of the omission."

185. Id. at 1346 n.4.
186. Id. at 1346 (emphasis added).
187. Id. at 1345-46.
188. Typically, a patentee is immune from antitrust liability for asserting its exclusive rights to a patent. But “[p]roof that a patentee has 'obtained the patent by knowingly and willfully misrepresenting facts to the Patent Office ... [is] sufficient to strip [the patentee] of its exemption from the antitrust laws.” Id. (quoting Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965)). A party asserting this type of fraudulently obtained patent may expose itself to a Walker Process antitrust claim. Dippin’ Dots, 476 F.3d at 1346. In order to prevail on a Walker Process claim, the claimant must demonstrate that the patent owner obtained the patent through either a fraudulent misrepresentation or fraudulent omission, evidencing a clear intent to deceive the patent examiner and cause the PTO to grant an invalid patent, and that the patentee was aware of the fraud when bringing suit to enforce the patent.
189. Dippin’ Dots, 476 F.3d at 1347.
190. Id. at 1348.
191. Id. at 1347.
Taken together, these statements seem to suggest that the intent element for inequitable conduct was inferred solely from the omission itself. But Federal Circuit precedent establishes that to prove intent for inequitable conduct "the alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the specific intent to . . . mislead[] or deceiv[e] the PTO." Thus, this discussion in the Walker Process antitrust analysis is confusing. If intent cannot be inferred solely from an applicant's omission, how was the defendant here able to prove such intent when they submitted no evidence aside from the omission of the sales information?

The end result of this case naturally raises the following questions. First, how may clear and convincing evidence of deceitful intent be established by relatively weak evidence of intent? Second, if the defendants "submitted no evidence of their own . . . which affirmatively show[ed] DDI's fraudulent intent," and if the omission could have occurred "for any number of nonfraudulent reasons," how could the defendant nonetheless have proven that the applicant had the specific intent to deceive the PTO? These statements seem to open the door to potentially expansive interpretation beyond the bounds of Kingsdown.

**E. Aventis**

The recent case of *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, also generated controversy on the metes and bounds of the intent element. This case centered on the disclosure of test data during patent prosecution for a pharmaceutical compound. The examiner initially rejected the claims for the compound, finding them both anticipated and obvious over several references, including

193. See Dippin' Dots, 476 F.3d. at 1346.
194. Id. at 1348.
195. Id. at 1347.
196. "[E]vidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement." Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008). In addition, "the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard." Id. (emphasis added).
197. Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334 (Fed. Cir. 2008). The authors' firm represented the plaintiffs-appellants in this case.
198. Id. at 1341.
European Patent 40,144 (EP '144). In response, the applicant amended claim one and submitted a declaration from a non-inventor (Dr. Uzan), distinguishing the claimed compound from the EP '144 formulations based on a half-life comparison. In the declaration, Dr. Uzan noted that the half-life data "represents an increase in 250% in the half life and is very significant because it enables the same effect to be achieved with lower dosages." 

Despite this declaration, the patent examiner issued another Office Action rejecting the claims. Responding to this Office Action, Dr. Uzan submitted a second declaration referencing data from a half-life comparison between the claimed compound and the EP '144 compound. The data was contained in five tables that were attached to the declaration. The half life data for the claimed compound was listed in one set of tables, while the half life data of the EP '144 compound was listed in a separate set of tables. Dr. Uzan included a statistical analysis demonstrating that the differences in half life between the claimed compound and the EP '144 compound were statistically significant. However, while the tables for the claimed compound listed the dosage, the tables for the EP '144 compound did not. The allegation of inequitable conduct arose from the fact that, while the EP '144 compound was tested at a different dosage than the claimed compound, the difference was not explicitly noted in the tables.

Addressing the intent element, the majority noted that "'the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.'" It is notable, however, that the majority did not reiterate that intent must be proven by clear and convincing evidence. Instead, after affirming that the court

199. Id. at 1338.
200. Id. at 1339.
201. Id. (emphasis added).
202. Id. at 1339-40.
203. Aventis Pharma, 525 F.3d at 1340.
204. Id.
205. Id. at 1340 n.5.
206. Id. at 1340.
207. Id.
208. Id. at 1341.
209. Id. at 1343 (quoting Impax Labs., Inc. v. Aventis Pharms., Inc., 468 F.3d 1366, 1375 (Fed. Cir. 2006)).
210. The court states only that "'given that direct evidence is often unavailable, intent is generally inferred from surrounding facts and circumstances.'" Id. at 1344.
shall balance the equities "upon finding materiality and intent," the majority then stated the balancing test.\textsuperscript{211} The court declared that "[t]he more material the omission or misrepresentation, the less intent that must be shown to elicit a finding of inequitable conduct."\textsuperscript{212} The court ultimately ruled that the omission was made with deceitful intent and constituted inequitable conduct.\textsuperscript{213}

There are several troubling aspects about the finding of deceitful intent. For example, in a prior appeal of this case, the Federal Circuit acknowledged the possibility that Dr. Uzan "may have intended" that his statement in the first declaration would convey that the half life comparisons were done at different doses.\textsuperscript{214} Thus, it remanded the case to the district court to consider the intent element. The district court ultimately ruled that the omission was made with intent to deceive and the majority affirmed. The Federal Circuit stated that the district court heard Dr. Uzan's testimony regarding intent, but that this "did not outweigh" other evidence evincing an intent to deceive.\textsuperscript{215} But whether evidence of deceitful intent "outweighs" other evidence suggests a preponderance of the evidence standard.\textsuperscript{216} In contrast, deceitful intent must be established by clear and convincing evidence. Further, to satisfy the clear and convincing requirement, intent may only be inferred from circumstantial evidence where it is "the single most reasonable inference able to be drawn from the evidence."\textsuperscript{217}

Another troubling aspect of this case is its reference to submitting information in a "misleading way." Noting that half life

\begin{itemize}
\item \textsuperscript{211} \textit{Id.}
\item \textsuperscript{212} \textit{Id.}
\item \textsuperscript{213} \textit{Id.} at 1349.
\item \textsuperscript{214} \textit{Id.} at 1348. The court noted that an earlier decision "left open the possibility" that Dr. Uzan's statement that "this represents an increase in 250% in the half life and is very significant because it enables the same effect to be achieved with lower dosages," may have been intended to convey that the half-life comparisons were done at different dosages. \textit{Id.} However, this characterization seems to ignore the full import of Dr. Uzan's statement. Here, Dr. Uzan specifically noted that his comparison showed that the same effect was "achieved at lower dosages." Furthermore, his statement explicitly drew attention to this result as "very significant." In contrast to the court's characterization, it is difficult to understand how Dr. Uzan could have possibly intended to convey anything other than the fact that the half-life comparison was performed at different dosages.
\item \textsuperscript{215} \textit{Id.}
\item \textsuperscript{216} Preponderance of the evidence is defined as the "[t]he greater weight of the evidence." \textit{BLACK'S LAW DICTIONARY} 1220 (8th ed. 2004). In contrast, clear and convincing evidence establishes a greater burden and is "[e]vidence indicating that the thing to be proved is highly probable or reasonably certain." \textit{Id.} at 596.
\item \textsuperscript{217} Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008).
\end{itemize}
data for the patented compound at two doses was presented in an example in the patent, the court stated that "[e]ven if we acknowledge that half-life data at other doses for the patent compound were provided to the examiner, the data were provided in a very misleading way." However, whether a submission is made in a misleading way seems to inject a subjective element into the inequitable conduct analysis. But Kingsdown was intended to establish objective standards for the inequitable conduct analysis. Further, the majority does not enunciate any standards for evaluating whether a submission is sufficiently misleading to constitute inequitable conduct. Thus, this statement provides litigants the opportunity to argue that, even if information was presented, it was presented in a misleading way and satisfies the intent element. This creates further potential for expanding the inequitable conduct doctrine based on subjective standards rather than objective criteria.

In light of these and other issues, Judge Rader's dissent suggested that the court occasionally revisit its Kingsdown opinion. Judge Rader opined that Kingsdown was intended to make inequitable conduct a rare occurrence. It "restricts a finding of inequitable conduct to only the most extreme cases of fraud and deception." Moreover, Kingsdown required substantially more than materiality. Indeed, Judge Rader thought it "hard to imagine" a more material mistake than that which occurred in Kingsdown. Yet in that case, the court failed to find inequitable conduct because there was no evidence of deceptive intent. However, Judge Rader observed that since Kingsdown, "the judicial process has too often emphasized materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct." Instead, "[m]erging intent

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218. Aventis Pharma S.A. v. Amphastar Pharms., 525 F.3d 1334, 1349 (Fed. Cir. 2008). The court relied on Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1191 (Fed. Cir. 1993), for this proposition. However, as noted supra note 173, the facts in Paragon were far more egregious.


220. Aventis Pharma, 525 F.3d at 1350 (Rader, J., dissenting).

221. Id.

222. Id. at 1349.

223. Id. at 1350.

224. Id. Compare the "lofty intent requirement" mandated by Kingsdown and espoused by Judge Rader with Critikon's proposition that intent may be inferred where the patentee "should have known" information was material.
and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic."\(^ {225} \)

Addressing the specific facts of the case, the dissent found it relevant that "Dr. Uzan did not attempt to conceal data that were otherwise present."\(^ {226} \) Instead, he submitted data without adding further to the disclosure.\(^ {227} \) Thus, "[t]his omission, even if negligent, is hardly *Kingsdown's* culpable intent to deceive."\(^ {228} \) Further, the dissent noted Dr. Uzan's testimony that the "different dose 'did not come to his mind.'"\(^ {229} \) The dissent found merit in this explanation, noting that "[c]omparison of drug properties at their clinically relevant (and different) dosages is, of course, completely appropriate."\(^ {230} \) Finally, the dissent noted that dosages were listed in several subsections, but were conspicuously absent from one of the subsections.\(^ {231} \) As a result, "the absence of a dosage in subsection 3 is blatantly obvious. Surely if Dr. Uzan had intended to deceive the USPTO, he would not have made this omission so conspicuous."\(^ {232} \) In sum, the dissent did not find clear and convincing evidence that the omission was made with intent to deceive.\(^ {233} \)

Again, *Aventis Pharma* raises significant questions about the inequitable conduct doctrine and the precise contours of the intent element. Like other cases, it illustrates differences within courts considering the inequitable conduct defense. It also demonstrates that what may appear to be an innocent oversight might nevertheless be construed as inequitable conduct. Unfortunately, this creates the potential for further uncertainty in the inequitable conduct analysis.

**F. Summary**

While the cases discussed in this section are not exhaustive, they represent some of the controversial decisions on inequitable conduct. Based on these cases, what can be learned about the intent element as analyzed by different Federal Circuit panels? Below is a short summary of the more salient points.

\(^{225} \) Id.
\(^{226} \) *Aventis Pharma*, 525 F.3d at 1351.
\(^{227} \) Id.
\(^{228} \) Id.
\(^{229} \) Id.
\(^{230} \) Id.
\(^{231} \) Id. at 1352.
\(^{232} \) *Aventis Pharma*, 525 F.3d at 1352.
\(^{233} \) Id. at 1349.
• Panels have inferred intent to deceive based on the materiality of an act or omission, finding deceitful intent where an applicant "should have known" the act or omission was material.  

• Panels have imputed knowledge of United States patent regulations from an attorney to an applicant and, based on this imputed knowledge, found that the applicant "should have known" that information was material.

• Panels have drawn negative inferences of deceitful intent where an applicant cannot give a reasonable explanation for an act or omission.

• Panels have required an applicant to provide a good faith explanation for an act or omission after an accused infringer has shown that it was material and that the applicant should have known it was material.

• Panels have affirmed a finding of deceitful intent based on admittedly "weak evidence."

IV. THE DANGERS OF A LOW INTENT THRESHOLD

Patentees are understandably concerned about the inequitable conduct doctrine and they have a substantial interest in ensuring that is not applied lightly. To procure a patent, an applicant must expend substantial resources, including both time and money. Patents may also represent a significant source of a company's value or revenue base. Thus, there are a number of reasons why it is essential to strictly apply the requirements for inequitable conduct.

First, the heightened requirements are essential because the penalty for inequitable conduct is severe. In short, inequitable conduct renders the entire patent unenforceable even where every claim clearly meets the requirement of patentability. This is quite different from invalidity, which only impacts claims. See MUELLER, supra note 188, at 348. Thus, some


237. Critikon, 120 F.3d at 1259.

238. Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1346 (Fed. Cir. 2007).


240. Star Scientific, 537 F.3d at 1365. This is quite different from invalidity, which only impacts claims. See MUELLER, supra note 188, at 348. Thus, even where one claim is deemed
courts have recognized that "[j]ust as it is inequitable to permit a patentee who obtained his patent by deliberate misrepresentation... it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability."

Lower thresholds increase the potential for an innocent party to have their patent rights entirely destroyed by a weak inequitable conduct charge. In some cases, this may nullify years of research and billions of dollars in investment and revenue. Due to the harshness of this remedy, it remains incumbent on the accused infringer to prove an elevated level of intent.

Another danger in lowering the threshold is the relative ease with which a party can misconstrue a patentee's actions or omissions after the fact. Armed with 20-20 hindsight and benefiting from the passage of time and fading memories, litigants may read a host of improper intentions into an innocent act or omission. The problem is that in the realm of research and development, researchers and patentees can make innocent mistakes. Researchers, under pressure to complete multiple projects, may accidently forget to record a piece of information or may inadvertently forget to label a data table. Patentees and attorneys may unintentionally forget a piece of information, may believe that the information is not material, or may simply not understand its relevance. While such actions may be understandable at the time they occur, it is far easier to read a sinister motive into these actions years after the fact when the particular details of the events have faded from memory.

The inequitable conduct doctrine also gives accused infringers a powerful incentive to overstate the significance of every act or

invalid, the remaining claims may remain valid and may still be asserted in an infringement suit.  

Id.  

241. Star Scientific, 537 F.3d at 1366.  

242. Id.  

243. The Federal Circuit has recognized this danger, noting in one case that "[t]he trial court, after the controversy had arisen, and with the '20-20 vision of hindsight,' read the patent entirely differently than did those concerned with its issue." Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1420 (Fed. Cir. 1988). The trial court found inequitable conduct from the patentees' inconsistent use of a term in the claims. Id. Nevertheless, the Federal Circuit declared that "[r]ather than anyone being a crook, it is surely a permissible inference that both the applicant's attorney and the examiner were alike confused, not being possessed of the analytical vision of hindsight." Id. at 1421. As a result, the Federal Circuit overruled the district court's finding of inequitable conduct. Id. at 1422.  

244. Indeed, the Federal Circuit has noted "the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive." N. Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 939 (Fed. Cir. 1990). Thus "[a] patentee's oversights are easily magnified out of proportion by one accused of infringement." Id.
omission, however small, for a huge payoff. A successful allegation of inequitable conduct allows an accused infringer to continue its course of conduct without showing non-infringement or invalidity of the patent.\textsuperscript{245} Thus, the infringer may view "every experiment done and not done, every scientific inference, every judgment or belief, [as] fair game for opportunistic attack."\textsuperscript{246} Under this lens, it is extremely rare that "some flaw cannot be found."\textsuperscript{247} Indeed, "[t]he uncertainties of the processes of scientific research, the vagaries of the inductive method, the complexities of patent procedures, and the twists of hindsight, all provide[] grist for this pernicious mill."\textsuperscript{248} As a result, "[a] litigant need only scour the prosecution history of the asserted patent to find any violation of the MPEP to trump up charges of inequitable conduct."\textsuperscript{249}

At the same time, such allegations may ignore the principle that "[i]ntent to deceive should be determined in light of the realities of patent practice."\textsuperscript{250} Some commentators have noted that recent trends in inequitable conduct fail to take into account "the commonsense realization that most inventors are not trained in law or patent prosecution, and many are foreign scientists whose first language is not English."\textsuperscript{251} Further:

[T]his trend fails to recognize that prosecuting attorneys generally do not monitor the day-to-day activities of their clients, are not likely to know about the results of experiments, and are unaware of the affiliations of scientists used to support patentability. It also fails to recognize that the time spent on a particular patent application is finite and that not every omission of information is the result of a deliberate decision that is required to find an intent to deceive.\textsuperscript{252}

Thus, the bar should be set high to mitigate "the ease with which ordinary actions in scientific research or patent prosecution can be distorted by zealous attack."\textsuperscript{253} Without such requirements,

\begin{itemize}
\item \textsuperscript{245} See Mueller, supra note 188, at 348.
\item \textsuperscript{246} Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1381 (Fed. Cir. 2003) (Newman, J., dissenting).
\item \textsuperscript{247} Id. One commentator has noted that "infringers are so quick to accuse patent prosecutors or inventors of inequitable conduct that it seems that any action or inaction undertaken can be grounds for inequitable conduct charges." Upadhye, supra note 112, at 696.
\item \textsuperscript{248} Hoffmann-La Roche, 323 F.3d at 1372.
\item \textsuperscript{249} Hanft & Kerns, supra note 17, at 5.
\item \textsuperscript{250} N. Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 939 (Fed. Cir. 1990).
\item \textsuperscript{251} Hanft & Kerns, supra note 17, at 5.
\item \textsuperscript{252} Id. at 5.
\item \textsuperscript{253} Hoffmann-La Roche, 323 F.3d at 1372.
\end{itemize}
commentators opine that "[p]roving inequitable conduct will simply be a matter of finding that someone should have known something; after that, a court can infer the intent to deceive the [USPTO]." 254

Lowered requirements also place a heavy burden on patentees by requiring them to explain an event that occurred long in the past that may have faded from memory. According to some opinions, a negative inference of intent may be found if the applicant cannot give a credible explanation for withholding information. 255 This may prove extremely difficult when the questioned actions occurred years earlier. Therefore, a good faith explanation should not be required until the accused infringer has proven both elements of the defense. To draw a negative inference of intent based on a patentee's lack of a reasonable explanation, before the challenger has actually proven specific intent to deceive, is unfair to the patentee.

A final danger, while perhaps less obvious than those enumerated above, should nevertheless be of concern to patent practitioners. Simply put, an increase in inequitable conduct charges casts a pall of suspicion around the parties involved in patent prosecution. Some judges have noted that, prior to Kingsdown, the onslaught of inequitable conduct charges caused courts to "suspect that all scientists [were] knaves and all patent attorneys [were] jackals." 256 Indeed, "judges came to believe that every inventor and every patent attorney wallowed in sharp practice." 257 These considerations led in part to the Federal Circuit's declaration that inequitable conduct charges had become an "absolute plague" in patent litigation. 258 Due to these undesirable effects, "[a] patent litigant should be made to feel, therefore, that an unsupported charge of 'inequitable conduct in the Patent Office' is a negative contribution to the rightful administration of justice." 259

Despite these dangers, some commentators and Federal Circuit judges allege that recent decisions have lowered the requirements for

254. Hanft & Kems, supra note 17, at 5.
255. See, e.g., Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1259 (Fed. Cir. 1997). But see Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1368 (Fed. Cir. 2008) ("[T]he accused infringer cannot carry its burden simply because [the patentee] failed to prove a credible alternative explanation. . . . The patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence.").
256. Hoffmann-La Roche, 323 F.3d at 1372.
259. Id.
inequitable conduct and revived the pre-Kingsdown analysis. Some courts appear to justify these lower requirements by stressing the difficulty in proving intent. For example, many cases cite the familiar adage that "intent can rarely be proven directly" as a justification for inferring intent from materiality. To be sure, the fact that intent can rarely be proven by direct evidence may increase the burden on the accused infringer. That should not, however, be a justification for lowering the requirements for intent. Indeed, this is the very purpose behind Kingsdown's high inequitable conduct threshold. The threshold is set high because an inequitable conduct finding was intended to be limited to particularly egregious behavior. Some judges have even stated that case law restricts an inequitable conduct finding "to only the most extreme cases of fraud and deception." Kingsdown does not suggest that the threshold should be lowered because the element of intent is difficult to prove. On the contrary, courts have acknowledged that it is equally inequitable to declare a patent unenforceable absent sufficient evidence of deceptive intent.

V. A Shift in the Analysis?

Up to this point, this paper has focused on cases that have been criticized for broadening the requirements for inequitable conduct. In two recent cases, however, separate Federal Circuit panels seem to have applied a more strict interpretation of the inequitable conduct doctrine. Thus, these cases demonstrate a heightened requirement for the intent analysis. At the same time, they suggest a model for a strict interpretation of inequitable conduct under Kingsdown.


261. See, e.g., Ferring, 437 F.3d at 1191 ("[I]ntent need not, and rarely can, be proven by direct evidence") (quoting Merck & Co., Inc., v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1422 (Fed. Cir. 1989)); Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997) ("Direct evidence of intent or proof of deliberate scheming is rarely available in instances of inequitable conduct" and thus "intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material.").

262. Aventis Pharma, 525 F.3d at 1350 (Rader, J., dissenting).

263. Id. at 1349.

A. Star Scientific

In the case of Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., the court applied reasoning similar to Kingsdown. The invention in Star involved a tobacco curing process intended to lower the levels of carcinogens known as tobacco specific nitrosamines (TSNAs) within cured tobacco. Star engaged an attorney to prosecute a patent application for the process. At the beginning of patent prosecution, the attorney received a letter disclosing a Chinese process that also yielded low TSNA levels. After considering the letter, the attorney concluded that it was not material to the application. The attorney subsequently filed a provisional patent application followed by a utility application, but he never disclosed the letter or its contents to the PTO. Shortly after the utility application was filed, Star terminated the prosecuting attorney’s firm and transferred the application file to a new firm. The new prosecuting attorney examined the file for prior art but failed to notice the letter. The PTO ultimately allowed the application and issued a patent.

Star subsequently brought suit against RJR for patent infringement. After the application was allowed, but before it issued as a patent, Star’s trial counsel learned about the letter and informed the new patent prosecution counsel of its existence. Upon consideration, the new patent prosecution counsel also determined that the letter was not material and thus did not need to be disclosed to the PTO. Nonetheless, the district court later ruled that this omission constituted inequitable conduct that rendered Star’s patents unenforceable. The district court inferred deceptive intent based on the theory that Star transferred patent prosecution to prevent the

265. Id.
266. Id. at 1361.
267. Id.
268. Id. at 1361-62.
269. Id. at 1362.
270. Star Scientific, 537 F.3d at 1362.
271. Id. at 1363.
272. Id.
273. Id.
274. Id.
275. Id.
276. Star Scientific, 537 F.3d at 1365.
previous prosecuting attorney from disclosing the letter to the PTO and to purposely keep the new firm ignorant of the letter.\textsuperscript{277}

At the outset of the opinion, the court highlighted the requirements for a finding of inequitable conduct, stressing that “[t]he burden of proving inequitable conduct lies with the accused infringer.”\textsuperscript{278} Discussing the materiality and intent elements, the court further noted that “at least a threshold level of each element . . . must be proven by clear and convincing evidence.”\textsuperscript{279} The court emphasized the necessity for elevated standards in the inequitable conduct analysis, declaring that “[t]he need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount.”\textsuperscript{280} Just as it is inequitable to allow a patentee to obtain a patent through deliberate misrepresentation, “it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability.”\textsuperscript{281} Accordingly, “courts must ensure that an accused infringer asserting inequitable conduct has met his burden on materiality and deceptive intent with clear and convincing evidence before exercising its discretion on whether to render a patent unenforceable.”\textsuperscript{282} Additionally, the decision noted that a finding of inequitable conduct is not mandatory, stating that even when both elements are established by clear and convincing evidence, “the court may still decline to render the patent unenforceable.”\textsuperscript{283}

Specifically addressing the intent element, the decision emphasized that “materiality does not presume intent.”\textsuperscript{284} Acknowledging that intent may be inferred from indirect and circumstantial evidence, the court noted that “such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement.”\textsuperscript{285} Furthermore, the

\begin{itemize}
  \item \textsuperscript{277} Id. at 1367.
  \item \textsuperscript{278} Id. at 1365.
  \item \textsuperscript{279} Id.
  \item \textsuperscript{280} Id.
  \item \textsuperscript{281} Id. at 1366.
  \item \textsuperscript{282} Star Scientific, 537 F.3d at 1366.
  \item \textsuperscript{283} Id. at 1365.
  \item \textsuperscript{284} Id. at 1366 (quoting GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001)). Further, the court noted that “clear and convincing evidence must prove that an applicant had the specific intent to . . . mislead[,] or deceiv[e] the PTO.” Id. (quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995)).
  \item \textsuperscript{285} Id. Compare Dippin’ Dots, Inc. v. Mosey, 476 F.3d 1337, 1346 (Fed. Cir. 2007) (stating that “the district court was permitted to balance the relatively weak evidence of intent”) (emphasis added).
\end{itemize}
inference must not only be reasonable, "but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard." Thus, the court may not balance the equities until "adequate showings are made as to both materiality and deceptive intent" by clear and convincing evidence.

Turning to the merits of the case, the court found that Star's conduct was not sufficient to warrant an inequitable conduct finding. Specifically, the alleged infringer had failed to prove intent by clear and convincing evidence. While the district court did not find the testimony of Star's witnesses to be credible regarding the reason for changing law firms, this was insufficient to warrant an inequitable conduct finding. The court emphasized that even if the applicant's explanations could not be believed, it remained the defendant's burden to prove its allegation. Thus, the "[accused infringer] cannot carry its burden simply because [the applicant] failed to prove a credible alternative explanation." Indeed, "the patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence.

On another note, the court did not follow Critikon's approach in inferring intent from materiality. Finding that the district court's ruling of deceptive intent was clearly erroneous as to one of the patents at issue, the court declined to address the materiality of the omission. This is consistent with Kingsdown, where the court also refused to consider materiality after finding there was insufficient evidence of intent.

B. Abbott

The Federal Circuit also refused to find inequitable conduct in the recent case of Abbott Laboratories v. Sandoz, Inc. The patents at issue centered on extended release versions of the antibiotic drug

286. *Star Scientific*, 537 F.3d at 1366.
287. *Id.* at 1367.
288. *Id.* at 1368.
289. *Id.*
290. *Id.*
291. *Id.*
292. See Part III.A.1.
293. *Star Scientific*, 537 F.3d at 1368 n.8.
294. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 n.5 (Fed. Cir. 1988) ("Because of our decision on intent, it is unnecessary to discuss materiality.").
clarithromycin. In this case, the defendant appealed a decision of the district court refusing to hold two patents unenforceable due to inequitable conduct. Regarding the first patent (‘718 patent), the defendant pointed to three separate omissions during prosecution as allegedly establishing inequitable conduct. The court only addressed intent for two of these omissions, finding that the third omission was not material.

As to the first omission, one of the inventors submitted a declaration during patent prosecution comparing the formulation of the pending application with the formulation of a prior art patent the plaintiff owned. In her declaration, the inventor included data showing that certain pharmacokinetic properties differed between the prior art formulation and the pending formulation. The declaration further stated that these differences were statistically significant. Nonetheless, during litigation, she acknowledged that she had not actually analyzed statistical significance. Further, it could not be definitively concluded from the data whether the differences were statistically significant. As a result, the defendant argued that the plaintiff had committed inequitable conduct before the PTO.

Addressing this argument, the majority noted that “[w]e have been directed to no evidence of deceptive intent, or ‘bad faith or intentional misconduct.’” The court also noted with approval the district court’s ruling that intent is not “inferred from materiality alone, for precedent requires independent proof of deceptive intent.” Thus, the Federal Circuit declined the defendant’s invitation to infer deceptive intent from the misstatement.

Next, the defendant alleged inequitable conduct based on the plaintiff’s failure to provide to the PTO the results of certain clinical

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296. Id. at 1343.
297. Id. at 1344.
298. Id. at 1353, 1355-56.
299. Id. at 1356.
300. Id. at 1353.
301. Id.
302. Abbott, 544 F.3d at 1353.
303. Id.
304. Id. at 1353-54.
305. Id. at 1354.
306. Id.
307. Id. at 1354-55 (citing Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed. Cir. 1988)).
308. Id. at 1355.
studies that were conducted after the patent application was filed.\textsuperscript{309} These studies, focusing on taste perversion tests, were provided to the FDA and included on the product label.\textsuperscript{310} According to the defendant, the plaintiff should have provided these results to the PTO since, contrary to the information in the application, they indicated that the immediate release version had lower taste perversion than the extended release version.\textsuperscript{311} In response, the plaintiff noted that the taste perversion tests "were from dosages that were not directly comparable, and that they did not change the correctness of the data in the patent application."\textsuperscript{312}

Once again, "the district court observed that there was no evidence of deliberate withholding of this information in order to deceive the patent examiner."\textsuperscript{313} Addressing the district court's ruling, the Federal Circuit emphasized that "[m]ateriality is not evidence of intent, which must be established as a separate factual element of a discretionary ruling of inequitable conduct."\textsuperscript{314} Since the court found insufficient evidence of deceitful intent, it disposed of the inequitable conduct charge.

Turning to the second patent ('616 patent), the defendant again alleged inequitable conduct based on the plaintiff's failure to report certain clinical trial results to the PTO.\textsuperscript{315} The court found that "[t]here was no evidence of intent to deceive with respect to the results of these clinical trials."\textsuperscript{316} The court went on to note:

Materiality, even if found, does not establish intent. This is not a case of new information that affects the fundamental invention; this is a case of challenging every action or inaction of the "conduct" of patent solicitation, although patentability is unaffected. The purpose of Kingsdown was to bring patent practice into the mainstream of the law and administrative practice. The law severely punishes fraudulent practices, and the patent practice includes recognition that the inventor usually knows more about the field than does the "expert" patent examiner. However, routine actions that do not affect patentability and that are devoid of fraudulent intent are not subject to a different standard than other

\textsuperscript{309} Id. at 1355.
\textsuperscript{310} Id.
\textsuperscript{311} Id.
\textsuperscript{312} Id.
\textsuperscript{313} Id.
\textsuperscript{314} Id. at 1356.
\textsuperscript{315} Abbott, 544 F.3d at 1357.
\textsuperscript{316} Id.
inquiries into fraudulent procurement. . . . "It was to mitigate the 'plague' whereby every patentee's imperfections were promoted to 'inequitable conduct' that this court reaffirmed that both materiality and intent must be established."^317

Thus, the court adhered to a rigorous standard for finding intent to deceive the PTO. In so doing, the court emphasized that intent is a separate factual inquiry and cannot simply be inferred from the materiality of an omission. Further, to establish intent, the court appeared to require actions approaching fraudulent conduct. This seems to present a departure from several of the cases discussed in Part III, supra.

C. Summary

In both Star Scientific and Abbott, separate Federal Circuit panels appeared to strictly apply the intent requirement of Kingsdown. Particularly in Star Scientific, the court outlined the rigorous requirements for an inequitable conduct finding. In both of these decisions, however, the court stressed that intent must be established by a separate inquiry. Further, the Federal Circuit emphasized that the challenger must prove both materiality and intent by clear and convincing evidence before a court undertakes any balancing of the elements. Though inferences may be drawn from circumstantial evidence, such evidence must still be clear and convincing. Absent such a showing by the accused infringer, these decisions recognize that there is no requirement for the patentee to establish a good faith explanation for an omission.

Again, while these particular cases adhere to a strict showing of intent to deceive, it is not clear whether they represent isolated instances or whether they represent a return to the heightened requirements of Kingsdown. Considering the wide range of inequitable conduct cases, it is possible that they merely represent differences among panels. On the other hand, they may represent an attempt to curb a return to the pre-Kingsdown "plague" of inequitable conduct charges. Only time will tell if they represent a change in inequitable conduct jurisprudence. At the very least, however, they illustrate an acknowledgement by some judges on the Federal Circuit that the intent element of inequitable conduct is to be strictly applied and not simply inferred from a finding of materiality.

317. Id. at 1357-58 (quoting Allied Colloids, Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1578 (Fed. Cir. 1995)).
VI. CONCLUSION

All individuals associated with the prosecution and filing of patent applications owe a duty of candor to the Patent Office. This duty requires applicants to disclose all information that is material to the patentability of an invention. In cases where an applicant intentionally attempts to deceive the PTO, an accused infringer may raise an inequitable conduct defense. Inequitable conduct provides a potent defense to the accused infringer, rendering the entire patent unenforceable.

Originally, the doctrine of inequitable conduct was applied in cases where applicants committed fraud on the Patent Office or engaged in other particularly egregious and intentional conduct. With the expansion of the doctrine over time, however, litigants began to grossly abuse the defense. Eventually, decrying the "plague" of inequitable conduct charges, the Federal Circuit reiterated the requirements for an inequitable conduct finding. In Kingsdown, the court emphasized that an accused infringer must prove that an act or omission was material to patentability and that it was made with the specific intent to deceive the PTO. Lest the defense be applied too lightly, the court stressed that both elements must be proven by clear and convincing evidence.

Despite Kingsdown's mandate, both judges and commentators have criticized what they view as a subsequent return to the plague. By allowing intent to be inferred from materiality, these observers allege that courts have abandoned the strict requirements for an inequitable conduct finding. Further, they maintain that inferring intent where a patentee knew or should have known about the materiality of an act injects a negligence element into the analysis, contrary to Kingsdown's requirements.

Indeed, as these observers noted, a number of cases raise legitimate questions regarding the intent element. For example, how may courts infer a specific intent to mislead or deceive the PTO based solely on the fact that an applicant should have known that information was material? How may the requirement for clear and convincing evidence be satisfied by "relatively weak evidence" that is "not particularly strong?" And how may knowledge of patent regulations be imputed to an inventor as the basis for a finding of intent when specific intent is required? These holdings create potential for confusion and are difficult to reconcile with each other. In the end, this paper recommends a strict application of Kingsdown's requirements. Due to the severity of the unenforceability remedy,
inequitable conduct should only be applied in extreme cases that clearly show intent to deceive. Without this, innocent omissions may once more serve as a basis for an inequitable conduct finding.