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Article

RESOLVING INEQUITABLE CONDUCT CLAIMS ACCORDING TO KINGSDOWN

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***270 I. Introduction-The Doctrine of Inequitable Conduct**

A. The Origins of the Doctrine of Inequitable Conduct

The law of inequitable conduct is a judicially created doctrine derived from the doctrine of unclean hands and designed to prevent fraud on the Patent Office.¹ It was established by the U.S. Supreme Court in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.* and is capable of rendering a fraudulently attained patent unenforceable.² Evaluating the public's interest in the doctrine, the Court stated that "[t]he far-reaching social and economic consequences of a patent . . . give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope."³ Following the lead of the courts, the U.S. Patent and Trademark Office (PTO) regulations state that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability."⁴

Since its 1945 *Precision Instrument* decision, the Supreme Court has left development of the inequitable conduct doctrine to the lower courts. Because inequitable conduct relies on the principles of equity, it encompasses technical fraud as well as "a wider range of 'inequitable' conduct found to justify holding a patent unenforceable."⁵ The basic elements of inequitable conduct are materiality and intent *271 to deceive.⁶ "Inequitable conduct resides in failure to disclose material information, or submission of false material information, with an intent to deceive, and those two elements, materiality and intent, must be proven by clear and convincing evidence."⁷ The standard for materiality has settled at what a reasonable examiner would consider important, though not necessarily determinative, when deciding whether to allow an application to issue as a patent.⁸ But while the standard for materiality has settled, the standard for establishing clear and convincing evidence of intent to deceive has varied and continues to do so.

B. The Elimination and the Return of a Negligence Standard for Inferring Deceptive Intent

In the early years of the Federal Circuit, the court at times used a gross negligence standard to infer deceptive intent.⁹ As one commentator pointed out, the low bar of the gross negligence standard induced alleged patent infringers to assert the inequitable conduct defense.¹⁰ In 1988, the Federal Circuit noted that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague."¹¹ Within the same year, the Federal Circuit sat en banc in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.* and adopted the view that "'gross negligence' does not of itself justify an inference of intent to deceive"; rather, "the involved conduct, viewed in light of all the evidence, including evidence *272 indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive."¹²

Though *Kingsdown* attempted to resolve conflicting precedents and to bring objectivity to charges of inequitable conduct, some Federal Circuit panels have slipped back into the "should have known" language that resembles negligence.¹³ While some panels have required evidence of "a deliberate decision to withhold a known material reference,"¹⁴ the majority in *Ferring B.V. v. Barr Laboratories, Inc.* found deceptive intent where the patent applicant should have known the materiality of the omitted information.¹⁵ Dissatisfied with the majority's "casually subjective standard," Judge Newman argued in dissent that a finding of deceptive intent based on what the patentee should have known "further revives the 'plague' of the past."¹⁶

C. Is the Inequitable Conduct Remedy Worse Than the Illness?

The varied intent standards for inequitable conduct warrant a review of the policy considerations that justify the doctrine and its limits. "The threat of inequitable conduct, with its 'atomic bomb' remedy of unenforceability, ensures . . . candor and truthfulness."¹⁷ Though the inequitable conduct doctrine is necessary to ensure the candor on which our ex parte system of patent examination depends, its abuse as a litigation tactic by defendants in patent infringement cases is harmful.¹⁸ "The

allegation of inequitable conduct opens new avenues of discovery; impugns the integrity of patentee, its counsel, and the patent itself; excludes the prosecuting attorney from trial participation (other than as a witness); and even offers the trial court a way to dispose of a case without the rigors of claim construction and other complex patent doctrines.”¹⁹

*273 The Federal Circuit recognized in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.* that “[j]ust as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith.”²⁰ There is certainly a need to ensure that patentees and their attorneys are communicating with the PTO honestly and ethically, but the doctrine does come with significant drawbacks. The use of a negligence standard by the courts opens the floodgates for alleged patent infringers to assert the inequitable conduct defense on the narrowest of grounds, thus magnifying the issue of “whether the remedy is worse than the illness.”²¹

D. Calls for Reform

The resurgence of a negligence standard for finding deceptive intent has been followed by calls for reform. A report by the National Academies of Science and Engineering recommended eliminating the doctrine of inequitable conduct altogether in view of the cost of litigation and what the Academies deemed to be a limited deterrent value.²² Other suggestions have been more measured. After calculating that 75% of decisions on inequitable conduct found no violation, one commentator suggested assessing attorney fees where allegations of inequitable conduct fail to raise a genuine issue of material fact.²³ This would presumably deter frivolous charges of inequitable conduct while maintaining the purpose of the doctrine.

Despite the calls from industry and legal commentators, patent reform has not been able to gain legislative traction. The Patent Reform Act of 2007 included a provision that tightened the standard for intent, requiring that “specific facts beyond *274 materiality of the information misrepresented or not disclosed must be proven.”²⁴ However, the 2007 Act failed to pass through Congress,²⁵ and the provision on inequitable conduct has been removed from the bill currently under consideration.²⁶ Furthermore, the Supreme Court has not directly reviewed the doctrine of inequitable conduct since its 1945 *Precision Instrument* decision.²⁷ Thus, it appears as if it will be up to the Federal Circuit to once again resolve its diverging precedents on the requirement of deceptive intent for inequitable conduct. While the Federal Circuit has denied recent requests to revisit the issue en banc, the notion seems to be gaining momentum. Multiple opinions have argued that the “should have known” standard is inconsistent with *Kingsdown*.²⁸ Noting the split, Judge Linn wrote a concurring opinion in *Larson Manufacturing Co. of South Dakota, Inc. v. Aluminart Products Ltd.* to “suggest that the time has come for the court to review the issue en banc.”²⁹

E. This Note’s Analysis

This Note analyzes multiple points of contention within the Federal Circuit’s case law regarding the standard for inferring deceptive intent when inequitable conduct has been charged. At the heart of the split is the following three-prong test, which some Federal Circuit panels have used to find deceptive intent: (1) the applicant failed to supply highly material information; (2) the applicant knew of the information and knew or should have known of its materiality; and (3) the applicant *275 failed to provide a credible explanation for the withholding.³⁰ Writing separately in *Larson Manufacturing*, Judge Linn summarized his opposition to this test as follows: “The first [prong] is evidence of materiality; the second is evidence of negligence. These two prongs are therefore insufficient as a matter of law to establish a clear and convincing ‘threshold level’ of deceptive intent before the third prong can ever properly come into play.”³¹ While the three contested points invariably overlap, this Note divides them for individual review.

Part II considers whether an inference of intent based on what the patent applicant “should have known” improperly replaces the intent requirement with mere negligence. Part III considers whether requiring the patentee to present a credible explanation for the withheld material information improperly relieves the accused infringers of their burden to present clear and convincing evidence of deceptive intent. Finally, Part IV analyzes whether the court’s consideration of a high level of materiality in the finding of deceptive intent improperly conflates the two basic requirements of materiality and intent. In particular, this Note compares the results of *Ferring B.V. v. Barr Laboratories, Inc.* and *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.* to other Federal Circuit decisions that more rigidly adhere to the principles set forth in *Kingsdown*.

II. Inferring Intent Based on What the Applicant Should Have Known

A. The Post-Kingsdown Return of a Negligence Standard

In 1997, the Federal Circuit's decision in *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.* reintroduced a negligence standard into the Federal Circuit's case law.³² *Critikon* cited *Driscoll v. Cebalo*,³³ which had previously been expressly overruled by *Kingsdown*,³⁴ for the 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."³⁵ Despite *276 *Critikon*'s inexplicable citation to *Driscoll*, the result was not necessarily inconsistent with *Kingsdown*.³⁶ First, evidence showed that *Critikon*'s patent counsel had actual knowledge of the materiality, not merely that he should have known of the materiality.³⁷ *Critikon*'s patent counsel had reviewed the prior art in detail, had cited the prior art in other patent applications, and knew that it disclosed an element the patent examiner considered to be a point of novelty in the application.³⁸ Furthermore, during reissue proceedings with the PTO, *Critikon*'s patent counsel had failed to inform the PTO of ongoing litigation over the original patent and charges of inequitable conduct.³⁹ Together, these circumstances were strong enough to infer a "relatively high degree of intent."⁴⁰

Critikon's holding may be reconciled with *Kingsdown* because the inference of deceptive intent in *Critikon* did not actually rely on the "should have known" standard. However, *Critikon*'s endorsement of the "should have known" standard spread to subsequent cases that relied directly upon the standard to establish an inference that a patentee acted with sufficient culpability to justify a holding of inequitable conduct.⁴¹

B. Ferring's Determinative Use of the "Should Have Known" Standard

More recently, in 2006, the majority in *Ferring B.V. v. Barr Laboratories, Inc.* quoted *Critikon* for the flawed proposition that "a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality" can find it difficult to prevent "an inference of intent to mislead."⁴² As explained below, *Ferring*'s use of the "should have known" standard determined the outcome of the case. Thus, unlike *Critikon*, the result in *Ferring* cannot be reconciled with *Kingsdown*.

*277 *Ferring* involved the nondisclosure of information regarding the affiliations of declarants with the patent assignee.⁴³ Dr. Vilhardt was a *Ferring* employee and the inventor of the patent at issue.⁴⁴ During prosecution of the patent, the PTO examiners suggested that the applicant "obtain evidence from a non-inventor" to support the applicant's interpretation of a critical term.⁴⁵ Through his counsel, Dr. Vilhardt submitted supporting non-inventor declarations from scientists, Dr. Miller and Dr. Czernichow.⁴⁶ Later, in response to an obviousness challenge, Dr. Vilhardt submitted more supporting declarations, this time from Dr. Miller, Dr. Czernichow, Dr. Robinson, and Dr. Barth.⁴⁷ The problem with these declarations was that they did not disclose the limited affiliations between *Ferring* and three out of the four declarants.⁴⁸ Based on the nondisclosure of these affiliations, the district court granted summary judgment for *Barr* on the issue of inequitable conduct.⁴⁹

On review, the Federal Circuit panel set out a three-prong test for intent to deceive in cases where material information was withheld during a patent's prosecution.⁵⁰ The test asked whether (1) the applicant withheld highly material information; (2) the applicant knew of the information and knew or should have known of the materiality of the information; and (3) the applicant failed to provide a credible explanation for the withholding.⁵¹ Addressing the second prong of the test, the *Ferring* majority relied on the district court's conclusion that Dr. Vilhardt "was on notice that disinterested affidavits were necessary" and that he "knew or should have known that the *Ferring* affiliations were material."⁵² To support its conclusion that the information was deliberately concealed, the majority pointed to the circumstances surrounding the submissions of the declarations.⁵³ The majority noted that *278 while Dr. Vilhardt submitted a CV, three of the four non-inventor declarants did not submit CVs, which would have presumably disclosed any such affiliation.⁵⁴ Furthermore, Dr. Czernichow, the one non-inventor who did submit a CV, did not include his partial research funding from *Ferring*.⁵⁵

But as highlighted in Judge Newman's dissent, more than one reasonable inference can be garnered from the circumstantial evidence, and on summary judgment, *Ferring* was entitled to the most favorable inference.⁵⁶ Further examination of the circumstantial evidence shows the limited scope of the affiliations.⁵⁷ None of the declarants were paid for their submissions, and none of them were employed by or affiliated with *Ferring* at the time of their declarations.⁵⁸ *Ferring* had provided funding for equipment used in a clinical trial that Dr. Czernichow previously conducted at his hospital, but Dr. Czernichow's CV was organized such that one would not expect to see partial funding for projects.⁵⁹ Dr. Barth had been paid "allowances and

accommodations and costs” for some experimental work, but he was not engaged in such work at the time of his lone declaration.⁶⁰ Dr. Robinson had previously been a research director at Ferring and then a consultant, but those relationships ended before he submitted his lone declaration.⁶¹ Finally, Dr. Miller had no research or employment history with Ferring at all.⁶² Based on the limited nature of the affiliations, it is reasonable to infer that Dr. Vilhardt considered each of the non-inventor declarants to be disinterested third parties as requested by the PTO *279 examiners. Thus, while the affiliations may have been material, they do not prove Dr. Vilhardt intended to deceive the PTO.

C. Comparing Ferring to Other Federal Circuit Decisions

In *Kingsdown*, the Federal Circuit sat en banc to establish that gross negligence alone is not enough to warrant a finding of deceptive intent.⁶³ Rather, “the involved conduct, viewed in light of all the evidence . . . must indicate sufficient culpability to require a finding of intent to deceive.”⁶⁴ As highlighted in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, the Federal Circuit has interpreted this standard to mean that “[i]n a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.”⁶⁵ The Ferring majority based its finding of intent on the fact that Dr. Vilhardt was on notice that disinterested affidavits were necessary.⁶⁶ But despite the previous affiliations, the evidence did not establish that the declarants were not in fact disinterested parties at the time of their declarations.⁶⁷ As Judge Newman stated in her dissent, “there is no evidence that Dr. Vilhardt even thought about whether or not to disclose these affiliations, much less that he made the deliberate decision to withhold material information from the PTO.”⁶⁸ The lack of evidence, or even allegation, that the non-inventor declarants had anything to gain as a result of the issuance of the patent undermines the majority’s assertion that the CVs of the declarants were abridged or withheld in attempt to deliberately conceal the affiliations to Ferring.⁶⁹ Thus, as Judge Newman concludes in dissent, the majority ignores *Kingsdown* and improperly “impose[s] a positive inference of wrongdoing” by “replacing the need for evidence with a ‘should have known’ standard of materiality, from which deceptive intent is inferred.”⁷⁰

***280 D. Problems with the “Should Have Known” Standard**

Use of the “should have known” standard for intent is problematic for at least two reasons. First, it is questionable “whether a fact-finder who has deemed information to be ‘highly material’ would not also be compelled to conclude that a reasonable patentee ‘should have known of the materiality.’”⁷¹ Second, “the notion that intent can be established by a ‘knew or should have known’ test gives patent experts virtually free rein to interpret the circumstances as breaching an ‘uncompromising duty.’”⁷² Inferences of deceptive intent are easily generated because “[g]iven an inconsistency or two, it is not difficult to construct a scenario that would support a position of blameworthy conduct by the patentee.”⁷³

The majority decision in *Ferring* illustrates both of these problems. First, despite the fact that the declarants had no personal stake in the matter and appeared to be disinterested parties,⁷⁴ the majority followed a finding of materiality with a finding that Dr. Vilhardt should have known of the materiality.⁷⁵ Second, the majority draws support for a finding of deceptive intent from the fact that Dr. Czernichow was the only non-inventor declarant to submit a CV and his CV did not disclose his affiliation with Ferring.⁷⁶ This support was drawn despite the fact that given the organization of Dr. Czernichow’s CV, one would not expect to find partial funding for a research project on the CV.⁷⁷ As the dissent points out, “the most reasonable inference . . . is that Dr. Czernichow’s relationship with Ferring was so remote as to not be worthy of listing on his CV.”⁷⁸

The “should have known” standard invites an analysis of inequitable conduct that overly emphasizes materiality over intent. The standard also allows interpretations *281 of marginal circumstances to be twisted into blameworthy conduct. Thus, it is not surprising that the defense of inequitable conduct is regaining its pre-*Kingsdown* popularity. In response, the Federal Circuit should fully adopt *Star Scientific*’s more stringent standard requiring evidence of a deliberate decision to deceive the PTO. This adoption would prevent holdings that go too far in establishing deceptive intent and would defend against the return of the “plague.”

III. Burden Shifting

A. The Origins of Burden Shifting in Inequitable Conduct Cases

The return of a negligence standard for inferring deceptive intent has been coupled with a burden-shifting mechanism that

requires the patentee to explain the nondisclosure of material information. In 1987, the Federal Circuit panel in *FMC Corp. v. Manitowoc Co.* stated that one who alleges inequitable conduct must offer clear and convincing proof of intent to mislead the PTO, but that a patentee can rebut such evidence with proof that the failure to disclose material information was not the result of intent to mislead the PTO.⁷⁹ This first statement is consistent with the proposition that the alleged patent infringer has the burden to first prove deceptive intent with clear and convincing evidence. However, *FMC Corp.* planted the seed of burden shifting when the panel also 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 of intent to mislead.”⁸⁰

This presumption against the patentee establishing subjective good faith in the face of high materiality has propagated through the Federal Circuit’s case law.⁸¹ It has been accompanied by a conflicting statement that “[m]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.”⁸² At least one commentator has recognized the inconsistency of these statements. “If materiality does not presume intent, then a patentee facing a high level of materiality should not have to establish subjective good faith because in the absence of *282 other evidence the defendant, who bears a clear and convincing burden of proof, has not established the basis for an inference of an intent to deceive.”⁸³

As seen in Parts III.B and III.C, the Federal Circuit is split on when to shift the burden of proof regarding deceptive intent to the patentee. Some panels have shifted the burden based on evidence of materiality and negligence, while other panels have more rigidly required the accused infringer to first provide clear and convincing evidence of deceptive intent independent from evidence of materiality and negligence.

B. Burden Shifting in Ferring

The *FMC Corp.* presumption surfaced as part of the three-prong test in *Ferring*, which requires the patentee to provide a credible explanation for the withheld material information.⁸⁴ The *Ferring* test stated that summary judgment on the issue of intent is proper if (1) the applicant failed to supply highly material information; (2) the applicant knew of the information and knew or should have known of its materiality; and (3) the applicant failed to provide a credible explanation for the withholding.⁸⁵ After finding that the withheld information was highly material and that the applicant should have known of the materiality, the *Ferring* majority held that *Ferring* “bore the burden of submitting an affidavit from Vilhardt to contradict the movant’s evidence of intent if they believed that testimony from Vilhardt would establish credible evidence for the withholding.”⁸⁶ Since *Ferring* failed to provide a credible explanation in response to Barr’s motion for summary judgment, the panel majority found intent to deceive and affirmed the district court’s grant of summary judgment to Barr.⁸⁷

The *Ferring* majority quoted *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.* for the justification that when a movant has “made a prima facie case of inequitable conduct by satisfying both elements thereof, the burden shift[s] to [the nonmovant] to come forward with evidence which would require reassessment of the validity of the defense.”⁸⁸ This statement illuminates the crux of the *283 disagreement between the majority and the dissent in *Ferring*: determining what constitutes a prima facie case of inequitable conduct.

The *Ferring* majority apparently considered fulfillment of the first two prongs of the test to be sufficient to present a prima facie case.⁸⁹ The majority proceeded to the third burden-shifting prong after finding that (1) the affiliations of the non-inventor declarants were highly material; and (2) the applicant knew of the affiliations, and that the applicant knew or should have known the materiality of the affiliations.⁹⁰ In fairness, it should be noted that the majority’s analysis did discuss other evidence, including circumstantial evidence that the non-inventor declarants either did not submit CVs, or submitted CVs that did not include their affiliations with *Ferring*.⁹¹ However, this evidence was discussed only in response to the patentee’s attempt to establish a credible explanation after the burden of proof had already shifted.⁹²

As the *Ferring* dissent argues, the majority incorrectly relied on *Paragon Podiatry* for when a prima facie case of deceptive intent is established.⁹³ “*Paragon* involved an affirmative misrepresentation, not an omission, and that case contains no suggestion of a ‘should have known’ standard of materiality.”⁹⁴ In *Paragon Podiatry*, the patentee submitted supportive affidavits that were drafted with “deliberate artfulness” to affirmatively misrepresent company stockholders as disinterested third parties by carefully stating that they had “not been in the past employed by,” nor did they “intend in the future to become employed by *Paragon*.”⁹⁵ Unlike the evidence in *Paragon Podiatry*, the picture in *Ferring* is not so clear.⁹⁶ Despite their previous affiliations, the *Ferring* declarants were not connected to *Ferring* at the time of their submissions.⁹⁷ Unlike the stockholders in *Paragon Podiatry*, the *284 *Ferring* declarants had nothing to gain from the issuance of the patent.⁹⁸ A key

factor in the Ferring majority’s opinion was that Dr. Vilhardt “was on notice that disinterested affidavits were necessary.”⁹⁹ But there was “no evidence, or even an allegation, that any of these scientists had anything to gain or lose as a result of the issuance of the [patent].”¹⁰⁰

Judge Newman’s dissent in Ferring repeats the commonly stated rule that “there must be clear and convincing evidence that the applicant made a deliberate decision to withhold a known material reference.”¹⁰¹ But unlike the majority, Judge Newman draws a clear line between evidence of materiality and negligence, and evidence of deceptive intent.¹⁰² Since there was no evidence of a deliberate decision, Judge Newman found that “[i]n its motion for summary judgment, Barr put forward no evidence of deceptive intent.”¹⁰³

Consistent with Judge Newman’s Ferring dissent, Judge Linn wrote separately in *Larson Manufacturing Co. of South Dakota, Inc. v. Aluminart Products Ltd.* and specifically pointed out the burden-shifting problem of the three-prong test for deceptive intent.¹⁰⁴ “The first [prong] is evidence of materiality; the second is evidence of negligence. These two prongs are therefore insufficient as a matter of law to establish a clear and convincing ‘threshold level’ of deceptive intent before the third prong can ever properly come into play.”¹⁰⁵ The burden-shifting function of the “credible explanation” prong is problematic because “it is the ‘accused infringer’--not *285 the patentee--who ‘must prove by clear and convincing evidence that the material information was withheld with the specific intent to deceive the PTO.’”¹⁰⁶

C. Star Scientific’s Requirement of Clear and Convincing Evidence Before Shifting the Burden

In the same mold as Judge Newman’s Ferring dissent and Judge Linn’s *Larson Manufacturing* concurrence, the panel’s decision in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.* explicitly held that “[t]he patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence.”¹⁰⁷ *Star Scientific* involved a piece of potentially material information that was not disclosed due in part to a change of law firms.¹⁰⁸ The alleged infringer accused *Star Scientific* of changing law firms during the prosecution of the patent in order to deliberately prevent the original firm from disclosing the Burton letter, which contained potentially material information.¹⁰⁹ *Star Scientific*’s witnesses testified that they changed law firms because a key partner passed away and another attorney at the firm had performed unsatisfactorily.¹¹⁰ However, the district court deemed this testimony not to be credible, and the determination of no credibility provided a major basis for its finding of deceptive intent.¹¹¹

On appeal, the *Star Scientific* panel noted that the alleged infringer “failed to elicit any testimony or submit any other evidence indicating that *Star* knew what the Burton letter said” prior to changing firms, “or that the letter was a reason for changing firms.”¹¹² Furthermore, contrary to the defendant’s “quarantine” theory, the inventor’s unchallenged testimony stated that he had never even seen the Burton *286 letter prior to the litigation.¹¹³ Without clear and convincing evidence of deceptive intent, the Federal Circuit held that “RJR [could not] carry its burden simply because *Star* failed to prove a credible alternative explanation.”¹¹⁴ Accordingly, the Federal Circuit held that the district court’s finding of deceptive intent was clearly erroneous and reversed the holding of inequitable conduct.¹¹⁵

D. Adopting the “Single Most Reasonable” Inference Rule

As recognized in many inequitable conduct cases, including *Star Scientific* and *Ferring*, the difficulty with proving intent is that direct evidence is rarely available.¹¹⁶ Thus, intent or lack thereof is typically inferred from the facts and circumstances surrounding the failure to disclose material information.¹¹⁷ The dependence on an inference from circumstantial evidence has undoubtedly contributed to a split. While some panels use evidence of materiality and negligence to infer intent,¹¹⁸ other panels require further evidence deemed to be independent from evidence of materiality and negligence.¹¹⁹ Further clouding the issue is that one set of facts can often support multiple reasonable inferences.¹²⁰ Thus, it can be difficult to determine when an alleged patent infringer, asserting a defense of inequitable conduct, has in fact met its initial burden to establish intent to deceive.

*287 The Federal Circuit panel in *Scanner Technologies Corp. v. ICOS Vision Systems Corp.* addressed the issue of multiple reasonable inferences, stating that “[w]henver evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”¹²¹ Building on *Scanner Technologies*, the panel in *Star Scientific* held that “the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable

inference able to be drawn from the evidence to meet the clear and convincing standard.²¹²²

To best adhere to the en banc precedent of *Kingsdown*, courts should adopt *Star Scientific's* “single most reasonable” inference test. Courts should not find that parties alleging inequitable conduct have met their burden to show clear and convincing evidence of deceptive intent until they have at least established that the single most reasonable inference is deceptive intent. More clearly than other precedents, the rule articulates a baseline before evidence of deceptive intent can be determined to be clear and convincing. If deceptive intent is not the single most reasonable inference, it cannot be said that deceptive intent was “highly probable” and thus satisfied the requirement for clear and convincing evidence.¹²³ Furthermore, the rule prompts a comparison between evidence of bad faith and evidence of good faith. Such a comparison keeps evidentiary analysis in line with *Kingsdown's* requirement that “all the evidence, including evidence indicative of good faith,” be considered before the court finds “sufficient culpability to require a finding of intent to deceive.”²¹²⁴

IV. The Conflation of Materiality and Intent

A. The History of the “Sliding Scale” of Materiality and Intent

Prior to the formation of the Federal Circuit, there were multiple standards regarding the interplay of materiality and intent. The Seventh Circuit clearly separated its analysis of these two elements. In *Scott Paper Co. v. Fort Howard Paper Co.*, the patentee had not disclosed to the Patent Office two pieces of known prior art, which were later held at trial to invalidate the patent as obvious.¹²⁵ Without “clear, unequivocal and convincing evidence” of a deliberate misrepresentation, the Seventh Circuit refused to find that the Patent Office had been defrauded despite the high materiality of the withheld information.¹²⁶ On the other hand, the First Circuit considered the analysis of materiality and intent to be directly related.¹²⁷ The First Circuit’s decision in *Digital Equipment Corp. v. Diamond* specifically stated that “‘materiality’ and ‘culpability’ are often . . . intertwined, so that . . . a greater showing of the materiality of withheld information would necessarily create an inference that its nondisclosure was ‘wrongful.’”¹²⁸

Soon after the formation of the Federal Circuit in 1982, the court’s holding in *American Hoist & Derrick Co. v. Sowa & Sons, Inc.* adopted the First Circuit’s view that the analyses of materiality and intent were interrelated.¹²⁹ *American Hoist* suggested that where materiality was high, evidence lower than that of gross negligence may be sufficient to infer deceptive intent.¹³⁰ But where “a reasonable examiner would merely have considered particular information to be important but not crucial” to patentability, a showing of “more than gross negligence or recklessness may be required.”²¹³¹ As illustrated below, the subsequent application of a sliding scale between materiality and intent has raised questions of whether the analysis of materiality has been overemphasized, to the exclusion of an independent analysis of intent to deceive.¹³²

B. *Aventis's* Use of the “Sliding Scale”

The district court in *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.* used a sliding scale for materiality and intent, stating that “[t]he quantum of proof required to show intent is tied to materiality; the ‘more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable art conduct.’”²¹³³ The case involved a submission of misleading information comparing a drug compound claimed in the patent application to a prior art drug compound.¹³⁴ Dr. Uzan, an employee of *Aventis*, submitted information to the PTO comparing the half-life of the claimed drug compound to the half-life of the prior art.¹³⁵ But Dr. Uzan’s submission failed to clearly indicate that different doses were used for the different compounds.¹³⁶ Though *Aventis* did not dispute that Dr. Uzan knew of the different dose levels, it did dispute the assertion that Dr. Uzan withheld the dose information with an intent to mislead, instead of by an inadvertent mistake.¹³⁷

The finding of intent turned on whether there was a legitimate reason for the different-dose information to be submitted in the first place.¹³⁸ Dr. Uzan claimed that the different-dose half-life comparison was reasonable because it addressed an obviousness rejection by showing different properties of the different drug compounds at their respective clinically and therapeutically relevant doses.¹³⁹ But the district court found Dr. Uzan’s clinical justification for the different-dose comparison to be unreasonable because the justification presumed compositional differences, and with respect to a prior art anticipation rejection, “the [patent examiner] was concerned precisely with the open question of compositional difference.”²¹⁴⁰ And to establish compositional difference, the properties of compounds must be compared at the same dose.¹⁴¹ Furthermore, the district court noted that only the forty mg dose (and not the twenty mg, sixty mg, or eighty mg dose) of the claimed art²¹⁴²

drug compound showed a statistically significant half-life difference over the prior art compound at sixty mg, and the disclosure compared only the forty mg dose of the claimed drug to the unlabeled sixty mg dose of the prior art drug.¹⁴² The district court did not believe the “magnitude of [this] coincidence,” and thus inferred that Aventis and Dr. Uzan had “‘cherry-picked’ the one dose permitting a favorable comparison” to the prior art.¹⁴³

The district court used the three-prong test from *Ferring*, inquiring whether (1) the applicant failed to supply highly material information; (2) the applicant knew of the information, and knew or should have known of the information’s materiality; and (3) the applicant did not provide a credible explanation.¹⁴⁴ Applying the test, the court concluded that a “finding of deceptive intent is legitimate” because “[t]he elements of nondisclosure and high materiality have been admitted, and no credible excuse demonstrated.”¹⁴⁵ But the Federal Circuit’s en banc holding in *Kingsdown* requires 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.”¹⁴⁶ On appeal, Judge Rader, in dissent, highlighted evidence of good faith that the district court and the affirming majority at the Federal Circuit failed to take into account.¹⁴⁷

In his dissent, Judge Rader criticized how “the judicial process has too often emphasized materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct.”¹⁴⁸ Vital to Judge Rader’s dissent were three points suggesting that Dr. Uzan lacked deceptive intent. First, Dr. Uzan merely assembled data supplied by other scientists, and some of the data he received did not have the dosage information.¹⁴⁹ Thus he did not “conceal data that were otherwise *291 present.”¹⁵⁰ Second, “the absence of a dosage in subsection 3 [was] blatantly obvious” when viewed in connection with subsections 1, 2, and 4, which all contained indications of dosage.¹⁵¹ Such a conspicuous omission suggests an inadvertent error more than an intent to deceive.¹⁵² Finally, with a “candor [that] is inconsistent with deceptive intent,” Dr. Uzan himself revealed the error in a later submission.¹⁵³ Judge Rader concluded that while Dr. Uzan’s omission may have been negligent, his actions “[did] not rise to the level of intent to deceive, particularly in comparison with *Kingsdown*.”¹⁵⁴

Though the determination of the case in *Kingsdown* was a panel decision and not en banc like the “Resolution of Conflicting Precedent” section, the case still provides a useful reference to compare to the facts of *Aventis*. The patentee in *Kingsdown* filed a continuation application, and in the process of copying twenty-two claims that had been previously allowed, he mistakenly copied the rejected preamendment version of one of the claims.¹⁵⁵ The Federal Circuit deemed this negligent act to lack deceitful intent.¹⁵⁶ Important to the court’s analysis was the fact that the act seemed to be a mere “ministerial act” involving two claims in which the differences were easy to overlook.¹⁵⁷

*292 In the *Aventis* dissent, Judge Rader relies on evidence of good faith to suggest a lack of culpability.¹⁵⁸ Particularly noteworthy is that Dr. Uzan merely submitted data that he had gathered, and did not conceal evidence that was otherwise already there.¹⁵⁹ While Dr. Uzan’s omission was not as easy to overlook as the error in *Kingsdown*, Judge Rader concluded that if Dr. Uzan had intended to deceive, he would not have made the omission so conspicuous.¹⁶⁰ This evidence suggests that Dr. Uzan’s omission was a ministerial error like the one in *Kingsdown*.¹⁶¹

While the district court considered circumstantial evidence surrounding the different dosage levels to support its finding of deceptive intent, its conclusion on intent still indicates a heavy reliance on materiality. Illustrating the importance placed on the materiality of the dosage information, the court noted that “[d]osage was the fulcrum on which *Aventis*’ entire case for patentability turned.”¹⁶² Furthermore, in its conclusion on the element of intent, the court found that “[t]he elements of nondisclosure and high materiality have been admitted, and no credible excuse demonstrated.”¹⁶³ But this finding shifted the burden to *Aventis* based on the elements of nondisclosure and the high materiality, regardless of other circumstantial evidence.¹⁶⁴ This reliance on materiality does not comport with the district court’s and the Federal Circuit’s statements that materiality does not presume intent.¹⁶⁵

C. The Expansion of the Sliding Scale Standard

The Federal Circuit’s affirmation in *Aventis*, ignoring the fact that the PTO had since reissued the patent without depending on the allegedly highly material information, shows that the sliding scale standard has expanded beyond its origins. When the Federal Circuit first adopted the sliding scale in *American Hoist*, it considered *293 different tests for materiality ranging from the objective “but for” standard to the “reasonable examiner” standard.¹⁶⁶ Under the objective “but for” standard, the “misrepresentation was so material that the patent should not have issued,” and under the “reasonable examiner” standard, information was material if “there [was] a substantial likelihood that a reasonable examiner would consider it important.”¹⁶⁷ *American Hoist* suggested that where the “but for” inquiry for materiality was satisfied, a showing of less than gross

negligence may be sufficient to infer deceptive intent.¹⁶⁸ But where “a reasonable examiner would merely have considered particular information to be important but not crucial” to patentability, a showing of “more than gross negligence or recklessness may be required, and good faith judgment or honest mistake might well be a sufficient defense.”¹⁶⁹ Despite the distinction made in *American Hoist*, the Federal Circuit has shifted over time toward exclusive use of the lesser “reasonable examiner” standard.¹⁷⁰ This shift toward the lesser standard for materiality expands the sliding scale if the lesser standard for materiality is not accompanied by a more rigid standard for deceptive intent.

As stated in Judge Rader’s dissent in *Aventis*, before *Aventis* filed the infringement suit against the defendants, the company filed for a reissue of the patent without the half-life data that became controversial at trial.¹⁷¹ The Patent Office subsequently reissued the patent with all of its original independent claims.¹⁷² Thus, while the half-life information may have been material under the “reasonable examiner” standard, it is evident that the half-life data was not necessary for patentability and would not have satisfied the objective “but for” standard for materiality.

***294** However, the district court in *Aventis* analyzed the issue of intent assuming the information was highly material, going so far as to assert that “[d]osage was the fulcrum on which *Aventis*’ entire case for patentability turned.”¹⁷³ The Federal Circuit held that the district court correctly “relied on the well-settled principle . . . that a reissue proceeding cannot rehabilitate a patent held to be unenforceable due to inequitable conduct.”¹⁷⁴ But regardless of whether the original patent can be rehabilitated, the reissue itself is evidence that the controversial half-life data in the original patent application was not highly material. At the most, the half-life data can be characterized as material under the lower “reasonable examiner” standard. Thus, while the courts were correct to analyze intent based on the conduct associated with the original patent application, they should have done so in the context of a low level of materiality rather than the high level of materiality that seemed apparent prior to the reissue.

Still, the district court in *Aventis* analyzed the issue of intent in the context of a highly material omission.¹⁷⁵ Specifically, the district court stated that it “may consider what he who failed to supply highly material information should have known about the information’s materiality.”¹⁷⁶ As previously discussed, the “should have known” language represents a negligence standard.¹⁷⁷ Furthermore, when considering the evidence of good faith discussed in Judge Rader’s dissent, Dr. Uzan’s actions appear to be limited to gross negligence rather than a deliberate attempt to mislead.¹⁷⁸ Thus, by upholding the district court’s finding of inequitable conduct, the *Aventis* majority arguably endorsed a sliding scale standard where inequitable conduct can be found based on the combination of gross negligence and a low level of materiality.

As shown, *Aventis* expands the application of the sliding scale standard past the limits of *American Hoist*, which required a showing of “more than gross negligence” if a reasonable examiner merely would have considered the information to ***295** be “important but not crucial” to patentability.¹⁷⁹ Given the Federal Circuit’s use of the “should have known” standard for inferring deceptive intent and the shift toward exclusive use of the broad “reasonable examiner” standard for materiality, this expansion seems likely to continue.

D. Alternative Method of Balancing Materiality and Intent

In contrast to *Aventis*, the Federal Circuit’s decision in *Star Scientific* stressed a cleaner separation of the elements of materiality and intent and provided firm support to the rule that “materiality does not presume intent, which is a separate and essential component of inequitable conduct.”¹⁸⁰ Consistent with this rule, *Star Scientific* required that the sliding scale between materiality and intent must not be applied until after the threshold level of both materiality and intent have been individually established by clear and convincing evidence.¹⁸¹ Only after “the facts of materiality and intent to deceive [have been] proven” may the district court “balance the substance of those now-proven facts and all the equities of the case to determine whether the severe penalty of unenforceability should be imposed.”¹⁸² “It is this balancing that is committed to the district court’s discretion.”¹⁸³

To combat the expansion of the doctrine of inequitable conduct seen in *Aventis*, the Federal Circuit should rigidly uphold *Star Scientific*’s requirement that the sliding scale between materiality and intent must not be applied until after the threshold level of both materiality and intent have been individually established by clear and convincing evidence.

V. Conclusion

The difficulty with proving intent is that direct evidence is rarely available, and thus intent must be inferred from indirect and circumstantial evidence.¹⁸⁴ *296 Without direct evidence, there will always be the danger of inferring too much on the one hand and the danger of inferring too little on the other hand. But unlike other areas of the law that require an inference of intent, patent law has a backstop when it comes to inequitable conduct and the unenforceability of a patent. Court decisions involving withheld material information may also hold that a patent is rendered invalid if the withheld information shows the patent to be anticipated or made obvious by prior art. A study of patent cases between 1995 and 2004 shows that where inequitable conduct was held, and a ruling on validity was made, a staggering 89% of inequitable conduct holdings were accompanied by invalidity holdings.¹⁸⁵ This data suggests that in cases where highly material information was withheld, patentees were likely to lose patent rights regardless of the holding on inequitable conduct. Thus, there is room to combat the “plague” by rigidly enforcing the accuser’s burden of proof to establish deceptive intent with clear and convincing evidence without substantially weakening the deterrent value of the threat of losing patent rights.¹⁸⁶

In this light, the Federal Circuit should abandon the three-prong test of *Ferring*, which allows the court to shift the burden of proof to the defendant based solely on a high level of materiality and a finding that the patentee should have known of that materiality. To better comply with *Kingsdown* and to defend against the “plague” that *Kingsdown* was designed to address, the court should fully adopt the rigid standards of *Star Scientific*. Adopting the “single most reasonable” inference test would ensure that an analysis of intent complies with *Kingsdown*’s mandate that all evidence, including evidence of good faith, is considered. Furthermore, requiring evidence of a deliberate decision to mislead the PTO would ensure that the analysis of intent is not unduly influenced by materiality and that a loss of patent rights under the doctrine of inequitable conduct is based on sufficient culpability rather than minor missteps made during prosecution.

Footnotes

^{a1} Mr. Thompsen is a 2010 J.D. Candidate at the University of Texas School of Law.

¹ See *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814-16 (1945) (applying the maxim that “he who comes into equity must come with clean hands” to a case involving fraudulently attained patents).

² *Id.* at 807-08, 819-20.

³ *Id.* at 816.

⁴ 37 C.F.R. §1.56(a) (2000).

⁵ *Norton v. Curtiss*, 433 F.2d 779, 793 (C.C.P.A. 1970).

⁶ *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988) (citing *J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1559 (Fed. Cir. 1984)). The Federal Circuit has not strayed from its requirement of clear and convincing evidence to establish inequitable conduct, but for a challenge to the appropriateness of a heightened burden of proof, see B.D. Daniel, *Heightened Standards of Proof in Patent Infringement Litigation: A Critique*, 36 *AIPLA Q.J.* 369, 411-12 (2008) (arguing that given the Supreme Court’s recognition of the public’s paramount interest in keeping patent monopolies within their legitimate scope, the standard of proof for resolving charges of inequitable conduct should be preponderance of the evidence rather than clear and convincing evidence).

⁷ *Kingsdown*, 863 F.2d at 872.

⁸ See, e.g., *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006).

9 Driscoll v. Cebalo, 731 F.2d 878, 885 (Fed. Cir. 1984); Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 1151 (Fed. Cir. 1983).

10 Robert J. Goldman, Evolution of the Inequitable Conduct Defense In Patent Litigation, 7 Harv. J.L. & Tech. 37, 85 (1993).

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

12 Kingsdown, 863 F.2d 867, 876 (Fed. Cir. 1988).

13 Paul M. Janicke, Inequitable Conduct: Out of the Frying Pan? (Aug. 7, 2008) P 4, <http://www.patentlyo.com/patent/2008/08/inequitable-con.html>.

14 Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995).

15 Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1191-92 (Fed. Cir. 2006).

16 Id. at 1196, 1203 (Newman, J., dissenting).

17 Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting), cert. denied, 129 S. Ct. 2053 (2009).

18 Id. at 1349-50.

19 Id.

20 Star Scientific, Inc. v. R.J. Reynolds Tobacco Co, 537 F.3d 1357, 1366 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 1595 (2009).

21 Aside from questions over what standard should be used to infer deceptive intent, one commentator poses the question of “whether the remedy is worse than the illness” when debating whether the goals of the inequitable conduct doctrine “justify putting every patentee through the cost and jeopardy of a trial on inequitable conduct.” Paul M. Janicke, Do We Really Need So Many Mental and Emotional States in United States Patent Law?, 8 Tex. Intell. Prop. L.J. 279, 292 (2000).

22 National Research Council, A Patent System for the 21st Century 123 (Stephen A. Merrill et al. eds., 2004), available at <http://www.nap.edu/html/patentsystem/0309089107.pdf>.

23 Katherine Nolan-Stevaux, Inequitable Conduct Claims in the 21st Century: Combating the Plague, 20 Berkeley Tech. L.J. 147, 163, 169 (2005).

24 The Patent Reform Act of 2007, H.R. 1908, 110th Cong. §12(c)(3) (as placed on calendar in Senate 2007).

25 Steve Tobak, Patent Reform Act Stalls in the Senate, Cnet May 12, 2008, http://news.cnet.com/8301-13555_3-9941241-34.html.

26 Stephanie Condon, Controversial Provisions Remain in Patent Reform Bill, Cnet Mar. 3, 2009 P 8, http://news.cnet.com/8301-13578_3-10187240-38.html.

27 The Supreme Court recently denied Ferring's petition for certiorari regarding use of the "should have known" standard for deceptive intent. *Ferring B.V. v. Barr Labs. Inc.*, 437 F.3d 1181 (Fed. Cir. 1995), cert. denied, 549 U.S. 1015 (2006). The Supreme Court also recently denied Aventis's petition for certiorari regarding use of the "sliding scale" for materiality and intent. *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 2053 (2009).

28 *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1201 (Fed. Cir. 2006) (Newman, J., dissenting), cert. denied, 549 U.S. 1015 (2006).; *Larson Mfg. Co. of S.D. Inc. v. Aluminart Prods. Ltd.*, 559 F.3d. 1317, 1343 (Fed. Cir. 2009) (Linn, J., concurring).

29 *Larson*, 559 F.3d at 1344 (Linn, J., concurring).

30 *Ferring*, 437 F.3d at 1191.

31 *Larson*, 559 F.3d at 1344 (Linn, J., concurring).

32 *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997).

33 *Driscoll v. Cebalo*, 731 F.2d 878 (Fed. Cir. 1984).

34 See *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part) (citing *Driscoll's* use of a gross negligence standard before explicitly overruling that standard).

35 *Critikon*, 120 F.3d at 1256 (emphasis added).

36 Lynn C. Tyler, *Kingsdown Fifteen Years Later: What Does It Take to Prove Inequitable Conduct?*, 13 Fed. Cir. B.J. 267, 278 (2003/2004).

37 *Critikon*, 120 F.3d at 1256.

38 *Id.*

39 *Id.* at 1255-56.

40 *Id.* at 1256.

41 See, e.g., *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181 (Fed. Cir. 2006).

42 *Id.* at 1191.

43 *Id.* at 1183-86.

44 *Id.* at 1183 n.1.

45 Id. at 1184.

46 Id.

47 *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1185 (Fed. Cir. 2006).

48 Id. at 1184, 1185.

49 Id. at 1186.

50 Id. at 1191.

51 Id.

52 Id. at 1192.

53 *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1193-94 (Fed. Cir. 2006).

54 Id. at 1193.

55 Id.

56 Id. at 1196-97 (Newman, J., dissenting).

57 Id. at 1197-98.

58 Id.

59 *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1197 (Fed. Cir. 2006).

60 Id.

61 Id. at 1198 (Newman, J., dissenting).

62 Id.

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

64 Id.

65 Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008), (quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995)), cert. denied, 129 S.Ct. 1595 (2009).

66 Ferring, 437 F.3d at 1192.

67 Id. at 1198 (Newman, J., dissenting).

68 Id. (emphasis added).

69 Id.

70 Id. at 1196.

71 Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd., 559 F.3d 1317, 1344 (Fed. Cir. 2009) (Linn, J., concurring). See also Janicke, supra note 13, at P 5 (asserting that a finding of materiality in a combative courtroom will almost always result in a finding that the patentee should have known of the materiality).

72 John F. Lynch, An Argument for Eliminating the Defense of Patent Unenforceability Based on Inequitable Conduct, 16 AIPLA Q.J. 7, 16 (1988).

73 Id.

74 Ferring, 437 F.3d at 1198 (Newman, J., dissenting).

75 Id. at 1192 (majority opinion).

76 Id. at 1193.

77 Id. at 1197 (Newman, J., dissenting).

78 Id.

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

80 Id. at 1416.

81 E.g., Ferring, 437 F.3d at 1191; GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1275 (Fed. Cir. 2001); Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997).

82 Ferring, 437 F.3d at 1190 (quoting GFI, Inc., 265 F.3d at 1274).

83 Tyler, supra note 36, at 280.

84 Ferring, 437 F.3d at 1191.

85 Id.

86 Id. at 1192.

87 Id. at 1194-95.

88 Ferring, 437 F.3d at 1192 (alteration in original) (quoting Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1191 (Fed. Cir. 1993)).

89 Id. at 1191-92.

90 Id.

91 Id. at 1193.

92 Id. at 1192-93.

93 Id. at 1201 (Newman, J., dissenting).

94 Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1201 (Fed. Cir. 2006).

95 Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1191 (Fed. Cir. 1993).

96 See Ferring, 437 F.3d at 1191-93.

97 Id. at 1197-98.

98 Id.

99 Id. at 1192.

100 Id. at 1198 (Newman, J., dissenting).

101 Id. at 1200 (Newman, J., dissenting) (quoting Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1329 (Fed. Cir. 1998)). For other example statements of the rule, see Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1363 (Fed. Cir. 2007) (stating that to find inequitable conduct, there must be clear and convincing evidence of (1) materiality and (2) intent to deceive the PTO) and Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 872 (Fed. Cir. 1988) (en banc in other part) (“Inequitable conduct resides in failure to disclose material information with an intent to deceive ... and those two elements, materiality and intent, must be proven by clear and convincing evidence.”).

¹⁰² See *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 2000 (Fed. Cir. 2006) (Newman, J., dissenting).

¹⁰³ *Id.* at 1201 (Newman, J., dissenting).

¹⁰⁴ *Larson Mfg. Co. of S.D. Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1343-44 (Fed. Cir. 2009) (Linn, J., concurring).

¹⁰⁵ *Id.* at 1344 (Linn, J., concurring).

¹⁰⁶ *Id.* at 1344 (Linn, J., concurring) (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 1595 (2009)).

¹⁰⁷ *Star Scientific*, 537 F.3d at 1368 (citing *Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 398 (Fed. Cir. 1996)).

¹⁰⁸ *Id.* at 1361-63.

¹⁰⁹ *Id.* at 1367.

¹¹⁰ *Id.* at 1368.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1368 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 1595 (2009)).

¹¹⁴ *Id.* (adding that “[w]hen the absence of a good faith explanation is the only evidence of intent ... that evidence alone does not constitute clear and convincing evidence warranting an inference of intent.” (quoting *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006))). The court also noted that a 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.” *Id.* (citing *Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 398 (Fed. Cir. 1996)).

¹¹⁵ *Id.* at 1369, 1373 (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)).

¹¹⁶ *Id.* at 1366; *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006) (quoting *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989)).

¹¹⁷ *Star Scientific*, 537 F.3d at 1366; *Ferring*, 437 F.3d at 1191 (quoting *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005)).

¹¹⁸ See *supra* notes 30-31 and accompanying text.

¹¹⁹ See *supra* note 65 and accompanying text. See also discussions *infra* Part IV.D, notes 179-182 and accompanying text.

120 See supra note 56 and accompanying text.

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

122 Star Scientific, 537 F.3d at 1366 (emphasis added).

123 See Black’s Law Dictionary 596 (8th ed. 2004) (defining “clear and convincing evidence” as “[e]vidence indicating that the thing to be proved is highly probable or reasonably certain.”).

124 Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) (citing Norton v. Curtiss, 433 F.2d 779 (C.C.P.A. 1970)) (en banc in relevant part).

125 Scott Paper Co. v. Fort Howard Paper Co., 432 F.2d 1198, 1202 (7th Cir. 1970).

126 Id. at 1204-05.

127 Digital Equip. Corp. v. Diamond, 653 F.2d 701, 716 (1st Cir. 1981).

128 Id. at 716 (citing United States v. Standard Elec. Co., 155 F. Supp. 949, 952-53 (D. Mass. 1957)).

129 Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1363 (Fed. Cir. 1984).

130 See id.

131 Id.

132 See Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334, 1350 (Fed. Cir. 2008) (Rader, J., dissenting), cert. denied, 129 S. Ct. 2053 (2009).

133 Aventis Pharma S.A. v. Amphastar Pharms., Inc., 475 F. Supp. 2d 970, 976 (C.D. Cal. 2007), (quoting Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1375 (Fed. Cir. 2000)), aff’d, 525 F.3d 1334 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 2053 (2009). The Federal Circuit reviewed the case on the same sliding-scale basis, stating that “[t]he more material the omission or misrepresentation, the less intent that must be shown to elicit a finding of inequitable conduct.” Aventis, 525 F.3d at 1344 (quoting Impax Labs., Inc. v. Aventis Pharms., Inc., 468 F.3d 1366, 1375 (Fed. Cir. 2006)).

134 Aventis, 525 F.3d at 1348-49.

135 Id. at 1338.

136 Id. at 1348-49.

137 Aventis, 475 F. Supp. 2d at 989-90.

138 See id. at 977-79.

139 Id. at 977.

140 Id. at 978-79.

141 Id. at 982.

142 Id. at 986.

143 Aventis Pharma S.A. v. Amphastar Pharms., Inc., 475 F. Supp. 2d 970, 986-87, 994 (C.D. Cal. 2007), aff'd, 525 F.3d 1334 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 2053 (2009).

144 Id. at 992-93. The district court cited the Federal Circuit's decision in Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006), for the legitimacy of the three-prong test for intent.

145 Aventis, 475 F. Supp. 2d at 992-93.

146 Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1998) (citing Norton v. Curtiss, 433 F.2d 779 (C.C.P.A. 1970)) (en banc in relevant part).

147 See Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334, 1350-52 (Fed. Cir. 2008) (Rader, J., dissenting), cert. denied, 129 S. Ct. 2053 (2009).

148 Id. at 1350.

149 Id. at 1351.

150 Id.

151 Id. at 1352.

152 See id. at 1351-52.

153 Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334, 1350-52 (Fed. Cir. 2008) (Rader, J., dissenting), cert. denied, 129 S. Ct. 2053 (2009). The Federal Circuit majority found that despite the later disclosure, "the data were provided in a misleading way." Id. at 1349 (majority opinion). The majority then cited Paragon Podiatry Labs., Inc. v. KLM Lab., Inc., 984 F.2d 1182, 1191 (Fed. Cir. 1993), for the proposition that deceptive intent may be inferred from the misleading character of an affidavit. Aventis, 525 F.2d at 1349. But Paragon Podiatry is easily distinguished from the facts of Aventis. In Paragon Podiatry, the patentee submitted supporting affidavits that had been affirmatively drafted with "deliberate artfulness" to misrepresent company stockholders as disinterested third parties. Paragon Podiatry, 984 F.2d at 1191. But as Judge Rader noted in dissent in Aventis, Dr. Uzan only submitted the Foquet chart without filling in the missing data; he did not affirmatively conceal something that was already there. Aventis, 525 F.3d at 1351 (Rader, J., dissenting).

154 Aventis, 525 F.3d at 1351-52 (Rader, J., dissenting).

155 Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 873 (Fed. Cir. 1988).

156 Id.

157 Id. at 875.

158 See supra notes 149-153 and accompanying text.

159 Aventis, 525 F.3d at 1351 (Rader, J., dissenting).

160 Id. at 1351-52.

161 See id.

162 Aventis Pharma S.A. v. Amphastar Pharms., Inc., 475 F. Supp. 2d 970, 993 (C.D. Cal. 2007), aff'd, 525 F.3d 1334 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 2053 (2009).

163 Id.

164 For an in-depth discussion on burden shifting, see supra Part III.

165 Aventis, 475 F. Supp. 2d at 976 (quoting GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001)).

166 Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1362-63 (Fed. Cir. 1984) (internal citations and emphasis omitted).

167 Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (citing Am. Hoist & Derrick Co., 725 F.2d at 1362).

168 Am. Hoist & Derrick Co., 725 F.2d at 1363.

169 Id.

170 See Digital Control, 437 F.3d at 1316 (“[B]ecause a party alleging inequitable conduct need only prove a ‘threshold level’ of materiality in order to proceed to the second ‘balancing’ portion of the inequitable conduct inquiry, and because the PTOs ‘reasonable examiner’ standard was broader than the other three standards, the PTO standard gradually became the sole standard invoked by this court.”).

171 Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334, 1352 (Fed. Cir. 2008) (Rader, J., dissenting), cert. denied, 129 S. Ct. 2053 (2009).

172 Id.

173 *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 475 F. Supp. 2d 970, 993 (C.D. Cal. 2007), *aff'd*, 525 F.3d 1334 (Fed. Cir. 2008), cert. denied, 129 S. Ct. 2053 (2009).

174 *Aventis*, 525 F.3d at 1341 n.6 (citing *Hoffman-La Roche Inc. v. Lemmon Co.*, 906 F.2d 684, 688 (Fed. Cir. 1990)).

175 *Aventis*, 475 F. Supp. 2d at 993.

176 *Id.* at 990 (emphasis added).

177 See *supra* note 13 and accompanying text. See also *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1344 (Fed. Cir. 2009) (Linn, J., concurring).

178 See *Aventis*, 525 F.3d at 1351-52 (Rader, J., dissenting).

179 *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir. 1984).

180 *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008) (quoting *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001)), cert. denied, 129 S. Ct. 1595 (2009).

181 *Id.* at 1367.

182 *Id.*

183 *Id.* (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)).

184 See *id.* at 1366 (“[B]ecause direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence.”); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006) (stating that intent rarely can be proven by direct evidence and is “generally inferred from the facts and circumstances surrounding a knowing failure to disclose information”) (citing *Merck & Co., v. Danbury Pharmacal., Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989) and quoting *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005) (emphasis added)).

185 *Nolan-Stevaux*, *supra* note 23, at 163.

186 However, the loss of patent rights because of invalidity may be less severe than for unenforceability under inequitable conduct. Invalidity is applied on a claim-by-claim basis. See 35 U.S.C. §253 (2006). But inequitable conduct will render the entire patent unenforceable. *Craig Allen Nard & R. Polk Wagner, Patent Law 186* (2008).