

# THE “ELEVATED EVIDENTIARY BURDEN” TO PROVE INEQUITABLE CONDUCT

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## I. INTRODUCTION

Inequitable conduct is a defense to patent infringement that carries a very big stick: a finding that an entire patent—or even numerous related patents—are unenforceable because of the patentee’s improper conduct before the PTO. This paper discusses the state of the law as reflected in a group of Federal Circuit opinions from approximately the last year.

If the August 2008 case of *Star Scientific*<sup>2</sup> were the latest word from the Federal Circuit, we would have little difficulty concluding that the most recent trend appears to be in the direction of strictly holding the defendant to its “elevated evidentiary burden”<sup>3</sup> of proof for inequitable conduct and limiting the application of the doctrine to only the most culpable behavior. Indeed, *Star Scientific* teaches not only that the inference of deceptive intent cannot be inferred from materiality, but that the clear and convincing standard requires that deceptive intent must be “the single most reasonable inference” from the evidence as a whole.<sup>4</sup>

The problem is that *Star Scientific* is “book-ended” by conflicting cases. *Praxair*,<sup>5</sup> which just issued on Sept. 29, 2008, sustained a finding of intent which was inferred simply from the high materiality of a withheld prior art reference. In the *Aventis* case decided in May 2008, the Federal Circuit denied a petition for rehearing and rehearing en banc on Sept. 25, 2008 that squarely raised the disparities between different panels in the Federal Circuit on the legal standard for intent.<sup>6</sup> There appears to be an ongoing intracircuit conflict that may only be resolved in an en banc proceeding, perhaps the vehicle being an en banc petition in the *Praxis* case.

The policy implications should be further explored. The Federal Circuit has long been concerned about the frequency with which inequitable conduct is alleged in patent cases and the harm to the patent litigation system (and individual attorneys) that results.<sup>7</sup> There is good reason for the Federal Circuit to focus on the problem of rampant inequitable conduct claims in litigation. Like willful infringement which the Federal Circuit addressed en banc in *In re Seagate*<sup>8</sup> last year, inequitable conduct threatens to be the tail wagging the dog in patent litigation.

But if the Federal Circuit signals that the unenforceability penalty will only be applied in cases that are exceptionally “egregious” or “extreme,” some patent applicants may decide that they can game the system. As the Federal Circuit pointed out in the recent *Aristocrat* case, inequitable conduct plays an important role in the system of remedies in patent litigation as the mechanism whereby

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2 *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. Aug. 25, 2008) (Michel, C.J.).

3 *Id.* at 1365.

4 *See id.* at 1366; *see also Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 538 F.3d 1365, 1366-67 (Fed. Cir. June 19, 2008) (Clevenger, J.).

5 *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. Sept. 29, 2008) (Dyk, J.; Lourie, J., dissenting from the affirmation of inequitable conduct).

6 *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, No. 2007-1280, September 25, 2008, Denial of Petition for Rehearing and Rehearing En Banc.

7 *See Kingdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988); *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418 (Fed. Cir. 1988).

8 *In re Seagate Tech. LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (en banc).

procedural irregularities during prosecution may be redressed in the courts.<sup>9</sup> Some applicants may conclude that the benefits of failing to fully meet the prescribed standards of conduct before the PTO outweigh the small risk that a finding of inequitable conduct will be affirmed on appeal.

For the inequitable conduct penalty to protect the ex parte system of patent examination, the Federal Circuit must continue to make clear that findings of inequitable conduct will be affirmed in cases where the applicant has intentionally engaged in conduct that falls short of the PTO’s standards for disclosure of material information during patent prosecution.

## II. LEGAL STANDARDS FOR INEQUITABLE CONDUCT

### A. *Kingsdown* and the Inequitable Conduct “Plague”

Any discussion of the Federal Circuit’s current inequitable conduct jurisprudence must begin with *Kingsdown*.<sup>10</sup> Twenty years ago, the Federal Circuit concluded that “the habit of charging inequitable conduct in almost every major patent case had become an absolute plague.”<sup>11</sup> Later that same year, the Federal Circuit issued an en banc opinion in the case of *Kingsdown Medical Consultants, Ltd.*<sup>12</sup> The *Kingdown* opinion is widely understood to reflect the Federal Circuit’s desire to curtail the use of inequitable conduct claims as a litigation tactic.

*Kingsdown* involved a continuation application which mistakenly carried forward certain broad claims that had been rejected in the original application. The broad claims had been found allowable only after *Kingsdown* amended them to overcome an indefiniteness rejection. When *Kingdown*’s attorney carried forward the claims into the new application, the attorney inadvertently copied the rejected, broad, unamended claims. The examiner did not notice the mistake and issued the claims in a patent. The district court deemed the mistake to be “gross negligence” by the patent attorney which rose to the level of intent to deceive the PTO.<sup>13</sup>

The Federal Circuit reversed the district court and found no inequitable conduct. The Federal Circuit held that the district court clearly erred because there was no evidence that *Kingsdown*’s attorney intended to act inequitably.<sup>14</sup> The Federal Circuit further held that gross negligence alone cannot justify an inference of intent to deceive the PTO.<sup>15</sup> Importantly, in *Kingsdown*, the Federal Circuit affirmed that proof of inequitable conduct requires clear and convincing evidence of *both* materiality and intent.<sup>16</sup>

### B. *Star Scientific* and the Current Law

Written by Chief Judge Michel, the August 2008 *Star Scientific* opinion includes a comprehensive review of the law of inequitable conduct.<sup>17</sup> In his review, Chief Judge Michel sets forth what he refers to as the “elevated evidentiary burden” that the defendant must meet to prove inequitable conduct.<sup>18</sup> As Chief Judge Michel explained:

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

9 *Aristocrat Techs. Australia Pty Ltd. v. Int’l Game Tech.*, 543 F.3d 657, 659 (Fed. Cir. Sept. 22, 2008) (holding there is no defense of “improper revival” of a patent application by the PTO) *cert. den.*, 129 S. Ct. 2719 (June 15, 2009).

10 *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (en banc to overrule precedent that stated “gross negligence” mandates a finding of intent to deceive).

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

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

13 *See id.* at 872.

14 *See id.* at 876.

15 *See id.*

16 *See id.* at 872.

17 *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365-66 (Fed. Cir. Aug. 25, 2008) (Michel, C.J.).

18 *See id.* at 1365.

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.<sup>19</sup>

### 1. The Applicability of the Inequitable Conduct Defense

The defense of inequitable conduct usually involves allegations that a patent-in-suit was procured through improper conduct before the PTO. Patent applicants “have a duty to prosecute patent applications in the Patent Office with candor, good faith, and honesty.”<sup>20</sup> That duty requires that persons involved in the prosecution of a patent disclose all known information material to patentability to the PTO.<sup>21</sup> A breach of this duty constitutes inequitable conduct and renders the entire patent (and, in appropriate cases, related patents) unenforceable.<sup>22</sup>

Although the defense is usually predicated on misrepresentations during patent prosecution, the defense is not so limited. One example is the incorrect payment of a small entity fee.<sup>23</sup> In *Ulead*, the Federal Circuit stated:

[W]e no reason why the doctrine should not extend into other contexts, like the present one, where the allegation is that inequitable conduct has occurred after the patent has issued and during the course of establishing and paying the appropriate maintenance fee. In this context, it is equally important that the PTO receive accurate information from those who practice before it.<sup>24</sup>

Thus, the inequitable conduct defense is not confined to instances of misrepresentation that bear on the patentability of claims in an application but may involve other types of misrepresentation to the PTO.

### 2. Framework of the Inequitable Conduct Analysis

The burden of proof lies with the accused infringer.<sup>25</sup> To prevail on the defense, the accused infringer must prove two factual elements: 1) materiality, and 2) intent to deceive the PTO.<sup>26</sup> Both elements are questions of fact that must be proven by clear and convincing evidence.<sup>27</sup> The defendant must make a threshold showing of *both* elements by clear and convincing evidence.<sup>28</sup> However, even after the threshold showing of both materiality and intent has been made, “[t]he district court must still balance the equities to determine whether the applicant’s conduct before the PTO was *egregious* enough to warrant holding the entire patent unenforceable.”<sup>29</sup> “Thus, even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the court may still decline to render the patent unenforceable.”<sup>30</sup>

19 *Id.* at 1365-66 (citations omitted).

20 *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007).

21 *See* 37 C.F.R. § 1.56(a).

22 *See id.*

23 *See, e.g., Nilsen v. Oram Sylvania, Inc.*, 504 F.3d 1223 (Fed. Cir. Oct. 10, 2007) (Lourie, J.).

24 *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1144 (Fed. Cir. 2003) (internal citations omitted).

25 *See Star Sci.*, 537 F.3d at 1365.

26 *See id.*

27 *Young v. Lumenis, Inc.*, 492 F.3d 1359, 1363 (Fed. Cir. 2007).

28 *See Star Sci.*, 537 F.3d at 1365.

29 *See id.* (emphasis added).

30 *Id.*

### 3. Materiality

The Federal Circuit has held that “information is material to patentability when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.”<sup>31</sup> The materiality element may be established by clear and convincing evidence that the patent applicant “made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information” to the PTO.<sup>32</sup> Information is not material when it is cumulative of information previously disclosed to the PTO.<sup>33</sup>

In evaluating materiality, the Federal Circuit has often looked to the PTO standard set forth in Rule 56.<sup>34</sup> Rule 56 imposes on “each individual associated with the filing and prosecution of a patent application ... a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.”<sup>35</sup> The current version of Rule 56 makes information material to patentability if it

is not cumulative to information already of record or being made of record in the application, and

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

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.<sup>36</sup>

A misstatement or omission that is material under the Rule 56 standard is considered material for the purposes of the inequitable conduct inquiry, but the converse is not true. A statement can be material for the purposes of showing inequitable conduct “even if it does not meet the standard for Rule 56 if, in the totality of the circumstances, a reasonable examiner would have considered such information important in deciding whether to allow the patent application.”<sup>37</sup> It is well settled that information may be material even if that information would not by itself invalidate the claims.<sup>38</sup>

### 4. Intent to Deceive the PTO

The showing required is *specific intent* to deceive the Patent Office. For example, where nondisclosure of prior art is alleged, “clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a known material reference.”<sup>39</sup>

31 *Id.* at 1367 (referencing *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1297 (Fed. Cir. 2008); *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314 (Fed. Cir. 2006)).

32 *See id.* at 1365 (referencing *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1363 (Fed. Cir. 2007)).

33 *See id.* at 1367 (referencing *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 1000 (Fed. Cir. 2007)).

34 *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1129 (Fed. Cir. 2006).

35 37 C.F.R. Section 1.56(a).

36 37 C.F.R. Section 1.56(b).

37 *Monsanto Co. v. Bayer Biosci. N.V.*, 514 F.3d 1229, 1238 n.11 (Fed. Cir. 2008).

38 *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007).

39 *Star Sci.*, 537 F.3d at 1366 (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1171, 1181 (Fed. Cir. 1995)) (emphasis supplied by Federal Circuit); *see also Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc) (showing of gross negligence does not meet requirement to prove intent).

Proof of intent does not require direct evidence; intent can be inferred from indirect and circumstantial evidence.<sup>40</sup> The indirect or circumstantial evidence must still be clear and convincing, however.<sup>41</sup> “[T]he 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.”<sup>42</sup> “Further, the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be *the single most reasonable inference* able to be drawn from the evidence to meet the clear and convincing standard.”<sup>43</sup>

“Materiality does not presume intent, which is a separate and essential component of inequitable conduct.”<sup>44</sup> The fact that information that is later determined to be material was not disclosed does not, standing alone, establish deceptive intent.<sup>45</sup> However, this principle has not always been strictly adhered to. As Judge Rader stated in his dissent in *Aventis*: “More recently, however, the judicial process has too often emphasized materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct. Merging intent and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic.”<sup>46</sup> This general issue—under what circumstances may deceptive intent be inferred—remains a source of uncertainty in the law and, apparently, conflict between different panels in the Federal Circuit.

### 5. Balancing by the Court

If, and only if, materiality and intent have both been shown by clear and convincing evidence, the court will engage in a balancing analysis to determine whether to exercise its discretion to hold the patent unenforceable.<sup>47</sup> “[T]he district court must balance the *substance* of those now-proven facts and all the equities of the case to determine whether the severe penalty of unenforceability should be imposed.”<sup>48</sup> However, even after the threshold showing of both materiality and intent has been made, “[t]he district court must still balance the equities to determine whether the applicant’s conduct before the PTO was *egregious* enough to warrant holding the entire patent unenforceable.”<sup>49</sup> “Thus, even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the court may still decline to render the patent unenforceable.”<sup>50</sup> “The more material the omission or the misrepresentation, the lower the level of intent is required to establish inequitable conduct, and vice versa.”<sup>51</sup>

### 6. Standard of Review by the Appellate Court

Most findings of inequitable conduct are appealed to the Federal Circuit after a bench trial. Accordingly, the usual standard of review is two-tier.<sup>52</sup> The Federal Circuit reviews the district court’s underlying factual determinations for clear error.<sup>53</sup> The Federal Circuit then reviews the district court’s ultimate decision as to inequitable conduct for abuse of discretion.<sup>54</sup> If the district court’s determination was based on a clearly erroneous finding of materiality or intent, a misapplication of law, or a clear error of judgment, the Federal Circuit will find that the district court abused its discretion and reverse.<sup>55</sup>

40 See *Star Sci.*, 537 F.3d at 1366 (referencing *Cargill*, 476 F.3d at 1364).

41 See *id.* (referencing *Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d 1181, 1186 (Fed. Cir. 2006)).

42 *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1374-75 (Fed. Cir. 2006) (quoting *Kingsdown*, 863 F.2d at 876).

43 *Star Sci.*, 537 F.3d at 1366-67 (referencing *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 538 F.3d 1365, 1376 (Fed. Cir. 2008)) (emphasis added).

44 *Id.* at 1366 (quoting *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001)).

45 See *id.*

46 *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1350 (Fed. Cir. May 14, 2008) (Rader, J., dissenting).

47 *Star Sci.*, 537 F.3d at 1367.

48 *Id.* (quoting *Molins*, 48 F.3d at 1178) (emphasis supplied by Federal Circuit).

49 See *id.* at 1365 (emphasis added).

50 *Id.*

51 *Id.* at 1367 (referencing *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997)).

52 See *id.* at 1365.

53 See *id.*

54 See *id.*

55 See *id.*; see also *Larson Mfg. Co. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1327 (Fed. Cir. Mar. 18, 2009) (“An abuse of discretion occurs when (1) the trial court’s decision is clearly unreasonable, arbitrary, or fanciful, (2) the court’s decision is based on an erroneous construction of the law, (3) the court’s factual findings are clearly erroneous, or (4) the record contains no evidence upon which the court rationally could have based its decision. See *W. Elec. Co. v. Piezo Tech., Inc.*, 860 F.2d 428, 430-31 (Fed. Cir. 1988).”).

Alternatively, if the appeal is from a grant of summary judgment by the district court, the Federal Circuit’s review is *de novo* and nondeferential.<sup>56</sup>

### III. RECENT CASES

In this section, we summarize recent Federal Circuit cases in chronological order. The following section discusses the trends in the cases and some additional issues.

#### A. *McKesson*<sup>57</sup>

In *McKesson*, the Federal Circuit affirmed a finding of inequitable conduct after a bench trial. Judge Newman dissented.

The alleged conduct involved the failure of a patent attorney to submit three pieces of material information during prosecution.<sup>58</sup> The case involved three applications pending in the PTO before two different examiners.<sup>59</sup> The attorney failed to disclose to the second examiner in the second case (1) a prior art patent found by the first examiner in the first case; (2) the initial rejection of broad claims by the first examiner in the first case; and (3) the allowance of claims in the third case by the second examiner (*i.e.*, failure to disclose to the same, second examiner).

The trial court held a bench trial limited to the inequitable conduct defense, which resulted in the judgment of unenforceability of the patent-in-suit. The district court found the three items of information to be individually and collectively material.<sup>60</sup> The district court also found that circumstantial evidence and the lack of a credible explanation warranted a finding of deceptive intent.<sup>61</sup> The intent finding was apparently buttressed by the patent attorney’s testimony that he would make the same decisions not to disclose if given the chance to prosecute the same applications again.<sup>62</sup>

Regarding the first allegation, the district court concluded that the second examiner would have found the new prior art patent highly material and not cumulative.<sup>63</sup> Among other reasons, before the first examiner found the new prior art patent, the same relevant prior art had been submitted in both the first and second cases.<sup>64</sup> Further, the first examiner found the new prior art patent was not cumulative. Intent to deceive was established, in part, because the new prior art patent rendered untrue a statement by the patent attorney to the second examiner just seventeen days before and the attorney “could not have (or certainly should not have) missed [the patent’s] significance.”<sup>65</sup>

The Federal Circuit held that the district court did not err in concluding that the new prior art patent was material and not cumulative.<sup>66</sup> Based on the circumstances of the attorney’s discussions with the two examiners, the Federal Circuit concluded that the attorney knew or should have known of the high materiality of the art, and that the district court did not err in finding that deceptive intent was established in light of the circumstantial evidence and the lack of a credible explanation.<sup>67</sup>

As to the second allegation concerning nondisclosure of rejections in the first case, the Federal Circuit found the rejections material because of the similarities between the claims in the two cases such that the rejections should have been disclosed to the second examiner.<sup>68</sup> Moreover, the

<sup>56</sup> See *Eisai Co. Ltd. v. Dr. Reddy’s Labs., Inc.*, 533 F.3d 1353, 1359 (Fed. Cir. July 21, 2008) (Rader, J.).

<sup>57</sup> *McKesson Inf. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir. May 18, 2007) (Clevenger, J.; Newman, J., dissenting).

<sup>58</sup> See *id.* at 901.

<sup>59</sup> See *id.* at 904.

<sup>60</sup> See *id.* at 901.

<sup>61</sup> See *id.*

<sup>62</sup> See *id.*

<sup>63</sup> See *id.* at 909.

<sup>64</sup> See *id.* at 908.

<sup>65</sup> See *id.*

<sup>66</sup> See *id.* at 913-17.

<sup>67</sup> See *id.* at 917-20.

<sup>68</sup> See *id.* at 919-23 (relying on Manual of Patent Examining Procedure Sections 2001.04, 2001.06).

Federal Circuit affirmed the finding of intent by clear and convincing evidence notwithstanding that the existence of the first case was disclosed to the second examiner.<sup>69</sup>

The third and last inequitable conduct allegation was based on the attorney's failure to inform the second examiner that the same, second examiner had granted a related case—the third case—a few months before. The existence of the third case had been disclosed to the second examiner, but not the fact that he granted the case. Although the Federal Circuit recognized that the information could have been cumulative and not material if the second examiner remembered that he granted the third case, the court said that there was no evidence on that point. The withholding of this information was deemed material and done with deceptive intent. The Federal Circuit found no clear error in the findings of materiality and intent to deceive and no abuse of discretion in the district court's finding of inequitable conduct.

Judge Newman's dissent<sup>70</sup> was focused on the failure to require clear and convincing evidence of deceptive intent. Judge Newman stated that the failure to require such evidence of intent to deceive would do nothing but encourage a return to the "plague" of inequitable conduct claims and opportunistic litigation that the Federal Circuit has tried to discourage.

### B. *Nilssen*<sup>71</sup>

In *Nilssen*, the Federal Circuit affirmed a holding of inequitable conduct after a bench trial that resulted in the unenforceability of fifteen patents.<sup>72</sup> *Nilssen* involved an inventor who represented himself in the prosecution of his patents.<sup>73</sup> There were numerous allegations of inequitable conduct, including failure to disclose that a person who submitted declarations to the PTO had a financial interest in Nilssen's patents; incorrect payment of small entity maintenance fees; intentionally misclaiming a priority date; failure to disclose ongoing litigation to the examiner; and failure to identify prior art in patent prosecution.<sup>74</sup> The Federal Circuit affirmed findings of inequitable conduct based on each of these allegations. The Federal Circuit concluded its opinion by commenting that it was the collection of the problems, not the allegations considered individually, that indicated "repeated attempts to avoid playing fair and square with the patent system" and that the outcome of the case indicates that Mr. Nilsson erred in his belief that he had no need of professional assistance in dealing with the complicated patent process.<sup>75</sup>

### C. *Innogenetics*<sup>76</sup>

In *Innogenetics*, the Federal Circuit affirmed a grant of summary judgment of no inequitable conduct on the grounds that alleged misrepresentations regarding a prior art reference were "mere attorney argument" and thus not material.<sup>77</sup>

In an EPO proceeding, the prosecuting attorney identified the Cha PCT application as the "closest prior art," under a "problem solution" framework that is used in European practice.<sup>78</sup> The attorney argued, however, that none of the submitted references taught or disclosed the claimed method.<sup>79</sup> The EPO found that certain claims were not novel in light of the Cha PCT application. Claims were therefore amended with a disclaimer that they were "amended to disclaim the teaching of the Cha PCT application."<sup>80</sup>

69 See *id.* at 922.

70 See *id.* at 926 (Newman, J., dissenting). Judge Newman filed an extensive dissent along the same lines in *Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d 1181, 1203 (Fed. Cir. 2006) (Newman, J., dissenting) ("The panel majority's holding that deceptive intent is established as a matter of law if the applicant 'should have known' that information might be material to patentability, further revives the 'plague' of the past, with burdens that far outweigh any conceivable benefits."). In *Ferring*, the Federal Circuit found inequitable conduct based on declarations submitted to the PTO where Ferring failed to disclose that the declarants had previously been paid consultants.

71 *Nilssen v. Osvam Sylvania, Inc.*, 504 F.3d 1223 (Fed. Cir. Oct. 10, 2007) (Lourie, J.).

72 See *id.* at 1226.

73 See *id.* at 1226-27.

74 See *id.* at 1227-29.

75 See *id.* at 1235.

76 *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363 (Fed. Cir. Jan. 17, 2008) (Moore, J.).

77 See *id.* at 1379.

78 See *id.* at 1378-79.

79 See *id.* at 1379.

80 See *id.*

In the prosecution of the patent-in-suit, the Cha PCT application was submitted with an international search report that noted the application as problematic.<sup>81</sup> The attorney that prosecuted the U.S. application submitted an accompanying prior art statement that “the references do not relate to the invention and, therefore, further discussion of the same is not necessary.”<sup>82</sup> The attorney later admitted, however, that he did not actually examine the prior art references and his statement was boilerplate that he used on other occasions.<sup>83</sup>

The Federal Circuit agreed with the district court that the materiality prong was not met. The statements regarding the Cha PCT application were “mere attorney argument.”<sup>84</sup> Moreover, because the Cha PCT application itself was submitted to the PTO examiner, he or she was free to examine it herself and accept or reject Innogenetics’ arguments.<sup>85</sup>

#### D. *Monsanto*<sup>86</sup>

In *Monsanto*, the Federal Circuit affirmed a holding of inequitable conduct after a bench trial.<sup>87</sup> The inequitable conduct was based on Bayer’s failure to submit a scientist’s notes from a scientific meeting that were inconsistent with arguments regarding patentability that Bayer was making.

The Barnes Abstract was submitted as prior art in the prosecution of the patent-in-suit.<sup>88</sup> The Barnes Abstract was published in conjunction with a scientific conference. In a poster presented at the meeting, Dr. Barnes presented additional data that confirmed additional accomplishments not mentioned in the Abstract. A Bayer scientist attended the meeting and took notes, which were later provided to others at Bayer, but were not disclosed to the PTO.<sup>89</sup>

The description of the additional accomplishments in the attendee’s notes were inconsistent with arguments made by Bayer to the PTO.<sup>90</sup> The district court found it “very obvious” that the content of the notes were in “sharp contradiction” to Bayer’s arguments to the examiner.<sup>91</sup> The district court found not credible testimony from Bayer that its scientists did not appreciate the content of the notes or that the notes were not submitted because they were illegible.<sup>92</sup>

The Federal Circuit affirmed. The Federal Circuit held that the notes were highly material because they directly contradicted arguments made to the PTO in support of patentability.<sup>93</sup> As to intent, the Federal Circuit stated 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.”<sup>94</sup> The Federal Circuit held that the district court did not clearly err in finding intent on the grounds that the explanations offered by Bayer were not credible.

#### E. *Pfizer*<sup>95</sup>

In *Pfizer*, the Federal Circuit affirmed a finding of no inequitable conduct after a bench trial because, even if the two nondisclosed prior art references were material, there was insufficient proof of intent to deceive.<sup>96</sup>

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81 *See id.*

82 *See id.*

83 *See id.*

84 *See id.*

85 *See id.*

86 *Monsanto Co. v. Bayer Biosci. N.V.*, 514 F.3d 1229 (Fed. Cir. Jan. 28, 2008) (Gajarsa, J.).

87 *See id.* at 1233, 1242.

88 *See id.* at 1234.

89 *See id.* at 1235-36.

90 *See id.* at 1238-39.

91 *See id.* at 1239.

92 *See id.* at 1241.

93 *See id.* at 1240.

94 *See id.* at 1241.

95 *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. Mar. 7, 2008) (Dyk, J.).

96 *See id.* at 1366.

The defendant argued on appeal that the materiality of the references, standing alone, was sufficient to establish intent, if the patent holder offered no credible explanation for withholding them.<sup>97</sup> But the district court found that Pfizer did offer a good faith explanation. One of the named inventors testified that Pfizer concluded that the prior art references were significantly distinct from the compounds in the application and did not meet the usual criteria for disclosing similar compounds to the PTO. The district court found the testimony credible and recognized Pfizer's "highly consistent pattern" when determining which compounds should be disclosed as supporting good faith. The Federal Circuit agreed that there was no basis for finding inequitable conduct, because the materiality of a reference is insufficient to establish intent where the applicant has provided a credible explanation for the withholding of a reference.<sup>98</sup>

#### F. *Ortho-McNeil*<sup>99</sup>

In *Ortho-McNeil*, the Federal Circuit affirmed summary judgment of no inequitable conduct. The inequitable conduct allegation involved tests by the applicant on prior art compounds.<sup>100</sup> The defendant contended that the applicant's own tests yielded data that were inconsistent with arguments that the applicant made during prosecution about the teachings of the prior art but the applicant did not disclose those test data to the PTO.<sup>101</sup> The Federal Circuit agreed with the district court that the applicant did not misrepresent the teachings in the references, and only repeated what the references themselves said.<sup>102</sup> Furthermore, the applicant never made any affirmative representations that contradicted its own test results regarding the properties of the prior art compounds.<sup>103</sup> The Federal Circuit thus affirmed the district court's dismissal of the inequitable conduct claims.<sup>104</sup>

#### G. *Symantec*<sup>105</sup>

In *Symantec*, the Federal Circuit affirmed a grant of summary judgment of no inequitable conduct.<sup>106</sup> *Symantec* involved three alleged material misrepresentations in declarations filed with the PTO.

The first inequitable conduct claim involved inventor-of-record Gray's alleged misrepresentation that he was an inventor in a declaration filed with the application.<sup>107</sup> At trial, the inventor was unable to identify with specificity what his contribution was. The Federal Circuit agreed with the district court that, particularly in light of a co-inventor's testimony that Gray came up with the idea for the invention, Gray's testimony only showed that his memory had lapsed and did not create a genuine issue of material fact that Gray was not an inventor.

The second inequitable conduct claim was based on Gray's statements in a second declaration responding to an office action.<sup>108</sup> Gray stated that he was familiar with the state of the art relating to computer viruses and computer virus prevention. Gray also stated that he set out to develop an algorithm to check a computer file for virus infections. These statements were allegedly false because Gray was a marketing and not a technical person, and someone else actually developed the algorithm itself. The Federal Circuit agreed with the district court that Gary's statements did not establish any genuine issue whether the declaration was false or misleading.

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97 See *id.* at 1366-67.

98 See *id.* at 1367 (relying on *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006) (three conditions must be met where a party relies solely on the materiality of the references to prove intent: "(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")).

99 *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358 (Fed. Cir. Mar. 31, 2008) (Rader, J.).

100 See *id.* at 1363.

101 See *id.*

102 See *id.*

103 See *id.*

104 See *id.*

105 *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279 (Fed. Cir. Apr. 11, 2008) (Dyk, J.).

106 See *id.* at 1296.

107 See *id.* at 1297.

108 See *id.*

The third inequitable conduct allegation was based on the statement in a declaration by another co-inventor Wakelin that he had reviewed and understood the contents of the application and the claims.<sup>109</sup> Wakelin later testified that he only understood the claims in general terms. The district court found that materiality was not established even if Wakelin did not fully understand the claim language, and the Federal Circuit agreed.

#### H. *Aventis*<sup>110</sup>

In *Aventis*, the Federal Circuit affirmed a finding of inequitable conduct after a bench trial. In an previous appeal, the Federal Circuit affirmed that the information at issue was material to patentability but reversed the grant of summary judgment of inequitable conduct because there were genuine issues of material fact as to intent.<sup>111</sup> In this appeal, the Federal Circuit affirmed the district court’s finding of an intent to deceive the PTO. Judge Rader dissented.

The inequitable conduct involved the failure of a noninventor scientist to disclose that two sets of data that he compared in submissions to the PTO were obtained at different dosages.<sup>112</sup> The patented drug consists of heparins that are used medically to prevent abnormal blood clotting. The comparison was between the half-lives of the claimed drug and a prior art drug. The scientist did not disclose that the two sets of data that he compared were obtained using different dosages.

In an earlier 2006 opinion, the Federal Circuit held that the withheld information was material to patentability in view of *Aventis*’ repeated arguments to the examiner that the half-life differences were highly significant.<sup>113</sup> On remand, the district court held a bench trial limited to the issue of intent. The district court rejected various explanations from the scientist, including that the clinically relevant dosages were different for the two compounds and the half-life data were appropriately compared at those relevant dosages. The Federal Circuit found that the district court did not clearly err in rejecting the proffered explanation of mere inadvertence and finding intent to deceive the PTO.<sup>114</sup>

Judge Rader dissented.<sup>115</sup> In introductory discussion, Judge Rader stated that “my reading of our case law restricts a finding of inequitable conduct to only the most extreme cases of fraud and deception.”<sup>116</sup> Judge Rader further stated that “equitable conduct has taken on a new life as a litigation tactic” and that “this court ought to revisit occasionally its *Kingsdown* opinion”<sup>117</sup> which “properly made inequitable conduct a rare occurrence.”<sup>118</sup> Judge Rader blamed a “judicial process [that] has too often emphasize materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct. Merging intent and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic.”<sup>119</sup> Judge Rader went on to note that “[t]his 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.”<sup>120</sup>

Judge Rader’s view was that the record did not show clear and convincing evidence of intent to deceive the PTO.<sup>121</sup> He noted that while the clear-error standard of review is high, “it is not insurmountable.”<sup>122</sup> Judge Rader observed that the failure to disclose the information was consistent with oversight and the evidence did not indicate active attempts to conceal information. Judge Rader

109 See *id.* at 1298.

110 *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334 (Fed. Cir. May 14, 2008) (Prost, J.; Rader, J., dissenting).

111 *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, No. 05-1513, 2006 U.S. App. LEXIS 14778, at \*19 (Fed. Cir. June 7, 2006) (Prost, J.) (nonprecedential).

112 See *Aventis*, 525 F.3d at 1341.

113 See *id.*

114 See *id.* at 1349.

115 See *id.* at 1349 (Rader, J., dissenting).

116 See *id.* (Rader, J., dissenting).

117 See *id.* (Rader, J., dissenting).

118 See *id.* at 1350 (Rader, J., dissenting).

119 See *id.* (Rader, J., dissenting).

120 See *id.* (Rader, J., dissenting) (citing cases); see also *Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247 (Fed. Cir. Aug. 1, 2008) (Rader, J.) (discussed *infra*).

121 See *Aventis*, 525 F.3d at 1349 (Rader, J., dissenting).

122 See *id.* at 1351 (Rader, J., dissenting).

stated that he found “it difficult to fathom” that a scientist of such stature would risk tarnishing his stellar professional reputation with a false submission to the PTO for an invention in which that scientist was not even involved. Judge Rader also pointed out that two individuals, the prosecuting attorney and the scientist, had apparently made the same mistake. Moreover, the scientist himself subsequently disclosed and corrected the error with a second declaration to the PTO.

The Federal Circuit recently denied rehearing and rehearing en banc in *Aventis*.<sup>123</sup> *Aventis*’s petition argued that the *Aventis* decision “effectively dispens[ed] with the separate element of ‘intent’ in inequitable conduct cases involving a material omission.”<sup>124</sup> *Aventis* further argued that courts applied this erroneous view of the law “regularly hold[ing] patents unenforceable for mere negligence.”

*Aventis*’s petition for en banc review was supported by numerous amici curiae, including the Biotechnology Industry Organization, the Pharmaceutical Research & Mfrs. of America, Johnson & Johnson, Eli Lilly & Co., Caterpillar Inc., 3M Co., and a group of law professors. Among other things, the amici stressed the inefficiencies and burden that result from forced overdisclosure of marginally relevant information during prosecution and “the potential under-explanation of what is salient to the examination process.”<sup>125</sup>

### I. *Scanner Technologies*<sup>126</sup>

In *Scanner Technologies*, the Federal Circuit reversed a finding of inequitable conduct after a bench trial because the district court clearly erred in its finding of materiality.<sup>127</sup>

*Scanner Technologies* involved a petition to make special.<sup>128</sup> The patent holder learned that the accused infringer had launched a competing product that allegedly infringed claims of its patent applications.<sup>129</sup> The applicant filed a petition to make special to seek accelerated review of its patent applications because of actual infringement.<sup>130</sup> A declaration in support of the petition allegedly contained false statements, including statements regarding the accused infringer’s conduct at trade shows where the patent holder’s invention had been displayed.<sup>131</sup> The petition to make special was granted.<sup>132</sup> The district court concluded that the allegedly false statements were intended to mislead the PTO into believing that the accused infringer had actually copied the patent holder’s invention after viewing it at trade shows.<sup>133</sup> The district court found to the contrary, that the alleged infringer had developed the accused product from an earlier product of its own.<sup>134</sup>

The Federal Circuit first held that the materiality prong could be met by false statements that did not relate to patentability: “When the setting involves a petition to make special, as is the case here, we 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.”<sup>135</sup>

However, the finding of materiality was overturned because the district court’s interpretation of those statements was rejected by the Federal Circuit.<sup>136</sup> The Federal Circuit stated that, in assessing the evidence, all reasonable inferences must be considered by the court: “Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally

123 *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, No. 2007-1280, September 25, 2008, Denial of Petition for Rehearing and Rehearing En Banc.

124 See Combined Petition for Panel Rehearing and Rehearing En Banc [*Aventis*] at 1-2, available at 2008 WL 2761591.

125 Brief for Multiple Companies as Amici Curiae in Support of Panel Rehearing or Rehearing En Banc at 3; see also, e.g., Amicus Brief of Biotechnology Industry Organization in Support of Plaintiff-Appellant *Aventis*’s Petition for Rehearing or Rehearing En Banc, available at 2008 WL 2952312; Brief for Johnson & Johnson as Amicus Curiae in Support of Panel Rehearing or Rehearing En Banc, available at 2008 WL 2952313.

126 *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 538 F.3d 1365 (Fed. Cir. June 19, 2008) (Clevenger, J.).

127 See *id.* at 1379.

128 See *id.* at 1370.

129 See *id.*

130 See *id.*

131 See *id.* at 1372 & n.2.

132 See *id.* at 1370.

133 See *id.* at 1372.

134 See *id.*

135 *Id.* at 1375.

136 See *id.* at 1379.

reasonable inference.”<sup>137</sup> The opinion further explained that “[i]n light of the requirement that inequitable conduct be found by clear and convincing evidence, the district court erred when it adopted an unfavorable inference regarding [one of the statements at issue] over an equally reasonable favorable inference.”<sup>138</sup>

According to the Federal Circuit, all the allegedly false statements relied on by the district court were subject to reasonable interpretations that were different from the ones that the district court reached.<sup>139</sup> The evidence was not clear and convincing that the patent holder falsely told the PTO that the accused infringer copied the invention.<sup>140</sup> The evidence showed that the patent holder simply told the PTO in the declaration that it believed there was infringement.<sup>141</sup>

#### J. *Eisai*<sup>142</sup>

In *Eisai*, the Federal Circuit affirmed findings of no inequitable conduct after a bench trial and on summary judgment.<sup>143</sup> There were five separate bases for the alleged inequitable conduct.<sup>144</sup> All the inequitable conduct allegations were rejected by the district court and the Federal Circuit affirmed.

The first four allegations were the subject of bench trial. The first allegation was that Eisai failed to disclose a co-pending application to the examiner of the patent-in-suit.<sup>145</sup> The Federal Circuit determined that the disclosure would have been prudent.<sup>146</sup> The Federal Circuit held, however, that the district court had ample evidence that the materiality of the other application was low based on testimony and evidence that the compounds in the two applications were believed to be separately patentable and were not viewed “primarily in relation to one another” by the Eisai scientists.<sup>147</sup> The Federal Circuit held, moreover, that the record was “devoid of any real suggestion of intent” to deceive the patent office.<sup>148</sup>

The second allegation was that Eisai failed to disclose rejections from the co-pending application.<sup>149</sup> The district court did not reach the issue of materiality, because it found insufficient evidence of intent to deceive the PTO. The Federal Circuit found that the facts alleged did not rise to the level of “culpability” required to establish intent under *Kingsdown*.<sup>150</sup>

The third allegation was Eisai’s failure to disclose a piece of prior art in the prosecution of the patent-in-suit.<sup>151</sup> The Federal Circuit was persuaded that the prior art patent offered “nothing new to the record” before the PTO.<sup>152</sup> Furthermore, the record lacked clear and convincing evidence of intent to deceive.

The fourth allegation was that Eisai submitted misleading data in a declaration to overcome an obviousness rejection during the prosecution of the patent-in-suit.<sup>153</sup> The data were allegedly misleading because they did not include the compound that was the subject of the co-pending application.<sup>154</sup> The district court found that the declaration itself was highly material, but Eisai had no obligation to provide the additional data.<sup>155</sup> The Federal Circuit affirmed the district court’s finding of no inequitable conduct, and noted that the record again lacked evidence of deceptive intent.<sup>156</sup>

137 *Id.* at 1376.

138 *Id.* at 1377.

139 *See id.* at 1376-79.

140 *See id.*

141 *See id.* 1378-79.

142 *Eisai Co. Ltd. v. Dr. Reddy’s Labs., Inc.*, 533 F.3d 1353 (Fed. Cir. July 21, 2008) (Rader, J.).

143 *See id.* at 1355.

144 *See id.* at 1360.

145 *See id.*

146 *See id.*

147 *See id.* at 1360-61.

148 *See id.*

149 *See id.*

150 *See id.*

151 *See id.* at 1361.

152 *See id.*

153 *See id.* at 1361-62.

154 *See id.*

155 *See id.*

156 *See id.*

The final allegation was disposed of by the district court on summary judgment.<sup>157</sup> The allegation was that Eisai concealed another pharmaceutical compound from the examiner. The district court found insufficient evidence of both materiality and intent. The Federal Circuit affirmed. The appeals court noted that the strongest evidence was that one Eisai “insider” made a “passing comment” that the similar of the claimed compound to another compound “bothers me.”<sup>158</sup> The Federal Circuit found this vague, subjective statement to be insufficient to establish a genuine issue regarding materiality or intent.<sup>159</sup>

#### K. *RCT*<sup>160</sup>

In *RCT*, the Federal Circuit reversed a finding of inequitable conduct after a bench trial because the district court failed to conduct a proper analysis and the Federal Circuit remanded for a proper consideration on the merits.<sup>161</sup>

The district court canceled a scheduled jury trial and held a bench trial limited to the issue of inequitable conduct.<sup>162</sup> The trial court further limited the testimony from RCT to inventor testimony on candor and good faith. The trial court specifically barred RCT from presenting expert evidence regarding materiality. The trial court thereafter ruled that RCT’s patents were unenforceable for inequitable conduct.<sup>163</sup>

The Federal Circuit reversed because the district court clearly erred by considering only one prong of the analysis, intent to deceive the PTO, and ignoring materiality.<sup>164</sup> The nondisclosed information consisted of data obtained after the filing of the patent applications. The Federal Circuit explained that this data was not material to the patentability of the claimed invention.<sup>165</sup> Furthermore, the Federal Circuit noted that the data was published, which is inconsistent with an intent to conceal data from the PTO.<sup>166</sup> Indeed, the Federal Circuit found that the intent analysis was clearly erroneous, since the district court relied on statements by the inventor that did not evidence that any of the submissions to the PTO were untrue.<sup>167</sup>

#### L. *Star Scientific*<sup>168</sup>

In *Star Scientific*, the Federal Circuit reversed a finding of inequitable conduct after a bench trial because it found the district court’s factual findings to be clearly erroneous. As to the first patent-in-suit, the finding of intent was clearly erroneous. For the second patent, the finding of materiality was held to be clearly erroneous.

The inequitable conduct involved an alleged conspiracy between the inventor and Star Scientific to prevent disclosure to the PTO of a letter from one of Star Scientific’s outside consultants (the “Burton letter”).<sup>169</sup> The technology-in-suit was for curing tobacco by a process that resulted in reduced levels of particular carcinogens.<sup>170</sup> The Burton letter discussed Dr. Burton’s new observation that reduced levels of the carcinogens had been achieved in Chinese tobacco products.<sup>171</sup> The Burton letter thus showed that the prior art had achieved low levels of the carcinogens.

<sup>157</sup> See *id.* at 1362.

<sup>158</sup> See *id.*

<sup>159</sup> See *id.*

<sup>160</sup> *Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247 (Fed. Cir. Aug. 1, 2008) (Rader, J.).

<sup>161</sup> See *id.* at 1250, 1254-55.

<sup>162</sup> See *id.*

<sup>163</sup> See *id.*

<sup>164</sup> See *id.* at 1252.

<sup>165</sup> See *id.* at 1252-53.

<sup>166</sup> See *id.* at 1252.

<sup>167</sup> See *id.* at 1253-54.

<sup>168</sup> *Star Sci., Inc., v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. Aug. 25, 2008) (Michel, C.J.).

<sup>169</sup> See *id.* at 1361-62.

<sup>170</sup> See *id.* at 1361.

<sup>171</sup> See *id.* at 1361-62.

Star Scientific switched prosecution firms during the prosecution of the first patent-in-suit.<sup>172</sup> The key allegation was that when Star Scientific changed firms, Star Scientific prevented the attorneys at the old firm, Sughrue, from disclosing the Burton letter to the attorneys at the new firm, Banner.<sup>173</sup> The Burton letter had been analyzed by an attorney at the Sughrue firm.<sup>174</sup> The attorney was initially concerned but, after investigation and further analysis, decided the letter and its content were not material.

The Federal Circuit concluded that with respect to the first patent-in-suit, there was no evidence of intent to deceive the PTO.<sup>175</sup> The district court clearly erred in concluding that Star Scientific deliberately prevented the Banner lawyers from learning of the letter. There was no evidence that the letter was a reason for changing firms. The defendant, furthermore presented no evidence that the either the inventor or the decision makers at Star Scientific were aware of the Burton letter or the information in it before the Sughrue firm was replaced. In short, the Federal Circuit found a “major gap” in the defendant’s evidence regarding intent.<sup>176</sup> The Federal Circuit noted that, even if Star Scientific’s explanations were not credible, as the district court found, Star Scientific was not required to offer a good faith explanation because the defendant did not first meet its burden to prove a threshold level of intent to deceive by clear and convincing evidence.<sup>177</sup>

With respect to the second patent-in-suit, the Federal Circuit held that the district court clearly erred in finding the Burton letter material.<sup>178</sup> To the contrary, the Burton letter was clearly cumulative to other information disclosed to the PTO, which included an interrogatory response from the litigation that stated the prior art had achieved low or insignificant levels of the carcinogens. The Federal Circuit made no determination whether the finding of deceptive intent as to the second patent was clearly erroneous.<sup>179</sup>

#### M. *Praxair*<sup>180</sup>

In *Praxair*, the Federal Circuit affirmed a finding of inequitable conduct as to one patent-in-suit and reversed a finding of inequitable conduct as to another patent-in-suit. The allegations of inequitable conduct were based on prior art that was allegedly withheld from the PTO.

As to the first patent-in-suit, the Federal Circuit affirmed the finding of inequitable conduct.<sup>181</sup> The appeals court agreed that the prior art was material. On the intent prong, the district court inferred intent to deceive from the high materiality of the prior art in the context of statements made during the prosecution. The Federal Circuit sustained the district court’s finding. The Federal Circuit found that there was no question that the prosecuting attorney and one of the inventors knew of the prior art, and that the attorney was aware of its obvious materiality.<sup>182</sup> The Federal Circuit also agreed that the applicants failed to present any good faith explanation for withholding the art.<sup>183</sup>

As to the second patent-in-suit, the Federal Circuit reversed. The district court relied on the statements during prosecution referred to above to establish a high degree of materiality. That was error, the Federal Circuit determined, because those statements were made only in the prosecution of the first patent and could not be used to establish materiality as to the second patent.

Judge Lourie dissented as to the affirmance of inequitable conduct for the first patent.<sup>184</sup> Judge Lourie stated that Federal Circuit law requires more than materiality for a finding of intent to

172 See *id.* at 1363.

173 See *id.* at 1367.

174 See *id.* at 1362.

175 See *id.* at 1367-68.

176 See *id.* at 1368.

177 See *id.*

178 See *id.* at 1371.

179 See *id.* at 1370.

180 *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306 (Fed. Cir. Sept. 29, 2008) (Dyk, J.; Lourie, J., dissenting from the affirmance of inequitable conduct).

181 See *id.* at \*9.

182 See *id.* at \*8.

183 See *id.* at \*8-9.

184 See *id.* \*19 (Lourie, J., dissenting-in-part).

deceive.<sup>185</sup> Judge Lourie also stated that the district court erred in failing to conduct a balancing of materiality and intent before determining whether inequitable conduct had occurred.<sup>186</sup> In addition, Judge Lourie criticized the majority for failing to properly analyze whether the attorney and the inventor “knew, or should have known,” of the materiality of the withheld art.<sup>187</sup>

## IV. DISCUSSION AND QUESTIONS

### A. Trends in the Cases

*Star Scientific's* strict application of legal standards for inequitable conduct is “book-ended” by *Praxair* and *Aventis*, which use a lower standard to find deceptive intent.

The Federal Circuit appears to be applying a strict legal standard for deceptive, if the cases of *Scanner Technologies*, *RCT*, *Eisai*, and *Star Scientific* are an accurate indication. These four recent cases suggest that the standard for proving the factual elements of materiality and intent is high and may be getting higher. Indeed, *Star Scientific* (August 2008) and *Scanner Technologies* (June 2008) suggest that the clear and convincing standard requires that the district court reject unfavorable inferences whenever there are competing favorable inferences that are equally reasonable. This latter standard seems to go further than simply strictly holding the accused infringer to his burden of proof.

Other cases apply lower standards for intent. Some cases explicitly apply a “knew or should have known” standard, which encompasses mistake or negligence. The latest example is *Praxair*, decided on September 29, which reaffirms that intent may be inferred from materiality in some circumstances.<sup>188</sup> *Aventis*, decided in May 2008, affirmed a finding of intent to deceive where the record was apparently ambiguous. In *Aventis*, Judge Rader argued in a strongly worded dissent that the noninventor scientist who was accused of wrongdoing had little incentive to risk his professional standing and that the scientist's later actions in disclosing the problem to the PTO were inconsistent with an intent to deceive.

A showdown appears inevitable. Cases like *Praxair* and *Aventis* conflict with the cases imposing a strict requirement for proof of intent to deceive, including *Kingsdown*, which is en banc precedent. Will it be necessary for the Federal Circuit to undertake another en banc review to resolve this persistent uncertainty in the law?

### B. Policy Issues

In *Star Scientific*, Chief Judge Michel described the fine line that the courts must walk to ensure that the severe penalty of unenforceability is applied appropriately.<sup>189</sup> His discussion and that of Judge Rader in his *Aventis* dissent appear to reflect a view that inequitable conduct should be limited only to the most egregious and extreme cases.<sup>190</sup> In a similar vein, Judge Lourie suggested in his *Praxair* dissent that the rule that intent may be inferred from materiality was never meant to apply except in a context with such egregious facts that the omission could not have been inadvertent.<sup>191</sup> As Judge Rader explained:

In *Kingsdown*, this court clearly conveyed that the inequitable conduct was not a remedy for every mistake, blunder, or fault in the patent procurement process. Even mistakes that struck at the heart and integrity of the process—

<sup>185</sup> See *id.* at \*20 (Lourie, J., dissenting-in-part).

<sup>186</sup> See *id.* (Lourie, J., dissenting-in-part).

<sup>187</sup> See *id.* (Lourie, J., dissenting-in-part).

<sup>188</sup> See *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-14 (Fed. Cir. Sept. 29, 2008) (“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.”) (citation and internal quotation marks omitted).

<sup>189</sup> *Star Sci.*, 537 F.3d at 1365-66 (citations omitted).

<sup>190</sup> See *id.* at 1365 (referencing *Monsanto Co. v. Bayer BioSci. B.V.*, 363 F.3d 1235, 1239 (Fed. Cir. 2004)); *Aventis*, 525 F.3d at 1349.

<sup>191</sup> *Praxair*, 543 F.3d at 1329 (Lourie, J., dissenting-in-part) (referencing *Bruno Independent Living Aids, Inc. v. Acorn Mobility Serus, Ltd.*, 394 F.3d 1348 (Fed. Cir. 2005)).

like repeatedly recopying and acquiring rights to a rejected claim—did not amount to inequitable conduct. Instead this court required “culpable” conduct supported by clear and convincing evidence of intent to deceive the USPTO.<sup>192</sup>

Judge Rader concluded: “*Kingsdown* properly made inequitable conduct a rare occurrence.”<sup>193</sup>

But is the standard in danger of being set too high and failing to act as a brake on the actions of applicants who prosecute patents under the ex parte examination system? The applicant’s incentives in ex parte prosecution run somewhat counter to the interests of the patent system and the public. If the Federal Circuit makes known that only the most extreme and rare cases of inequitable conduct will trigger the remedy of unenforceability, it would not be surprising if some applicants will see an opportunity and take advantage. What will be the effect of making it more difficult to prove inequitable conduct? Who will benefit the most?

### C. Inequitable Conduct Issues in the Reexamination Content

We conclude by raising a few questions about reexamination and inequitable conduct:

- If the PTO finds a substantial new question of patentability based on a prior art reference that was not before the PTO during the original prosecution, may an inequitable conduct charge be brought on the grounds that the applicant, at a minimum, should have known of the reference?
- If a reexamined patent is a member of a family of patents, can reexamination of the one patent “cure” inequitable conduct problems for the whole family?
- Does the existence of a protective order in litigation trump the duty to disclose material information to the PTO?

## V. EPILOGUE

As this article is being prepared for publication, seven months later, the proper standard for inferring deceptive intent remains unsettled. Rehearing was not sought in the *Praxair* case. En banc rehearing and certiorari review were denied in *Star Scientific*<sup>194</sup> and certiorari was denied in *Aventis*.<sup>195</sup>

In March 2009, the Federal Circuit issued an opinion in *Larson Manufacturing Co. v. Aluminart Products Ltd.*, which again underscored the inconsistency in the case law.<sup>196</sup> The panel reversed a finding of inequitable conduct and remanded for determination of whether deceptive intent was present in the withholding of two office actions in a copending prosecution from a panel of PTO examiners who were reexamining the patent-in-suit. The Federal Circuit provided specific guidance to the district court on remand. Among other things, the panel stated that “just as merely withholding a reference cannot support an inference of deceptive intent, so too an accused infringer cannot carry its threshold burden simply by pointing to the absence of a credible good faith explanation.”<sup>197</sup> Moreover, the court must weigh any evidence of good faith against the evidence favoring a finding of deceptive intent.<sup>198</sup>

Judge Linn filed a concurring opinion in *Larson* urging the Federal Circuit to undertake en banc review to clarify the test for inferring deceptive intent. As Judge Linn noted, the sole issue at trial

<sup>192</sup> *Aventis*, 525 F.3d at 1350.

<sup>193</sup> *Id.*

<sup>194</sup> *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. Aug. 25, 2008), *reh’g & reh’g en banc den.*, (Fed. Cir. Oct. 22, 2008), *cert. den.*, 129 S. Ct. 1595 (Mar. 9, 2009).

<sup>195</sup> *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1350 (Fed. Cir. May 14, 2008), *reh’g & reh’g en banc den.*, (Fed. Cir. Sept. 25, 2008), *cert. den.*, 129 S. Ct. 2053 (Apr. 27, 2009).

<sup>196</sup> 559 F.3d 1317 (Fed. Cir. Mar. 18, 2009).

<sup>197</sup> *Id.* at 1340-41 (citations omitted).

<sup>198</sup> *See id.* at 1341.

was the inequitable conduct and, after this remand, the case would continue to focus on the inequitable conduct—again, the tail wagging the dog.<sup>199</sup> He further noted that the current case law permits an inference of deceptive intent whenever “(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.”<sup>200</sup> This, Judge Linn argued, allows a finding of deceptive intent based on evidence of simple negligence, which is inconsistent with Supreme Court precedent and with the intent of the Federal Circuit to do away with the “plague” of alleging inequitable conduct in almost every patent case.<sup>201</sup> In addition, the obligation to produce a “credible explanation” improperly shifts the burden to the patentee to prove that the patentee did *not* intend to deceive the PTO.<sup>202</sup> Finally, the test conflicts with the directive in *Star Scientific* that deceptive intent must be the “single most reasonable inference.”<sup>203</sup> Despite Judge Linn’s concurrence, the Federal Circuit denied a petition for rehearing in *Larson* on April 13, 2009. Perhaps the persistent uncertainty in the legal standard will have the salutary effect of deterring withholding of material art during patent prosecution that might otherwise occur under the very high standard of *Star Scientific*.

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199 *See id.* at 1343 (Linn, J., concurring).

200 *Id.* (Linn, J., concurring) (internal quotation marks omitted).

201 *See id.* at 1344 (Linn, J., concurring).

202 *See id.* (Linn, J., concurring).

203 *See id.* (Linn, J., concurring).

