



WAKE FOREST
INTELLECTUAL PROPERTY
LAW JOURNAL

VOLUME 10

2009 - 2010

NUMBER 1

***KINGSDOWN TWENTY YEARS LATER: WHAT IT TAKES TO PROVE
INEQUITABLE CONDUCT IS NO CLEARER***

By Lynn Tyler*
©2009, Barnes & Thornburg LLP
All Rights Reserved

INTRODUCTION

In 2004, the author published an article that analyzed the requirements for proving the defense of inequitable conduct to a claim of patent infringement.¹ In particular, the article focused on the second element of inequitable conduct – intent to deceive – and whether it can be inferred from the failure to disclose a material or highly material reference.² The article noted that in *Kingsdown Med. Consultants Ltd. v. Hollister, Inc.*,³ the Federal Circuit ruled *en banc* in relevant part:

We adopt the view that a finding that particular conduct amounts to “gross negligence” does not of itself justify an inference of an intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.⁴

* The author is a partner in the Indianapolis office of Barnes & Thornburg LLP. The views expressed in this article are those of the author and not of Barnes & Thornburg LLP, its other attorneys, or its clients.

¹ Lynn C. Tyler, *Kingsdown Fifteen Years Later: What Does It Take To Prove Inequitable Conduct?*, 13 FED. CIR. B.J. 267 (2004).

² *Id.* at 270-83.

³ *Kingsdown Med. Consultants Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (en banc).

⁴ *Id.* at 876.

The court overruled *Driscoll v. Cebalo*,⁵ which had concluded that gross negligence would support the finding of an intent to deceive.⁶ Specifically, in *Driscoll*, the court had written that, “Where [the inventors and their attorneys] knew, or should have known, that the withheld reference would be material to the PTO’s consideration, their failure to disclose the reference is sufficient proof of the existence of an intent to mislead the PTO.”⁷ The court’s *en banc* decision in *Kingsdown* rejected this rule. Nonetheless, the earlier article reviewed at least four Federal Circuit decisions that appeared to have resurrected the overruled standard from *Driscoll*.⁸ An early case to have gone astray on this issue was *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*,⁹ which inexplicably relied solely on *Driscoll* as support for the very proposition on which *Driscoll* had been overruled by *Kingsdown*, namely, “[I]ntent 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.”¹⁰

It is now five years later, twenty years after the *Kingsdown* decision, and unfortunately the conflicting state of the case law has not improved. On the one hand, there have been several Federal Circuit decisions that have relied upon or otherwise remained true to *Kingsdown* by finding that the failure to disclose a material reference alone is insufficient to support a finding of an intent to deceive the PTO and, therefore, inequitable conduct.¹¹ On the other hand, the

⁵ *Driscoll v. Cebalo*, 731 F.2d 878 (Fed. Cir. 1984). *See id.* at 876 (rejecting the *Driscoll* standard).

⁶ *Driscoll*, 731 F.2d at 885.

⁷ *Id.*

⁸ Tyler, *supra* note 1, at 276-83.

⁹ *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997). *See LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066 (Fed. Cir. 1992), as an earlier case that went astray on the issue, but later cases picked up the erroneous standard from *Critikon* rather than *LaBounty*.

¹⁰ *Critikon*, 120 F.3d at 1256. As shown in the earlier article, this proposition was not necessary to the decision in *Critikon* because *Critikon* “involved more than the failure to disclose a known material reference; it also involved the knowing failure to disclose that invalidity and inequitable conduct were being asserted as defenses in litigation.” Tyler, *supra* note 1, at 278.

¹¹ *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340-41 (Fed. Cir. 2009); *Eisai Co. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1360-61 (Fed. Cir. 2008); *Scanner Tech. Corp. v. Icos Vision Sys. Corp., B.V.*, 528 F.3d 1365, 1376-79 (Fed. Cir. 2008); *Star Scientific, Inc. v. R. J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365-71 (Fed. Cir. 2008); *In re Metoprolol Succinate Patent Lit.*, 494 F.3d 1011, 1020-21 (Fed. Cir. 2007); *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 1001-02 (Fed. Cir. 2006); *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006); *Old Town Canoe Co. v. Confluence*

earlier article has now been cited in the separate opinions of two judges of the Federal Circuit.¹² Judge Newman appeared to agree with the article that *Critikon* is “bad law” because it relied on the overruled *Driscoll*.¹³ Judge Linn cited the article as tracing to *Critikon* the adoption of a simple negligence standard even lower than the gross negligence standard expressly rejected in *Kingsdown*.¹⁴ Notwithstanding its awareness of the issue, however, in the past five years the Federal Circuit has issued several more precedential opinions that continue to rely upon *Critikon* or its erroneous version of the standard.¹⁵ Some of these cases are not necessarily inconsistent with *Kingsdown*,¹⁶ while several other decisions are difficult to reconcile with the *Kingsdown* standard for finding an intent to deceive.¹⁷

Against this background, this article will first review in more detail the post-2004 Federal Circuit cases that have followed *Kingsdown* and held that the intent to deceive cannot be inferred merely from the failure to disclose a known material reference. Second, the article will analyze in more detail post-2004 Federal Circuit cases that have continued to inappropriately follow *Critikon* or other cases upholding a finding of intent to deceive based solely on the failure to disclose a known material reference. Finally, the article will review several reasons, apart from its precedential status, that the

Holdings Corp., 448 F.3d 1309, 1322 (Fed. Cir. 2006); *Purdue Pharma LP v. Endo Pharm., Inc.*, 438 F.3d 1123, 1134 (Fed. Cir. 2006).

¹² *Larson*, 559 F.3d at 1344 n.1 (Linn, J., concurring) (noting that prior article traced divergence in Federal Circuit precedent on this issue to *Critikon*, which relied on the “should have known” standard of *Driscoll*, which in turn had been overruled by *Kingsdown*); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1202 (Fed. Cir. 2006) (Newman, J., dissenting). See *Kingsdown*, 863 F.2d at 876; *Driscoll*, 731 F.2d at 885; *Critikon*, 120 F.3d at 1256.

¹³ *Ferring*, 437 F.3d at 1202.

¹⁴ *Larson*, 559 F.3d at 1344 n.1.

¹⁵ *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1341 (Fed. Cir. 2008); *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1240-41 (Fed. Cir. 2008); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1314-15, 1318 (Fed. Cir. 2008); *Cargill, Inc. v. Canbra Foods Ltd.*, 476 F.3d 1359, 1365-66 (Fed. Cir. 2007); *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1345-46 (Fed. Cir. 2007); *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1235 (Fed. Cir. 2007); *Agfa Corp. v. Creo Prods., Inc.*, 451 F.3d 1366, 1378 (Fed. Cir. 2006); *Ferring*, 437 F.3d at 1190-91; *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354-55 (Fed. Cir. 2005); *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1359-62 (Fed. Cir. 2005); *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1371-73 (Fed. Cir. 2005).

¹⁶ See *Cargill*, 476 F.3d at 1366-68; *Dippin’ Dots*, 476 F.3d at 1345-46; *Nilssen*, 504 F.3d at 1235; *Pharmacia*, 417 F.3d at 1373.

¹⁷ See *Monsanto*, 514 F.3d at 1240-42; *Praxair*, 543 F.3d at 1313-19; *Agfa*, 451 F.3d at 1378-80; *Ferring*, 437 F.3d at 1191-94; *Bruno*, 394 F.3d at 1351-55; *Novo Nordisk*, 424 F.3d at 1359-62.

Federal Circuit should uniformly and strictly enforce the higher *Kingsdown* standard for proving an intent to deceive.

I. THE GOOD: SEVERAL POST-2004 CASES HAVE
STRICTLY FOLLOWED *KINGSDOWN*.

The first post-2004 decision that followed the *Kingsdown* standard, albeit without citing *Kingsdown* directly, is *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*¹⁸ Purdue alleged that Endo's proposed generic versions of OxyContin, a painkiller, would infringe three Purdue patents.¹⁹ The specification of each of the patents-in-suit included language to the effect that, using a four-fold range of dosages, the claimed oxycodone formulation achieved the same clinical results as the prior art opioid formulations achieved using an eight-fold range of dosages.²⁰ The specification further explained that the "clinical significance" of the four-fold dosage range of the claimed oxycodone formulations was "a more efficient titration process, which is the process of adjusting a patient's dosage to provide acceptable pain relief without unacceptable side effects."²¹ Endo alleged, and the trial court found, that Purdue was guilty of inequitable conduct because it had failed to disclose that the claim about the four-fold range of dosages, compared to the eight-fold range for other opioids, was based on "insight" rather than "scientific proof."²² Purdue appealed the inequitable conduct judgment to the Federal Circuit.²³

On appeal, Purdue did "not dispute the absence of clinical evidence during the relevant time-frame to support its claim of a four-fold dosage range for oxycodone."²⁴ After a lengthy discussion of materiality, the Federal Circuit affirmed the trial court's finding that the failure to disclose the absence of experimental evidence to support the four-fold range of dosages claim was material but stressed that "[T]he level of materiality is not especially high."²⁵ The Federal Circuit noted that Purdue had not misrepresented that it had obtained experimental results, but "Instead Purdue made statements implying that an empirical basis existed for its discovery and then failed to disclose that the discovery was based only on insight."²⁶ On the issue

¹⁸ *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123 (Fed. Cir. 2006).

¹⁹ *Id.* at 1125-26.

²⁰ *Id.* at 1127.

²¹ *Id.*

²² *Id.* at 1128.

²³ *Id.*

²⁴ *Id.* at 1130.

²⁵ *Id.* at 1133.

²⁶ *Id.*

of intent, however, the Federal Circuit vacated the inequitable conduct judgment and remanded the case to the trial court to reconsider the evidence.²⁷

After noting that direct evidence of intent to deceive is rare and that intent to deceive can be inferred solely from the surrounding circumstances,²⁸ the court went on to state, “Intent to deceive, however, cannot be ‘inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.’”²⁹ The court then quoted *Critikon* for the proposition 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.”³⁰ The court then stated, “Nevertheless, it is important to remember that ‘materiality does not presume intent, which is a separate and essential component of inequitable conduct.’”³¹

Turning to the facts of the case, the Federal Circuit found two errors with the trial court’s analysis of the evidence of intent to deceive. First, according to the court, the trial court improperly discounted evidence of good faith offered by Purdue.³² The court found that evidence that Purdue had difficulty proving its efficient titration claim related more to its attempt to obtain FDA approval for a proposed labeling claim than it did to Purdue’s attempt to obtain allowance of its patent claims and was not inconsistent with Purdue’s asserted belief that it had discovered its oxycodone was effective over a four-fold dosage range.³³ Second, the Federal Circuit held that the trial court had failed to consider properly the level of materiality.³⁴ As noted above, the Federal Circuit found that the level of materiality was low and, accordingly, there was less of a basis to infer intent from materiality alone.³⁵ Because of these two errors, the Federal Circuit vacated the inequitable conduct judgment and remanded to the lower court to re-weigh the evidence, with the recommendation that the trial

²⁷ *Id.* at 1135.

²⁸ *Id.* at 1133-34 (citing *Baxter Int’l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1329 (Fed. Cir. 1998)).

²⁹ *Id.* at 1134 (quoting *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996)).

³⁰ *Id.* at 1134 (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997)).

³¹ *Id.* (quoting *Allen Eng’g Corp. v. Bartel Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2002)).

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.* at 1134-35.

court “keep in mind that when the level of materiality is relatively low, the showing of intent must be proportionately higher.”³⁶

The *Purdue Pharma* case was followed shortly by *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*³⁷ In *M. Eagles*, the patent-in-suit covered a device for removing decals from a motor vehicle.³⁸ One of the defendants’ inequitable conduct allegations was based on the plaintiff’s failure to disclose during prosecution the Model 220 die grinder which had been sold for 20 years prior to the date of the application for the patent-in-suit and which included some of the elements of the proposed claims that the examiner had not been able to find in the prior art.³⁹ The district court granted summary judgment of inequitable conduct, finding that the withheld Model 220 was material because it included some elements on whose absence from the prior art the examiner had relied while allowing the patent and because the plaintiff did not offer a good faith explanation for its failure to disclose the Model 220.⁴⁰ Accordingly, as summarized by the Federal Circuit, “The issue central to the disposition of this case is whether a lack of a good faith explanation for a nondisclosure of prior art, when nondisclosure is the only evidence of intent, is sufficient to constitute clear and convincing evidence to support an inference of intent.”⁴¹ The court then concluded “that a failure to disclose a prior art device to the PTO, where the only evidence of intent is a lack of a good faith explanation for the non-disclosure, cannot constitute clear and convincing evidence sufficient to support a determination of culpable intent.”⁴² After again noting that “Intent need not be proven by direct evidence,”⁴³ and that intent is generally inferred from the circumstances, the court stated that “There still must be a factual basis, however, for a finding of intent.”⁴⁴ The court concluded that “When the absence of a good faith explanation is the only evidence of intent, however, that evidence alone does not constitute clear and convincing evidence warranting an inference of intent.”⁴⁵

³⁶ *Id.* at 1135.

³⁷ *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335 (Fed. Cir. 2006).

³⁸ *Id.* at 1336.

³⁹ *Id.* at 1338.

⁴⁰ *Id.*

⁴¹ *Id.* at 1341.

⁴² *Id.*

⁴³ *Id.* at 1341 (citing *Merck & Co. v. Danbury Pharm., Inc.*, 873 F.2d 1418 (Fed. Cir. 1989)).

⁴⁴ *Id.* (citing *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996)).

⁴⁵ *Id.* *But see* *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997) (“Intent may be inferred where a patent applicant knew,

*Atofina v. Great Lakes Chemical Corp.*⁴⁶ is similar in its basic facts, rationale, and result to *M. Eagles*. In *Atofina*, the patent-in-suit covered a method of synthesizing difluoromethane.⁴⁷ After a bench trial, the district court held the patent-in-suit was unenforceable because of inequitable conduct.⁴⁸ The inequitable conduct decision was based on Atofina's failure to disclose the full English translation of a Japanese reference, JP 51-82206, to the PTO.⁴⁹ The district court found that JP 51-82206 was highly material because it anticipated several claims of the patent-in-suit.⁵⁰ The district court also based its finding of deceptive intent on certain alleged misrepresentations regarding the JP 51-82206 reference.⁵¹

In its opinion, the Federal Circuit reversed the district court's finding of intent to deceive and, thus, of inequitable conduct.⁵² Consistent with *M. Eagles*, the court held:

The issue here is whether Great Lakes proved intent by clear and convincing evidence. The district court inferred intent from the applicants' failure to disclose the full English translation of JP 51-82206 and its alleged mischaracterizations of that reference. However, the applicant's failure to disclose the full English translation of JP 51-82206 is not in and of itself enough to infer intent, even if the full English translation went beyond the Derwent Abstract, which is far from clear Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.⁵³

The court then went on to analyze the three alleged mischaracterizations of JP 51-82206 and found that none of them were actual mischaracterizations.⁵⁴ Accordingly, the only evidence of intent to deceive was the failure to disclose, which was insufficient as a matter of law.⁵⁵

or should have known, that withheld information would be material to the PTO's consideration of the patent application.").

⁴⁶ See *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991 (Fed. Cir. 2006).

⁴⁷ *Id.* at 993.

⁴⁸ *Id.* at 994.

⁴⁹ *Id.* at 994-95.

⁵⁰ *Id.*

⁵¹ *Id.* at 995.

⁵² *Id.* at 1002.

⁵³ *Id.* at 1001-02 (quoting *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996)).

⁵⁴ *Id.* at 1002.

⁵⁵ *Id.*

In *Old Town Canoe Co. v. Confluence Holdings Corp.*,⁵⁶ the district court had granted the patentee, Old Town's, motion for judgment as a matter of law that there was insufficient evidence of inequitable conduct.⁵⁷ The inequitable conduct charge was based on an allegation that approximately 500 canoes had been made using the patented method and sold more than one year prior to the date of the application for the patent-in-suit.⁵⁸ Acknowledging that the alleged prior art canoes could be material, the Federal Circuit nonetheless affirmed the judgment as a matter of law of no inequitable conduct, noting that "Confluence points to no evidence of intent to deceive the PTO."⁵⁹ The court relied on the familiar principle that "Materiality does not presume intent, which is a separate and essential component of inequitable conduct."⁶⁰ The court declined Confluence's invitation to draw an inference of intent to deceive on appeal from the alleged materiality alone and stated that Confluence's "general argument on this record is not sufficient to enable us to conclude that the district court abused its discretion."⁶¹

*In re Metoprolol Succinate Patent Litigation*⁶² reversed a summary judgment of inequitable conduct entered against AstraZeneca and affiliates in a consolidated multi-district case against several defendants alleging infringement of patents covering Toprol-XL. The inequitable conduct allegations arose out of an inventorship dispute between AstraZeneca and two former employees who had left to join another company.⁶³ The two companies settled the dispute by dividing certain claims out of a pending patent application, assigning them to AstraZeneca, and naming the former employees as the inventors of those claims.⁶⁴ The inventorship dispute was never disclosed to the PTO during the prosecution of the patents-in-suit.⁶⁵

The district court based its summary judgment of inequitable conduct on the conclusions that the inventorship dispute was highly material and AstraZeneca had a strong incentive not to disclose the dispute to the PTO.⁶⁶ According to the district court, if the patent

⁵⁶ *Old Town Co. v. Confluence Holdings Corp.*, 448 F.3d 1309 (Fed. Cir. 2006).

⁵⁷ *Id.* at 1313.

⁵⁸ *Id.* at 1321-22.

⁵⁹ *Id.* at 1322.

⁶⁰ *Id.* (quoting *Allen Eng'g Corp. v. Bartel Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2002)).

⁶¹ *Id.*

⁶² *In re Metoprolol Succinate Patent Litig.*, 494 F.3d 1011, 1013-14 (Fed. Cir. 2007).

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.* at 1014.

⁶⁶ *Id.* at 1020.

examiner had resolved the inventorship dispute unfavorably to AstraZeneca, one of its metoprolol succinate patents would have lost its priority date and may have been rejected as anticipated by the prior art of an intervening publication of a European patent application.⁶⁷ The Federal Circuit, however, found that there was a genuine issue of material fact regarding AstraZeneca's intent to deceive because:

[T]he deposition of Astra's in-house patent counsel indicates that he did not know of and was not concerned about the incentives identified by the district court in its but for analysis. Therefore, the record reveals a genuine factual dispute of whether Astra had an intent to deceive the US Patent & Trademark Office.⁶⁸

Metoprolol Succinate thus supports the statement in several cases that, while it is possible to find inequitable conduct on summary judgment, it should be rare given the inherently factual nature of the issues.⁶⁹

In *Scanner Technologies Corp. v. Icos Vision Systems Corp. N.V.*,⁷⁰ the inequitable conduct defense was based on statements made in a Petition to Make Special that were alleged to be false.⁷¹ After a bench trial, the district court concluded that statements in a petition to make special are always material and that some of the statements were false, supporting a conclusion of intent to deceive and thus inequitable conduct.⁷²

On appeal, the Federal Circuit agreed that false statements in a successful petition to make special are material.⁷³ The Federal Circuit held, "[W]e reaffirm that a false statement that succeeds in expediting the application is, as a matter of law, material for purposes of assessing the issue of inequitable conduct."⁷⁴ The court began its analysis of whether the statements were false by citing *Akron Polymer Container Corp. v. Exxel Container, Inc.*⁷⁵ for the following rule:

Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a

⁶⁷ *Id.*

⁶⁸ *Id.* at 1021.

⁶⁹ *See, e.g.,* *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006) ("Determining at summary judgment that a patent is unenforceable for inequitable conduct is permissible, but uncommon."); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006); *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1190 (Fed. Cir. 1993).

⁷⁰ *Scanner Tech. Corp. v. Icos Vision Sys. Corp. N.V.*, 528 F.3d 1365 (Fed. Cir. 2008).

⁷¹ *Id.* at 1372.

⁷² *Id.*

⁷³ *Id.* at 1375.

⁷⁴ *Id.*

⁷⁵ *Id.* at 1376 (citing *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380 (Fed. Cir. 1998)).

district court clearly errs in overlooking one inference in favor of another equally reasonable inference. All reasonable inferences must be drawn from the evidence, and a judgment then rendered on the evidence as informed by the range of reasonable inferences. Where the rule is breached, no inequitable conduct may be found. The rule is necessary, for without it findings of inequitable conduct, with the punishment of unenforceability of the entire patent, could wrongly stand.⁷⁶

The court then reviewed in considerable detail the evidence concerning several statements from the Petition to Make Special that were allegedly false, found the evidence equivocal, and concluded that the evidence did not meet the clear and convincing standard applicable to inequitable conduct.⁷⁷ Although *Scanner Technologies* did not address the intent to deceive issue, which the court found to be moot,⁷⁸ it is noteworthy for its discussion of the rule of *Akron Polymer*, which did turn on the intent to deceive issue.⁷⁹ The *Akron Polymer* rule is consistent with *Kingsdown* in its insistence on clear and convincing evidence of a high standard for intent to deceive.

Eisai Co. v. Dr. Reddy's Laboratories, Ltd.,⁸⁰ a relatively recent decision that quoted the *Kingsdown* standard for finding an intent to deceive, noted that “Gross negligence is not sufficient,” and commented that “This is a high bar.”⁸¹ Eisai sued Dr. Reddy's for infringing a patent covering rabeprazole, part of a class of drugs that suppresses stomach acid.⁸² Dr. Reddy's and another defendant alleged five grounds for inequitable conduct: (1) the failure to disclose a co-pending application claiming the “ethyl homolog” of rabeprazole; (2) withholding rejections from the prosecution of the co-pending application that would have also been applicable to the prosecution of the patent-in-suit; (3) failing to disclose a particular prior patent; (4) submitting an allegedly misleading declaration, and (5) concealing a patent application for a prior compound in the same class of drugs.⁸³ The district court rejected the last assertion on summary judgment and the other four after a bench trial.⁸⁴

⁷⁶ *Id.* (footnotes omitted).

⁷⁷ *Id.* at 1376-78.

⁷⁸ *Id.* at 1379.

⁷⁹ *See id.* at 1375; *Akron Polymer*, 148 F.3d at 1382.

⁸⁰ *Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008).

⁸¹ *Id.* at 1360.

⁸² *Id.* at 1355-56.

⁸³ *Id.* at 1360.

⁸⁴ *Id.*

In its opinion, the Federal Circuit likewise rejected each of the five alleged grounds for inequitable conduct.⁸⁵ For present purposes, the fourth ground, the allegedly misleading declaration, is most significant. The declaration was submitted to overcome an obviousness rejection and Dr. Reddy's argued that it was misleading in part because it did not include data comparing the patented compound to the ethyl homolog.⁸⁶ Although the Federal Circuit found the declaration itself highly material, it found that the materiality of the ethyl homolog was low and in any event it found no separate evidence of an intent to deceive.⁸⁷ In other words, the high materiality of the declaration itself, and the low materiality of the omitted compound were not sufficient to support an inference of intent to deceive and there was no other evidence of intent to deceive, dooming the inequitable conduct allegation.⁸⁸ The other allegations based on a failure to disclose were doomed for the same reasons, *i.e.*, their materiality, if any, was low and there was no independent evidence of an intent to deceive.⁸⁹

The final two cases to be discussed contain some of the strongest language supporting *Kingsdown's* high standard for proving intent to deceive and also the strongest actual applications of the standard. In *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*,⁹⁰ the patents-in-suit covered methods of curing tobacco designed to lower the levels of tobacco specific nitrosamines ("TSNAs") – carcinogens – in the cured tobacco.⁹¹ Star hired a patent attorney to file an application on its curing method in August 1998.⁹² Later that same month, Star's attorney received a letter from a scientist and Star consultant suggesting that the prior art technique was responsible for producing cured tobacco with low levels of TSNA in China.⁹³ A provisional application was filed in September 1998 and one year later a utility application was filed.⁹⁴ Shortly after the utility application was filed, Star decided to change its prosecution counsel from one firm to another and the transfer from the first to the second was handled by yet another firm.⁹⁵ The change of counsel and method of transferring the file led to the theory of inequitable conduct, namely,

⁸⁵ *Id.* at 1360-62.

⁸⁶ *Id.* at 1361-62.

⁸⁷ *Id.* at 1362.

⁸⁸ *Id.*

⁸⁹ *Id.* at 1360-62.

⁹⁰ *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008).

⁹¹ *Id.* at 1361.

⁹² *Id.*

⁹³ *Id.* at 1361-62.

⁹⁴ *Id.* at 1362.

⁹⁵ *Id.* at 1363.

that the switch was made to prevent the new counsel from learning about the consultant's August 1998 letter and to prevent the letter from being disclosed to the PTO.⁹⁶ The district court held a bench trial and accepted this theory, declaring the patents in suit unenforceable for inequitable conduct.⁹⁷

On appeal, the Federal Circuit reversed, finding "that the district court clearly erred in finding that RJR had proven that . . . Star had an intent to deceive the PTO."⁹⁸ After reciting the elements of inequitable conduct, the court next highlighted the importance of upholding the high standards of proof for this defense:

The need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability. This penalty was originally applied only in cases of "fraud on the Patent Office" Subsequent case law has broadened the doctrine to encompass misconduct less egregious than fraud . . . but the severity of the penalty has not changed, and thus courts must be vigilant in not permitting the defense to be applied too lightly. Just 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. As a result, 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.⁹⁹

The court then emphasized that there must be separate proof of an intent to deceive; in other words, proof that material information was withheld does not alone satisfy the deceptive intent element.¹⁰⁰ Acknowledging that intent to deceive can be proven by inference from circumstantial evidence, the court nonetheless cited *Scanner Technologies* (discussed above) for the proposition that "[T]he 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*

⁹⁶ *Id.* at 1367.

⁹⁷ *Id.* at 1365.

⁹⁸ *Id.*

⁹⁹ *Id.* at 1365-66.

¹⁰⁰ *Id.* at 1366.

reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.”¹⁰¹

Applying these standards to the facts of the case, the Federal Circuit found that the defendants’ “quarantine” theory – that the first law firm was replaced in a manner designed to keep the new firm from learning of the consultant’s letter – was not supported by clear and convincing evidence, so the finding of intent to deceive was clearly erroneous.¹⁰² The court noted that Star had offered an unrelated explanation for its decision to change prosecution counsel, but the district court found that the explanation was not credible.¹⁰³ The explanation was that a key partner had passed away and that Star’s inventor believed another attorney in the firm had performed unsatisfactorily in an unrelated prosecution. The Federal Circuit rejected the district court’s credibility finding as a basis for inequitable conduct, however:

But even if Star’s explanations are not to be believed, it remained RJR’s burden to prove its allegation regarding the reason for the [first] firm’s dismissal. RJR cannot carry its burden simply because Star 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. 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.¹⁰⁴

The court then noted that there was unbridgeable gap in RJR’s evidence, namely, it had no evidence that Star knew what the consultant’s letter said prior to replacing the first firm or that the letter was a reason for the change of firms. In fact, the inventor testified that he had never seen the consultant’s letter prior to his deposition in the case. The court then observed that “[N]o inference can be drawn if there is no evidence, direct or indirect, that can support the inference. RJR’s lack of any evidence at all on the crux of its theory, let alone clear and convincing evidence, demonstrates that it failed to carry its

¹⁰¹ *Id.* (citing *Scanner Tech. Corp. v. Icos Vision Systems Corp. N.V.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008))

(emphasis added).

¹⁰² *Id.* at 1367-68.

¹⁰³ *Id.* at 1368.

¹⁰⁴ *Id.* (emphasis in original; citations omitted). Note that the quoted passage, like the passages from *M. Eagles* quoted in *supra* text accompanying notes 42 and 45 appears to contradict the passage from *Critikon* quoted in *supra* text accompanying note 10.

burden.”¹⁰⁵ The court also noted that the second firm was given the consultant’s letter, likewise undermining the entire theory.¹⁰⁶ Given the absence of any intent to deceive, the Federal Circuit reversed the finding of inequitable conduct.¹⁰⁷

The last of the post-2004 pro-*Kingsdown* decisions (at least as of the writing of this article), *Larson Manufacturing of South Dakota v. Aluminart Products Ltd.*,¹⁰⁸ followed *Star Scientific* and applied many of its key principles. In *Larson*, the patent-in-suit covered a storm door with a retractable screen feature.¹⁰⁹ Aluminart filed a request for reexamination with the PTO. The PTO conducted the reexamination at the same time as the prosecution of a continuation application from the patent-in-suit. The re-examination concluded with some claims canceled, some confirmed, and some allowed with slight modifications.¹¹⁰ After the district court proceeding resumed, Aluminart amended its pleadings to include a counterclaim for inequitable conduct during the reexamination. Aluminart alleged that Larson had withheld three material references and the last two (of four total) office actions from the prosecution of the continuation application.¹¹¹ The district court sided with Aluminart, finding each of the three prior art references and both office actions material.¹¹² The district court found that Larson’s intent to deceive could be inferred from its failure to disclose several material references but also from its failure to provide any plausible excuse for the withholding.¹¹³

The Federal Circuit gave a detailed analysis of the materiality of the three withheld prior art references and two withheld office actions, concluding that the three references were cumulative and therefore not material but that the two office actions were not cumulative and were material.¹¹⁴ The court then turned to the question of deceptive intent. Because the district court had based its finding of deceptive intent on the failure to disclose all five withheld items, three of which the Federal Circuit found were not material, and Larson’s failure to provide any explanation, the Federal Circuit vacated the district court’s finding of deceptive intent and remanded the case to the district court to determine whether Larson withheld the

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* at 1369.

¹⁰⁷ *Id.* at 1369-70.

¹⁰⁸ *Larson Mfg. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317 (Fed. Cir. 2009).

¹⁰⁹ *Id.* at 1321.

¹¹⁰ *Id.* at 1325.

¹¹¹ *Id.*

¹¹² *Id.* at 1325-26.

¹¹³ *Id.* at 1326.

¹¹⁴ *Id.* at 1327-39.

two office actions from the continuation application with deceptive intent.¹¹⁵

“[I]n the interest of judicial economy,” the court then offered “some guidance to the district court with respect to the issue of deceptive intent.”¹¹⁶ After stating that the district court need not accept new evidence on remand, the court stated “[M]ateriality does not presume intent, and nondisclosure, by itself, cannot satisfy the deceptive intent element.”¹¹⁷ The court quoted *Star Scientific* for the proposition that the inference of deceptive intent “must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.”¹¹⁸ The court emphasized that a patentee’s failure to establish a good faith explanation for having withheld material prior art is not sufficient to prove inequitable conduct, noting that “[S]o too an accused infringer cannot carry its threshold burden simply by pointing to the absence of a credible good faith explanation.”¹¹⁹ Indeed, the Federal Circuit went further and stated that while a district court must consider any evidence of good faith provided by the patentee, “[T]he patentee is not required to offer evidence of good faith unless the accused infringer first meets its burden to prove – by clear and convincing evidence – the threshold level of deceptive intent.”¹²⁰ Judge Linn filed a concurring opinion in *Larson* to call attention to the same issue addressed by this article, an issue for which he concluded “[T]he time has come for the court to review . . . *en banc*.”¹²¹

II. THE BAD AND THE UGLY: A REVIEW OF POST-2004 CASES DEPARTING FROM *KINGSDOWN* TO VARYING DEGREES.

As shown in the prior section, there is an impressive list of post-2004 cases following or at least invoking the standard for inferring deceptive intent adopted in *Kingsdown*. Unfortunately, there is an even longer list of post-2004 cases that cite or follow the *Critikon* standard for inferring deceptive intent and which are therefore inconsistent with *Kingsdown* to varying degrees. The first of these is

¹¹⁵ *Id.* at 1339-40.

¹¹⁶ *Id.* at 1340.

¹¹⁷ *Id.* (citing, *e.g.*, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

¹¹⁸ *Id.* (quoting *Star Scientific*, 537 F.3d at 1366).

¹¹⁹ *Id.* at 1341 (citing *Star Scientific*, 537 F.3d at 1368; *M. Eagles Tool Warehouse Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006)).

¹²⁰ *Id.* (citing *Star Scientific*, 537 F.3d at 1368).

¹²¹ *Id.* at 1344 (Linn, J., concurring).

Bruno Independent Living Aids, Inc. v. Acorn Mobility Services Ltd., in which the patent-in-suit covered a stairlift, a device that allows people with impaired mobility to travel up and down stairs on a chair that travels along a rail.¹²² Acorn accused Bruno of inequitable conduct in connection with the patent-in-suit by failing to disclose to the PTO several invalidating prior art stairlifts, including one known as the Wecolator, that Bruno had disclosed to the FDA when seeking approval to sell the stairlift covered by the patent-in-suit.¹²³ The district court noted that the disclosure to the FDA had occurred concurrently with the prosecution of the patent-in-suit and that Bruno had not offered a good faith explanation for failing to disclose the same information to the PTO and inferred from those facts that Bruno had withheld the information with deceptive intent.¹²⁴

The Federal Circuit affirmed the district court's finding of inequitable conduct and that the case was exceptional, warranting an award of attorneys' fees.¹²⁵ The court stated that "[I]n 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."¹²⁶ The court then went on to state that "The fact that an official of Bruno, who was involved in both the FDA and PTO submissions, chose to disclose the Wecolator to the FDA, but not to the PTO, certainly supports a finding of deceptive intent to withhold the disclosure from the PTO."¹²⁷ In support of the ability to draw an adverse inference from the absence of a credible explanation, the court explained, "Normally, it can be expected that an innocent party will be motivated to try to present convincing reasons for its actions or inaction. That did not occur here."¹²⁸ As noted in the prior article, however, there can be a variety of perfectly innocent reasons that the patentee would not or could not offer a good faith explanation.¹²⁹ First, the patentee's good faith explanation may be privileged and the patentee may choose not to waive the privilege. In other contexts, the Federal Circuit has held that an adverse inference cannot be drawn from a patent litigant's refusal to waive the attorney-client privilege.¹³⁰

¹²² *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1350 (Fed. Cir. 2005).

¹²³ *Id.* at 1350.

¹²⁴ *Id.* at 1350-51.

¹²⁵ *Id.* at 1355.

¹²⁶ *Id.* at 1354 (citing *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1193 (Fed. Cir. 1993)).

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ Tyler, *supra* note 1, at 285-86.

¹³⁰ *In re Seagate Tech., L.L.C.*, 497 F.3d 1360, 1370 (Fed. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1445 (2008); *Knorr-Bremse SystemeFuer Nutzfahrzeuge GmbH*

Second, in *Bruno* the patent-in-suit issued in July, 1993, and the district court's final judgment was entered in November, 2003.¹³¹ As the prior article noted, "In cases where years have passed between the non-disclosure of the reference and litigation, the inventor or prosecuting counsel may legitimately no longer recall the reason(s) a particular reference was not disclosed. Patent counsel may have passed away."¹³² While it is unknown if either of these reasons applied in *Bruno*, nothing in the Federal Circuit's opinion rules them out and, given that the burden of proving inequitable conduct rests on the defendant by clear and convincing evidence, it should be up to the defendant to rule them out rather than the patentee to establish them. Otherwise, the inference of intent to deceive is not the "single most reasonable inference" as required by *Larson*, *Star Scientific* and other cases reviewed above.

Pharmacia Corp. v. Parr Pharmaceuticals, Inc.,¹³³ although containing some unfortunate language inconsistent with *Kingsdown*, is actually not inconsistent with *Kingsdown*. After Parr filed an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of a glaucoma medication named Xalatan, Pharmacia filed a suit for patent infringement.¹³⁴ Parr alleged inequitable conduct on the basis of an allegedly inaccurate or misleading declaration submitted during prosecution by Pharmacia to overcome a rejection.¹³⁵ The declaration contrasted the decrease in intraocular pressure caused by two different compounds, one the subject of the patent and one the subject of the prior art.¹³⁶ These statements in the declaration conflicted with an article co-authored by the declarant and with two Japanese articles cited in the declarant's article.¹³⁷ The district court found that the misleading statements in the declaration were highly material because they were important to overcoming a rejection. Because the declarant's statements contradicted statements in an article he co-authored, the district court inferred deceptive intent.¹³⁸ Accordingly, the district court declared the patent unenforceable for inequitable conduct.¹³⁹

v. Dana Corp., 383 F.3d 1337, 1344 (Fed. Cir. 2004) (en banc) (invoking the attorney-client privilege or work-product immunity does not give rise to an adverse inference of willful infringement).

¹³¹ *Bruno*, 394 F.3d at 1350-51.

¹³² Tyler, *supra* note 1, at 286.

¹³³ *Pharmacia Corp. v. Parr Pharm., Inc.*, 417 F.3d 1369 (Fed. Cir. 2005).

¹³⁴ *Id.* at 1370.

¹³⁵ *Id.* at 1371.

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.* at 1372.

¹³⁹ *Id.*

The Federal Circuit affirmed the district court's conclusion of inequitable conduct.¹⁴⁰ Specifically, the court wrote that "Given the highly material nature of these misleading statements and the failure to submit a directly conflicting article co-authored by the declarant himself, the district court did not clearly err in inferring an intent to deceive."¹⁴¹ The court cited *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*¹⁴² for the proposition that "Proof of high materiality and that the applicant knew or should have known of that materiality makes it difficult to show good faith to overcome an inference of intent to mislead."¹⁴³ Although this quotation deviates from *Kingsdown* by suggesting that a known failure to disclose highly material information alone can support an inference of intent to deceive, the misleading statements in the declaration alone are sufficient to support the judgment of inequitable conduct. The Federal Circuit has held repeatedly that affirmative misstatements in a declaration are alone sufficient to establish an intent to deceive for purposes of inequitable conduct.¹⁴⁴ Thus, the failure to disclose the declarant's conflicting article was not necessary to the court's decision. It is worth noting that the *Pharmacia* decision was authored by Judge Rader and joined by Judge Linn, both of whom are among the staunchest advocates for the *Kingsdown* standard.¹⁴⁵

*Warner-Lambert Co. v. Teva Pharmaceuticals U.S., Inc.*¹⁴⁶ cites *Critikon* for the now infamous proposition 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

¹⁴⁰ *Id.* at 1375.

¹⁴¹ *Id.* at 1373.

¹⁴² *Semiconductor Energy Lab. Co. v. Samsung Elec. Co.*, 204 F.3d 1368, 1375 (Fed. Cir. 2000).

¹⁴³ *Pharmacia*, 417 F.3d at 1373.

¹⁴⁴ *See, e.g.*, *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983) ("Submissions [of misleading affidavits] usually will support the conclusion that the affidavit in which they were contained was the chosen instrument of an intentional scheme to deceive the PTO." (quoted in *ESpeed, Inc. v. Brokertec U.S., L.L.C.*, 480 F.3d 1129, 1138 (Fed. Cir. 2007), *Gen. Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994))); *see also* *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.*, 984 F.2d 1182, 1191 (Fed. Cir. 1993) ("The inference [of an intent to mislead] arises not simply from the materiality of the affidavits, but from the affirmative acts of submitting them, their misleading character, and the inability of the examiner to investigate the facts." (quoted in *Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1582 (Fed. Cir. 1996))).

¹⁴⁵ *See, e.g.*, *Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1342-44 (Fed. Cir. 2009)

(Linn, J., concurring); *Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1359-60 (Fed. Cir. 2008).

¹⁴⁶ *Warner-Lambert Co. v. Teva Pharm. U.S., Inc.*, 418 F.3d 1326 (Fed. Cir. 2005).

establish subjective good faith sufficient to prevent the drawing an inference of an intent to deceive.”¹⁴⁷ Ultimately, the case is not troubling, however, because the district court found that the inventors had not appreciated the materiality of the withheld information and did not find inequitable conduct.¹⁴⁸ The Federal Circuit simply affirmed the district court’s decision, made after a bench trial, as not being clearly erroneous.¹⁴⁹

In *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*,¹⁵⁰ Novo sued Bio-Technology General (“BTG”) for infringing a patent covering a process for producing “ripe” human growth hormone (“hGH”) protein in bacteria by using recombinant DNA techniques.¹⁵¹ BTG’s inequitable conduct defense was based on the fact that Example 1 of Novo’s patent purported to disclose test results showing that ripe hGH protein was purified from an extract of a fusion protein.¹⁵² It was undisputed, however, that when the original application including Example 1 was filed, the inventors had not successfully prepared hGH with the procedures described in Example 1.¹⁵³ In fact, the Federal Circuit affirmed the district court’s findings that Novo was never able to make ripe hGH according to the method of Example 1.¹⁵⁴ The district court also found, and the Federal Circuit agreed, that Novo’s failure to disclose that it had never been able to produce ripe hGH using the method of Example 1 was material.¹⁵⁵ The PTO had declared an interference between Novo’s application and a BTG application, and Novo had relied on Example 1 as establishing its right to priority.¹⁵⁶ Further, during prosecution of Novo’s patent, the examiner relied upon Example 1 in deciding issues of enablement and priority.¹⁵⁷

Turning to the issue of intent to deceive, the district court found that element satisfied because Novo knew or should have known the examiner would have considered important the fact that

¹⁴⁷ *Id.* at 1346 (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997)).

¹⁴⁸ *Id.* at 1347.

¹⁴⁹ *Id.*

¹⁵⁰ *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347 (Fed. Cir. 2005).

¹⁵¹ *Id.* at 1349.

¹⁵² *Id.* at 1357 (A fusion protein is one produced from two genes that have been spliced (“fused”) together.).

¹⁵³ *Id.*

¹⁵⁴ *Id.* at 1360.

¹⁵⁵ *Id.* at 1361-62.

¹⁵⁶ *Id.* at 1360 (Indeed, the district court had noted that whether Example 1 enabled the claimed invention “was the sole focus of the interference.”).

¹⁵⁷ *Id.*

Example 1 contained merely prophetic data when deciding the issues of enablement and priority.¹⁵⁸ Similarly, the board determining the interference would have found Novo's failure to produce ripe hGH according to the method of Example 1 important to the same issues.¹⁵⁹ Again, the Federal Circuit agreed.¹⁶⁰ On appeal, Novo attempted to argue that the inventors did not realize that using the past tense in the description of Example 1 suggested that it had actually been performed and had not told Novo's attorney that Example 1 was prophetic.¹⁶¹ Thus, Novo argued that the attorneys could not be guilty of a failure to disclose. The court rejected this argument as follows:

Novo asks us to hold, on the one hand, that the failure of . . . [the] 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.¹⁶²

Although the court did not really discuss the standards for inferring an intent to deceive, it affirmed a finding of intent based solely on the failure to disclose that Example 1 was prophetic. As will be seen below, a possible important factor was that the failure occurred on more than one occasion, that is, with both the PTO and the Board.¹⁶³

*Ferring B.V. v. Barr Laboratories, Inc.*¹⁶⁴ reached the somewhat remarkable (although not unheard of) result of affirming a summary judgment of inequitable conduct based on a failure to disclose material information.¹⁶⁵ In *Ferring*, the patent covered a solid oral dosage form of an anti-diuretic compound to prevent diuretic

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.* at 1361.

¹⁶² *Id.* at 1361-62 (quoting *Brassler, U.S., I.L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001); *Molins PLC v. Textron, Inc.*, 48 F. 3d 1172, 1178 (Fed. Cir. 1995)).

¹⁶³ There is at least one other Federal Circuit decision where the court concluded that an unfortunate choice of verb tense in the description of an experiment could potentially support a finding of inequitable conduct. *See Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1363-67 (Fed. Cir. 2003).

¹⁶⁴ *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181 (Fed. Cir. 2006).

¹⁶⁵ *Id.* at 1183.

symptoms associated with diabetes.¹⁶⁶ After the application for the patent was filed, one of the inventors and his counsel appeared at a preliminary interview with the examiners. The examiners were concerned that a prior art patent's disclosure of a "peroral" application of the same compound suggested oral administration of the compound for gastrointestinal absorption, just like the claimed solid oral dosage form sought to patented.¹⁶⁷ The inventor argued that "peroral" referred to absorption through the walls of the mouth, not gastrointestinal absorption, and the examiner suggested that the applicants obtain evidence from a non-inventor to support that interpretation.¹⁶⁸ The applicants later supplied declarations from non-inventors, but failed to disclose various connections between the inventors and Ferring.¹⁶⁹ As summarized by the Federal Circuit, "[F]our of the five declarations submitted to the PTO in 1990 were written by scientists who had been employed or had received research funds from Ferring"¹⁷⁰ The district court found that the failure to disclose the financial connections between the declarants and Ferring amounted to inequitable conduct.¹⁷¹ According to the district court, "[I]t must have been clear to [the inventor] at the preliminary meeting with the inventor that a non-inventor affidavit was sought for purposes of obtaining *objective evidence* that the invention was not anticipated by the prior art or obvious."¹⁷² Thus the failure to disclose the financial connection between the declarants and Ferring was highly material and "[T]hat three of the challenged declarations were submitted after several iterations of rejected attempts to obtain the patent's issuance speaks loudly as to motive and intent."¹⁷³

The Federal Circuit first found that the declarations were highly material, noting that the "[G]eneral law of evidence has long recognized that the testimony of any witness may be rendered suspect by a past relationship with a party."¹⁷⁴ On the issue of intent, the Federal Circuit first noted that "Materiality does not presume intent, which is a separate and essential component of inequitable conduct."¹⁷⁵ Shortly thereafter, however, the court quoted *Critikon* for the proposition that "[A] patentee facing a high level of materiality

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.* at 1183-84.

¹⁶⁹ *Id.* at 1184-85.

¹⁷⁰ *Id.* at 1185.

¹⁷¹ *Id.* at 1186.

¹⁷² *Id.* (quoting district court opinion) (emphasis in original).

¹⁷³ *Id.* (quoting district court opinion).

¹⁷⁴ *Id.* at 1187.

¹⁷⁵ *Id.* at 1190 (quoting *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001)).

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.”¹⁷⁶ Over a dissent by Judge Newman, which included a citation to the earlier article and numerous contrary cases, the majority continued as follows:

Suffice it to say that we have recognized, in cases such as *Paragon* that summary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.¹⁷⁷

The court then went on to determine that each of the three identified conditions was satisfied and affirmed the summary judgment of inequitable conduct.¹⁷⁸

In *Agfa Corp. v. Creo Products, Inc.*,¹⁷⁹ Agfa sued Creo for allegedly infringing six different patents covering an automated computer-to-plate system for making multiple printing plates.¹⁸⁰ Creo’s inequitable conduct defense was based on Agfa’s failure to disclose at least three prior art systems, including one by Creo, to the PTO during prosecution.¹⁸¹ The trial court found, and the Federal Circuit agreed, that the withheld prior art was material because it created a prima facie case of unpatentability and also was inconsistent with a position taken during examination.¹⁸² On the issue of intent, the Federal Circuit found that the evidence of Agfa’s knowledge of the prior art, particularly the prior art Creo product, was “overwhelming.”¹⁸³ The court then relied upon the principle 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.”¹⁸⁴ Noting that it “must defer heavily to the trial court’s credibility determinations,”¹⁸⁵ the Federal

¹⁷⁶ *Id.* at 1191 (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997)).

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 1191-94.

¹⁷⁹ *Agfa Corp. v. Creo Prods., Inc.*, 451 F.3d 1366 (Fed. Cir. 2006).

¹⁸⁰ *Id.* at 1369.

¹⁸¹ *Id.* at 1371.

¹⁸² *Id.* at 1377.

¹⁸³ *Id.* at 1378.

¹⁸⁴ *Id.* (quoting *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1275 (Fed. Cir. 2001)).

¹⁸⁵ *Id.* at 1379.

Circuit rejected Agfa's arguments that its patent agents did not appreciate the materiality of the undisclosed references.¹⁸⁶

Although the intent section of the *Agfa* opinion focuses primarily on the knowing failure to disclose material prior art, the section of the opinion discussing the balance between materiality and intent to deceive provides more compelling support for the court's decision:

The district court paints a picture of a group of engineers and patent agents who set out to design their own version of their competitors' products by attending trade shows and reviewing literature, all the while taking notes and holding meetings to decide which features from which printing presses would work well in Agfa's Galileo system. Those same agents then prepared and prosecuted the asserted patents, never sharing with the PTO any of the information they had compiled about the products upon which they modeled their system. The trial court thus found high levels of both materiality and intent, and did so with respect to numerous undisclosed pieces of prior art.¹⁸⁷

Thus, while the intent section of *Agfa* alone may be dubious under the *Kingsdown* standard, there is reason to believe that the overall decision was correct. *Agfa* could be construed as a failure to disclose case, but in the end is consistent with the *Kingsdown* standard.

In *Dippin' Dots, Inc. v. Mosey*,¹⁸⁸ sales of the presumably patented product were made at the Festival Market Mall in Lexington, Kentucky, more than a year before Dippin' Dots ("DDI") filed its patent application.¹⁸⁹ There was evidence that these sales were not experimental and it was undisputed that they were never disclosed to the PTO during the prosecution of the patent-in-suit.¹⁹⁰ Not surprisingly, the defendants' inequitable conduct was based in part on the failure to disclose these sales. The district court conducted a jury trial and ultimately concluded that the patent was unenforceable for inequitable conduct.¹⁹¹

The Federal Circuit had little difficulty concluding that the failure to disclose the Festival Market sales was material because the "sales render the '156 patent invalid for obviousness."¹⁹² The court

¹⁸⁶ *Id.* at 1378.

¹⁸⁷ *Id.* at 1379-80.

¹⁸⁸ *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337 (Fed. Cir. 2007).

¹⁸⁹ *Id.* at 1340.

¹⁹⁰ *Id.* at 1340-41.

¹⁹¹ *Id.* at 1342.

¹⁹² *Id.* at 1345.

then noted that the intent to deceive issue was “more difficult.”¹⁹³ The court affirmed, however, stating:

We have noted that omission of sales made before the critical date is especially problematic:

Absent explanation, the evidence of a knowing failure to disclose sales that bear all the earmarks of commercialization reasonably supports an inference that the inventor’s attorney intended to mislead the PTO. The concealment of sales information can be particularly egregious because, unlike the applicant’s failure to disclose, for example, a material patent reference, the examiner has no way of securing the information on his own.¹⁹⁴

While DDI wholly neglected to disclose the Festival Market sales to the PTO, it enthusiastically touted sales made after the critical date as evidence of the commercial appeal of its process. That combination of *action and omission* permits an inference of the minimum, threshold level of intent required for inequitable conduct.¹⁹⁵

The court then concluded that the district court was within its discretion “to balance the relatively weak evidence of intent together with the strong evidence that DDI’s omission was highly material” and to hold that DDI had committed inequitable conduct.¹⁹⁶ Because the Federal Circuit’s decision relied not only on the failure to disclose, but also on the “action” of relying on evidence of sales when it was helpful to the prosecution, the decision is consistent with *Kingsdown*. It is also noteworthy that the court found that even the combination of action and failure to disclose still amounted only to “relatively weak” evidence of intent to deceive.

A mere five days after its decision in *Dippin’ Dots*, the Federal Circuit handed down another decision addressing inequitable conduct, *Cargill, Inc. v. Canbra Foods, Ltd.*¹⁹⁷ Cargill sued Canbra and other defendants for infringing four patents, two of which are relevant to the inequitable conduct decision and related to a non-hydrogenated canola oil that possessed superior oxidative and fry stability.¹⁹⁸ The claimed oil, designated IMC 130 by the patents, was allegedly novel because its oxidative stability as measured by Active Oxygen Method (“AOM”) was about thirty-five to forty hours.¹⁹⁹ During prosecution,

¹⁹³ *Id.*

¹⁹⁴ *Id.* at 1345-46 (quoting *Paragon Podiatry Lab. v. KLM Lab.*, 984 F.2d 1182, 1193 (Fed. Cir. 1993)).

¹⁹⁵ *Id.* at 1346 (emphasis added).

¹⁹⁶ *Id.*

¹⁹⁷ *Cargill, Inc. v. Canbra Foods Ltd.*, 476 F.3d 1359 (Fed. Cir. 2007).

¹⁹⁸ *Id.* at 1362.

¹⁹⁹ *Id.*

the examiner initially rejected the proposed claims as anticipated by a European patent application that disclosed a canola oil with a fatty acid composition similar to that of IMC 130 on the theory that oxidative stability is based directly on fatty acid composition, so the oxidative stability of IMC 130 and the oil disclosed in the European patent application should be similar.²⁰⁰ In response, Cargill argued that another oil, designated IMC 129, had a similar fatty acid composition to IMC 130 yet the two oils had “strikingly different oxidative stability values.”²⁰¹ Thus, Cargill argued that the European application could not be found to anticipate IMC 130 based solely on the similar fatty acid composition.²⁰²

The *Cargill* defendants’ inequitable conduct allegations were based on Cargill’s failure to disclose two documents: a report containing test data indicating that three samples of IMC 129 had oxidative stabilities in a range similar to and, in one instance, actually overlapping that of IMC 130; and data showing that the oxidative stability of IMC 129 appeared to be superior to that of IMC 130 using a different, but accepted, measure.²⁰³ In light of the prosecution history in which Cargill represented that IMC 129 and IMC 130 had different oxidated stabilities notwithstanding their similar fatty acid composition, the district court found and the Federal Circuit agreed that the two documents were material.²⁰⁴

On the deceptive intent issue, the district court found the element was satisfied based on three circumstantial factors – the repeated nature of the omission, the applicant’s motive to conceal the data inconsistent with its argument, and the high materiality of the undisclosed data.²⁰⁵ The Federal Circuit found that the combination of these three factors was sufficient to support a finding of the intent to deceive.²⁰⁶ As to the repeated nature of the omission, the court stated that it was relevant “because 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.”²⁰⁷ The court noted that “[E]ach of the examiners’ *five* rejections involved the issue of whether the oxidative stability of IMC 130 was superior to that of oil with a similar fatty acid

²⁰⁰ *Id.*

²⁰¹ *Id.* at 1362-63.

²⁰² *Id.* at 1363.

²⁰³ *Id.* at 1365.

²⁰⁴ *Id.* at 1365-66.

²⁰⁵ *Id.* at 1366.

²⁰⁶ *Id.* at 1366-68.

²⁰⁷ *Id.* at 1366 (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1366 (Fed. Cir. 1997)) (internal quotations omitted).

composition.”²⁰⁸ The court also noted that Cargill’s motive to conceal referred to more than just “some general desire to obtain a patent.”²⁰⁹ Rather, there was a “specific motive to conceal the two specific documents at issue,” because they precluded any effort to portray IMC 130 as more than an incremental improvement.²¹⁰

Although the Federal Circuit relied almost exclusively on *Critikon* in its discussion of intent, the two additional factors – the repeated nature of the omission and the specific motive to conceal the two documents at issue – make *Cargill* consistent with the *Kingsdown* standard. Common sense supports the conclusion that when an applicant withholds information that is inconsistent with its response to *five* separate rejections, the applicant is doing so intentionally to deceive the PTO. Each time the same issue is raised, it is more and more likely that the decision to withhold the undisclosed information is intentional and less and less likely that the information is withheld through mere oversight. Further, *Cargill* could also be viewed as an affirmative misrepresentation case since Cargill had argued that IMC 129 and IMC 130 oils had “strikingly different oxidative stability values” when Cargill’s own files contained evidence to the contrary.²¹¹

In *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*,²¹² the patent-in-suit covered a patient identification system for “relating items with patients and insuring that an identified item corresponds to an identified patient.”²¹³ The patent-in-suit was related to another patent prosecuted by the same attorney at the same time before a different examiner.²¹⁴ Although the co-pending application was disclosed, the allegations of inequitable conduct arose out of the attorney’s failure to disclose the application of the patent-in-suit and the existence of a particularly relevant prior patent cited in the co-pending application, rejections issued in the co-pending application, and allowance of the claims in another related application.²¹⁵

Although it probably would not have mattered to the outcome of the case, the opinion is not entirely clear on the standard employed to prove intent to deceive. On the one hand, the court cited the express holding of *Kingsdown* that gross negligence is not sufficient to establish an intent to deceive and that all of the evidence, including

²⁰⁸ *Id.* (emphasis added).

²⁰⁹ *Id.* at 1367.

²¹⁰ *Id.*

²¹¹ *See id.* at 1363.

²¹² *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir. 2007).

²¹³ *Id.* at 902.

²¹⁴ *Id.* at 904.

²¹⁵ *Id.* at 908.

evidence showing good faith, must be considered.²¹⁶ On the other hand, the court also wrote that “Intent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible.”²¹⁷ This quotation at least suggests that when a defendant produces evidence that material information was knowingly withheld, the patentee has some burden to provide reasons for having done so. As noted in Section I, evidence of the failure to disclose material information alone should not warrant an inference of intent to deceive and therefore should not place any burden to produce evidence on the patentee.²¹⁸ Further, the *McKesson* court discussed *Critikon*, but only in the context of rebutting McKesson’s attempt to distinguish *Critikon*.²¹⁹ In any event, the court’s incredibly thorough review of the evidence, filling approximately eighteen pages in the Federal Reporter, shows that the case is consistent with the *Kingsdown* standard, although reasonable minds could differ (as Judge Newman did in dissent).

In *Nilssen v. Osram Sylvania, Inc.*,²²⁰ an inventor attempted to navigate the prosecution process *pro se* with unfortunate results.²²¹ Nilssen sued Osram Sylvania on fifteen different patents related to fluorescent light bulbs, although four were withdrawn shortly before the six-day bench trial on inequitable conduct.²²² The district court found all the patents unenforceable on one or more of several grounds, including (i) submission of an affidavit in support of patentability that failed to disclose the affiant’s personal and professional association with Nilssen and financial interests in Nilssen’s patents, (ii) improper failure to pay large entity and maintenance fees, (iii) intentionally misclaiming an effective priority date, (iv) failure to disclose ongoing litigation, and (v) knowing failure to identify relevant prior art.²²³ With respect solely to Nilssen’s failure to disclose certain prior art, the Federal Circuit did not cite any authority discussing the standard for establishing an intent to deceive.²²⁴ The court affirmed the district court on this issue, however, writing:

The fact that Nilssen had repeatedly cited or had cited to him the prior art references in question makes it highly likely that a reasonable examiner would have wanted to

²¹⁶ *Id.* at 913.

²¹⁷ *Id.* (quoting *Dayco Prod., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003)).

²¹⁸ *See supra* notes 37-45, 107-120 and accompanying text.

²¹⁹ *See McKesson*, 487 F.3d at 918-19.

²²⁰ *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223 (Fed. Cir. 2007).

²²¹ *See id.* at 1235.

²²² *Id.* at 1226-27.

²²³ *Id.* at 1227-28.

²²⁴ *Id.* at 1234-35.

consider the information in the withheld patents in determining patentability. Given that these material references were repeatedly before Nilssen, and his failure to offer any good faith explanation for withholding them other than mere oversight, we find an inference that Nilssen intended to deceive the PTO not unreasonable.²²⁵

In other words, this case is consistent with the *Cargill* case discussed above where the repeated failure to disclose material information was held to support the conclusion of an intent to deceive and thus inequitable conduct. Again, it comports with common sense to infer from a repeated failure to disclose material information that the failure is intentional. In this connection, the court noted that Nilssen did offer defenses to each of the charges of inequitable conduct, which “were not per se unreasonable when considered in isolation.”²²⁶ The court nonetheless affirmed each of the findings, and the ultimate conclusion, noting:

However, this case presents a collection of such problems, which the district court evaluated thoroughly and considered, including making credibility findings, and it concluded that the record and testimony indicated repeated attempts to avoid playing fair and square with the patent system. Mistakes do happen, but inadvertence can carry an applicant only so far.²²⁷

In other words, the court agrees that each separate failure to disclose material information (or other ground of inequitable conduct) makes it more likely that the applicant was acting intentionally or, in other words, less likely that the applicant was acting inadvertently.

*Monsanto Co. v. Bayer Bioscience N.V.*²²⁸ began as a declaratory judgment action by Monsanto challenging the validity and enforceability of four Bayer patents related to transgenic corn.²²⁹ More specifically, Bayer’s patent related to plants that expressed a shortened form of a protein that is toxic to certain insects.²³⁰ During prosecution, Bayer disclosed a prior art abstract from a presentation at a scientific conference, which noted, among other things, that the second half of the relevant protein was dispensable for producing an active insecticide.²³¹ In an office action, the examiner rejected all of the pending claims as obvious over various prior art references,

²²⁵ *Id.* at 1235.

²²⁶ *Id.*

²²⁷ *Id.*

²²⁸ *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229 (Fed. Cir. 2008).

²²⁹ *Id.* at 1231.

²³⁰ *Id.* at 1231-32.

²³¹ *Id.* at 1234.

including the abstract.²³² Bayer responded in part by pointing out some of the shortcomings or deficiencies of the abstract.²³³ Bayer did not disclose, however, that one of its scientists had attended the conference and taken detailed notes on a poster to which the abstract related.²³⁴ In her deposition, the Bayer scientist “carefully and extensively described the content of her handwritten notes” which showed that “The poster contained much more information than the abstract itself.”²³⁵ In her deposition testimony, the scientist “was clearly and articulately able to describe the contents of the Barnes poster as detailed in the notes.”²³⁶ Worse yet for Bayer, the scientist’s notes were “widely circulated” among relevant scientists at Bayer, including one who was responsible for prosecution of the patents at issue and admitted that he had seen the notes during prosecution of the patent-in-suit and spoken about them with the scientist who had taken them.²³⁷ The district court found that the failure to disclose the scientist’s notes was highly material because they contradicted Bayer’s arguments and established a *prima facie* case of unpatentability.²³⁸ Based on the failure to disclose this highly material reference, the district court also found the intent to deceive or mislead the examiner.²³⁹ Finally, the district court also found that Bayer had made a false or affirmative misrepresentation when it told the examiner that its invention had solved the problem of the unpredictability of expression of foreign genes in plants.²⁴⁰

When analyzing the intent to deceive issue, the Federal Circuit began by noting correctly that “Bayer’s failure to disclose the highly material [scientist’s] notes to the PTO during the prosecution of the [patent-in-suit] is not sufficient to prove inequitable conduct.”²⁴¹ Shortly thereafter, however, the court stated that it has “held that absent a credible reason for withholding the information, ‘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.’”²⁴² Because the Federal Circuit agreed that

²³² *Id.* at 1234-35.

²³³ *Id.* at 1235.

²³⁴ *Id.*

²³⁵ *Id.*

²³⁶ *Id.* at 1236.

²³⁷ *Id.*

²³⁸ *Id.* at 1236-37 (quoting *Monsanto Co. v. Bayer Bioscience N.V.*, 2006 U.S. Dist. LEXIS 97254, at *168 (E.D. Mo. 2006) [hereinafter *Monsanto I*]).

²³⁹ *Id.* at 1237 (quoting *Monsanto I*, 2006 U.S. Dist. LEXIS 97254, at *168).

²⁴⁰ *Id.* at 1235, 1237 (citing *Monsanto I*, 2006 U.S. Dist. LEXIS 97254, at *168).

²⁴¹ *Id.* at 1240.

²⁴² *Id.* at 1241 (citing *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997)). See also *Bruno Indep. Living Aids, Inc. v. Acorn*

Bayer's attempts to explain the failure to disclose the information were not credible, it affirmed the conclusion of inequitable conduct, expressly stating that it did not need to consider the alternative ground based on the affirmative misrepresentation.²⁴³ Thus, *Monsanto* represents a clear holding that inequitable conduct can be inferred solely from the knowing failure to disclose highly material information in the absence of a credible explanation. This places it clearly in the *Critikon* camp and in stark contrast to *Kingsdown*, *Star Scientific*, *Larson* and other cases reviewed in Section I.

In *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*,²⁴⁴ the patent in suit was related to low molecular weight heparin, a drug used to prevent blood clotting while minimizing the possibility of hemorrhaging.²⁴⁵ The PTO's first office action rejected the claims as anticipated and obvious over several references, including a particular European patent. The examiner stated that the references taught heparin mixtures within the molecular weight range of the claims and therefore the applicant would have to demonstrate that the claimed product provided some unexpected or unobvious property not included in the prior products.²⁴⁶ In response, Aventis relied on Example 6 of the patent as showing that its claimed compound had a significantly longer half-life than the formulations of the European patent on which the examiner had relied and that this difference in half-life was evidence of a difference in structure.²⁴⁷ The examiner was not convinced and issued a final rejection,²⁴⁸ leading Aventis to amend the claim and also submit a declaration from a non-inventor scientist arguing that the claimed formulation had a much longer half-life and that the longer half-life was significant because it enabled the formulation to achieve the same result at a lower dosage.²⁴⁹ After the examiner maintained the rejection based on the European patent, Aventis filed yet another declaration from the same scientist which provided an analysis showing a statistically significant difference between the mean half-life for the claimed compound and that of the

Mobility Servs., Ltd., 394 F.3d 1348, 1354 (Fed. Cir. 2005); cf. *Dayco Prod., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003).

²⁴³ *Monsanto*, 514 F.3d at 1241-42.

²⁴⁴ *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1344 (Fed. Cir. 2008).

²⁴⁵ *Id.* at 1337.

²⁴⁶ *Id.*

²⁴⁷ *Id.*

²⁴⁸ *Id.* at 1339.

²⁴⁹ *Id.*

European patent and also presented additional argument.²⁵⁰ The examiner then relented and allowed the patent.²⁵¹

Amphastar's inequitable conduct defense was based on the allegation that the scientist failed to disclose that the half-life studies comparing the claimed compound to the compound of the European patent were made at different doses.²⁵² The district court granted summary judgment in favor of Amphastar on this defense, finding that the materiality of the half-life representations was established by the fact that Aventis referred to the improved half-life at least four times during prosecution and that the claims were allowed following the representation that the difference in mean half-life was statistically significant.²⁵³ The district court inferred Aventis' intent to deceive because it "could find no credible explanation for comparing half-lives at different doses and because comparisons at the same dose showed little difference in half-life."²⁵⁴ In an earlier opinion, the Federal Circuit found it was error to enter summary judgment on the intent to deceive issue and remanded the case for trial.²⁵⁵ At the trial, Aventis presented three explanations for the failure to disclose the dose of the European patent composition in the half-life comparisons, all of which were rejected by the district court, which again found the intent to deceive element and concluded Aventis was guilty of inequitable conduct.²⁵⁶

In its opinion on the second appeal, the Federal Circuit considered in some detail additional arguments by Aventis seeking to overturn the finding of an intent to deceive, including at least one justification offered the first time on the second appeal.²⁵⁷ Not only did the court reject all these proposed explanations, but one gets the impression from reading the opinion that the number of different justifications, combined with the fact at least one was new on the second appeal, may have served to undermine Aventis' credibility.²⁵⁸ Thus, the decision could be read to support the proposition that the failure to disclose highly material information, in the absence of a credible good faith explanation, supports the finding of inequitable

²⁵⁰ *Id.* at 1339-40.

²⁵¹ *Id.* at 1340.

²⁵² *Id.* at 1341 (citing *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 390 F. Supp. 2d 936, 941-44 (C.D. Cal. 2005) [hereinafter, *Aventis I*]).

²⁵³ *Id.* (citing *Aventis I*, 390 F. Supp. at 950-51).

²⁵⁴ *Id.*

²⁵⁵ *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 176 Fed. App. 117, 122-23 (Fed. Cir. 2006).

²⁵⁶ *Aventis*, 525 F.3d at 1342-43.

²⁵⁷ *Id.* at 1344-49.

²⁵⁸ It is not unlike the murder defendant whose position is, "I wasn't there, but if I was, I didn't do it, and if I did, it was self-defense."

conduct, which would be consistent with *Critikon* and inconsistent with *Kingsdown*. There is one passage in the opinion, however, where the court notes that, in the alternative, if “half-life data at other doses for the patented compound were provided to the examiner, the data were provided in a very misleading way.”²⁵⁹ This passage could make the decision consistent with *Kingsdown*, but such a reading of the case is strained given that the passage appears as an alternative ground for rejecting one of Aventis’ many arguments. It is more accurate to say, as Judge Rader did in his dissent, that the case merged “intent and materiality at levels far below the *Kingsdown* rule.”²⁶⁰

*Praxair, Inc. v. ATMI, Inc.*²⁶¹ is the most recent case (as of the writing of this article) that falls squarely within the *Critikon* camp. Praxair filed suit against ATMI for infringing three patents that related to “pressurized storage containers that limit potentially rapid accidental discharges of hazardous gasses [sic] that could otherwise pose a serious threat to health and safety.”²⁶² More specifically, two of the patents (the “115 patent” and “609 patent”) related to flow restrictors comprised of multiple capillary passages in the path through which the gas is dispensed.²⁶³ ATMI based its inequitable conduct allegations against these two patents on Praxair’s failure to disclose several pieces of prior art, including restricted flow orifice (“RFO”) devices. An RFO “is a flow restrictor device presenting small holes, as small as 0.1 millimeters . . . through which gas flows.”²⁶⁴ The district court found that the failure to disclose the RFO devices was material because their use in the prior art was inconsistent with four statements made in the prosecution history of the “115 patent characterizing the prior art.”²⁶⁵ The district court found that the inventors of both the 609 and 115 patents and their counsel knew about RFO devices, which were widely used prior to the time the applications for the 115 and 609 patents were filed.²⁶⁶ Based on the failure of the inventors and their attorneys to disclose material prior art of which they were aware, and the failure to offer an explanation, the district court inferred an intent to deceive and declared both patents unenforceable for inequitable conduct.²⁶⁷

²⁵⁹ *Aventis*, 525 F.3d at 1349.

²⁶⁰ *Id.* at 1350.

²⁶¹ *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. 2008).

²⁶² *Id.* at 1310.

²⁶³ *Id.*

²⁶⁴ *Praxair, Inc. v. ATMI, Inc.*, 489 F. Supp. 2d 387, 391 (D. Del. 2007).

²⁶⁵ *Praxair*, 543 F.3d at 1312.

²⁶⁶ *Id.*

²⁶⁷ *Id.* at 1312-13.

In the section of its opinion on the standards for inequitable conduct, the Federal Circuit cited *Ferring* and *Critikon* in support of the proposition that “An inference of intent to deceive is generally appropriate, however, when (1) highly material information is withheld; (2) ‘the applicant knew of the information [and] . . . knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.’”²⁶⁸ In the section of its opinion on intent to deceive, the Federal Circuit analyzed each of these three elements, affirmed the district court’s conclusions on each of them, and affirmed the district court’s ultimate conclusion of inequitable conduct for the 115 patent. As to the high degree of materiality, the court again noted that the RFO devices were inconsistent with four statements that were made during the prosecution of the 115 patent and that this inconsistency made the RFOs highly material.²⁶⁹ The court quoted testimony from both an inventor and the prosecuting attorney establishing that they were aware of the RFO devices at the relevant time.²⁷⁰ Finally, the court noted that Praxair had not offered a good faith explanation for its failure to disclose the RFOs but rather offered only conclusory testimony from the prosecuting attorney that he had never intentionally misled the PTO.²⁷¹ The court determined that the conclusory testimony was not entitled to any weight and that what was necessary was testimony establishing the reason for the non-disclosure as of the relevant time.²⁷² The court reached a different conclusion as to the 609 patent, however, because it had already been allowed at the time the four statements were made during the prosecution of the 115 patent and thus the four statements could not have infected the prosecution of the 609 patent.²⁷³ *Praxair* falls squarely into the *Critikon* camp because intent to deceive was inferred based solely on the failure to disclose a known material reference without a good faith explanation. This is confirmed in part by Judge Lourie’s dissenting opinion in *Praxair* which asserted, among other things, that “[T]he district court incorrectly conflated intent with materiality. It cited no evidence of intent to deceive. Non-citation of a reference does not necessarily justify an inference of intent to deceive.”²⁷⁴

²⁶⁸ *Id.* at 1313-14 (quoting *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181 (Fed. Cir. 2006)).

²⁶⁹ *Id.* at 1315-16.

²⁷⁰ *Id.* at 1316.

²⁷¹ *Id.* at 1317.

²⁷² *Id.* at 1317-18.

²⁷³ *Id.* at 1318.

²⁷⁴ *Id.* at 1329 (Lourie, J., dissenting) (citing *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1342-43 (Fed. Cir. 2006)).

III. THE COURT SHOULD REVERT TO THE *KINGSDOWN* STANDARD EITHER EN BANC OR BY REJECTING THE *CRITIKON* LINE OF CASES IN FUTURE PANEL DECISIONS.

The Federal Circuit was created in part to revitalize and bring uniformity to patent law.²⁷⁵ On many important issues, the court has done an excellent job on this score. Some of the more recent and noteworthy opinions include *Cardiac Pacemakers*,²⁷⁶ *In re Seagate Technology*,²⁷⁷ *Knorr-Bremse*,²⁷⁸ and *Phillips v. AWH Corp.*²⁷⁹ As shown by the two previous sections, however, the same cannot be said for the standard for proving the intent to deceive element of inequitable conduct. Depending on one's view of whether some of the cases in Section II can be reconciled with *Kingsdown*, there is a roughly even split of cases following the higher *Kingsdown* standard and cases following the lower *Critikon* standard. This would be troubling under any circumstances, but is even more so given that at least some, and presumably all, of the members of the court are aware of the issue. As long ago as 2006, Judge Newman's dissent in *Ferring* pointed out that *Critikon* does not really stand for the proposition for which it has so often been cited and further rests on the dubious foundation of a case expressly overruled in *Kingsdown*.²⁸⁰ More recently, Judge Linn's concurring opinion in *Larson* noted that *Kingsdown* held that "gross negligence" was not sufficient to warrant an inference of intent to deceive but that "[I]n seeming contradiction with *Kingsdown*, a standard even lower than 'gross negligence' has propagated through our case law."²⁸¹ Judge Linn further noted that *Critikon* is the source of the problem and that it had relied on a decision expressly overruled by *Kingsdown*.²⁸²

In part because the standard for proving intent to deceive is so unclear, the parties to patent cases can and do sometimes devote enormous resources to litigating the issue. A win on inequitable

²⁷⁵ Senior Judge Marion T. Bennett, *The United States Court of Appeals for the Federal Circuit – Origins*, in *THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, A HISTORY: 1990-2002*, at 3-15 (2002).

²⁷⁶ *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348 (Fed. Cir. 2009).

²⁷⁷ *In re Seagate Tech., L.L.C.*, 497 F.3d 1360 (Fed. Cir. 2007).

²⁷⁸ *Knorr-Bremse SystemeFuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004).

²⁷⁹ *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

²⁸⁰ *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1202 (Fed. Cir. 2006) (Newman, J., dissenting).

²⁸¹ *Larson Mfg. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1343 (Fed. Cir. 2009) (Linn, J., concurring).

²⁸² *Id.* at 1317-18.

conduct for the defense not only ends the case, but can lead to the recovery of its attorneys' fees if the case is declared exceptional under 35 U.S.C. § 285.²⁸³ There is too much at stake to ignore the issue. With the cases evenly split, the failure to pursue the defense may not be "zealous advocacy." If the district court and Federal Circuit follow the *Critikon* line of cases, the proof necessary to prevail is not particularly onerous. The Federal Circuit itself has noted "the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive."²⁸⁴ From this perspective, to quote Justice Brandeis, "[I]t is more important that the applicable rule of law be settled than that it be settled right."²⁸⁵ In other words, if the standard were clearer, parties could devote fewer resources to the defense because they would be able to better assess the likelihood of success or failure and litigate or settle accordingly. As things stand now, the likelihood of ultimate success on this issue cannot be determined until the composition of the Federal Circuit panel on appeal is known.

One obvious solution to this difficulty would be for the court to return to following strictly its en banc decision in *Kingsdown*. Indeed, Judge Rader recommended in his dissent in *Aventis* that "[T]his court ought to revisit occasionally its *Kingsdown* opinion."²⁸⁶ He added that "*Kingsdown* properly made inequitable conduct a rare occurrence."²⁸⁷ As an en banc decision, *Kingsdown* can only be overruled en banc; panels are obligated to follow it. Another obvious action would be for the court to take up the issue en banc again at its earliest opportunity, as Judge Linn recommended in his *Larson* concurrence.²⁸⁸

Several of the post-2004 opinions have identified a number of reasons that the standard adopted in *Kingsdown* is correct and should be maintained. For example, as quoted above, in *Star Scientific* Judge Michel wrote for the court that it is important to have a high standard for inequitable conduct "because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability."²⁸⁹

²⁸³ See, e.g., *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1350 (Fed. Cir. 2005).

²⁸⁴ *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990).

²⁸⁵ *Comm'r v. Coronado Oil & Gas Co.*, 285 U.S. 393, 406 (1932) (Brandeis, J., dissenting).

²⁸⁶ *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1350 (Fed. Cir. 2008).

²⁸⁷ *Id.*

²⁸⁸ *Larson Mfg. of S.D. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1344 (Fed. Cir. 2009) (Linn, J., concurring).

²⁸⁹ See *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008); see also Tyler, *supra* note 1, at 269-70 ("Because inequitable conduct

Another reason to maintain the heightened standard for finding intent to deceive adopted in *Kingsdown* is because otherwise there is a tendency for inequitable conduct to become the affirmative defense tail that wags the litigation dog. Once again, both Judges Linn and Rader have observed this tendency. In his *Larson* concurrence, Judge Linn noted that the patent-in-suit had undergone examination twice in the PTO and after both examinations the patentee had been accused of inequitable conduct for allegedly withholding material information, despite having disclosed hundreds of references.²⁹⁰ The district court case was stayed pending the second examination and when it resumed the “second inequitable conduct allegation was the sole issue at trial.”²⁹¹ Judge Linn further noted that, following the Federal Circuit’s remand, the litigation would continue to focus on inequitable conduct “to the exclusion of the patentee’s infringement contentions.”²⁹²

For his part, Judge Rader wrote:

Although designed to facilitate USPTO examination, inequitable conduct has taken on a new life as a litigation tactic. The allegation of inequitable conduct opens new avenues of discovery; impugns the integrity of [the] 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. This court has even observed a number of cases, such as this one, that arrive on appeal solely on the basis of inequitable conduct where the trial court has apparently elected to try this issue in advance of the issues of infringement and validity.²⁹³

requires ‘forfeiture of all patent rights,’ the courts should require more compelling evidence than a mere inference that the wrongful acts were intentional.” (quoting *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1574 (Fed. Cir. 1991))).

²⁹⁰ *Larson*, 559 F.3d at 1343.

²⁹¹ *Id.*

²⁹² *Id.*

²⁹³ *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting). *See also* Tyler, *supra* note 1, at 283 (noting that inequitable conduct allegations lead “to motions to disqualify trial counsel on the grounds that he or she will be a witness”). Within the last four years, the author alone has been involved in two cases, one as a plaintiff and one as a defendant, in which separate district courts elected to try an inequitable defense first and disposed of one patent-in-suit on that basis. In light of its tendency to overwhelm other issues in a case, the inequitable conduct defense should also be kept in check through rigorous adherence to the heightened pleading requirements of Fed. R. Civ. P. 9(b), which apply to inequitable conduct. *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., L.L.C.*, 350 F.3d 1327, 1342-44 (Fed. Cir. 2003). Courts should be even more demanding in their requirements to plead inequitable

In addition to these problems, the inequitable conduct defense also leads to difficult and contentious attorney-client privilege issues and contributes to an overall acrimonious atmosphere in a case given that most lawyers do not appreciate being accused of fraud.²⁹⁴

Several post-2004 decisions have also pointed out the errors in the *Critikon* standard (in addition to the fact it was based on an overruled decision). First, allowing an inference of intent to deceive to be drawn based on the high materiality of the withheld reference “[c]onflat[es] materiality and intent in [a] manner . . . inconsistent with the principle that ‘materiality does not presume intent, which is a separate and essential component of inequitable conduct.’”²⁹⁵ Second, allowing the inference of intent to deceive to be drawn where the patentee knew or “should have known” of the materiality of the withheld information “sets forth a simple negligence standard, lower even than the ‘gross negligence’ standard that was expressly rejected in *Kingsdown*.”²⁹⁶ Third, allowing the inference of intent to deceive to be drawn where the patentee does not provide a good faith explanation for withholding information:

effectively shifts the burden to the patentee to prove a negative: that it did not intend to deceive the PTO. But it is the ‘accused infringer’ – not the patentee – who “must prove by clear and convincing evidence that the material

conduct in light of the Supreme Court’s decisions in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009). In *Twombly* and *Ashcroft*, the Supreme Court adopted a two-step approach for determining the adequacy of a pleading. The first step is to identify any conclusory allegations, which should be ignored. The second step is to determine whether the remaining, specific and factual, allegations state a plausible claim. A plausible claim is one that describes conduct that is more likely to be illegal than legal. See *Ashcroft*, 129 S. Ct. at 1949-50; *Twombly*, 550 U.S. at 555-57. In light of these cases, sufficient allegations of inequitable conduct should be required to include specific, factual allegations that make out a plausible claim that the patentee’s conduct was more likely than not to have been intentionally deceptive. The Federal Circuit’s recent decision in *Exergen Corp. v. Wal-Mart Stores, Inc.*, No. 2006-1491, 2009 U.S. App. LEXIS 17311, at **27-47 (Fed. Cir. Aug. 4, 2009), very strictly applied the heightened pleading requirements of Rule 9(b) in holding proposed allegations of inequitable conduct were insufficient, even without citing *Twombly* or *Ashcroft*.

²⁹⁴ See, e.g., Tyler, *supra* note 1, at 286-87.

²⁹⁵ *Larson*, 559 F.3d at 1344 (Linn, J., concurring) (quoting *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir. 1990)). See also *Aventis*, 525 F.3d at 1350 (“Merging intent and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic.”) (Rader, J., dissenting); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1314-15, 1329 (Fed. Cir. 2008) (“[T]he district court incorrectly conflated intent with materiality.”) (Lourie, J., concurring in part and dissenting in part).

²⁹⁶ *Larson*, 559 F.3d at 1344 (Linn, J., concurring).

information was withheld with the specific intent to deceive the PTO.”²⁹⁷

Further, “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.”²⁹⁸

IV. CONCLUSION

Notwithstanding the Federal Circuit’s avowed purpose to bring uniformity to patent law, and the awareness of at least some members of the court of the issue, since 2004 the court’s decisions have continued to diverge on the proper standard for finding the intent to deceive element of inequitable conduct. This situation should be remedied by strict adherence to the *Kingsdown* standard, which was adopted *en banc*, in all future decisions or, if necessary, by having the court revisit the issue *en banc* to confirm the *Kingsdown* standard. The *Kingsdown* standard is the appropriate one for several reasons. The lower standard conflates the separate issues of materiality and intent, does not require clear and convincing evidence of intent, impugns patents, patentees, and their counsel, leads to acrimonious discovery battles and motions to disqualify, subjects patent rights (important to the nation’s economy) to undue risks, and allows one affirmative defense to overwhelm other issues in a case, among other defects. Moreover, the sooner the issue is settled the better, because under the present law parties devote enormous resources to litigating this issue given that it can be dispositive, it can lead to the recovery of attorneys’ fees, both sides can cite cases supporting their position, and the outcome cannot be predicted with any reasonable degree of certainty until the identity of the Federal Circuit panel hearing the appeal is known. None of this is good, and it should be remedied.

²⁹⁷ *Id.* (citing *Star Scientific, Inc. v. R. J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

²⁹⁸ *Star Scientific*, 537 F.3d at 1368 (emphasis added). *See id.* at 1334, 1341 (Linn, J., concurring) (“[S]o too an accused infringer cannot carry its threshold burden simply by pointing to the absence of a credible good faith explanation.”).