

## ***Therasense v. Becton, Dickinson:***

### **An Opportunity for the Federal Circuit to Mend Its Fractured Inequitable Conduct Rulings**

**By Daniel H. Shulman and Donald W. Rupert**

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In November 2010, the *en banc* Court of Appeals for the Federal Circuit will, for the first time in more than 20 years, reconsider nearly all facets of its inequitable conduct jurisprudence when it hears oral argument in *Therasense, Inc. v. Becton, Dickinson & Co.*<sup>1</sup> The court's need to resolve its often confusing and divergent precedent concerning inequitable conduct should have been apparent from a survey of the court's inequitable conduct cases in the last few years. After a year, 2007, that was relatively free from controversy—just a single dissent was filed on an inequitable conduct issue<sup>2</sup>—2008, 2009, and the first half of 2010 have seen significant fracturing of the court. This article addresses a number of significant inequitable conduct cases since 2008. The first three cases<sup>3</sup> contained two dissents and one unanimous opinion critical of the court's inequitable conduct jurisprudence. An *en banc* hearing was sought in each of those three cases, and each was denied.<sup>4</sup> Against that fact, the fourth case included a concurring opinion suggesting that *en banc* consideration of inequitable conduct was overdue.<sup>5</sup> And, in the span of approximately one month, from April 27 to May 28, 2010, the court issued four additional inequitable conduct opinions,<sup>6</sup> not a single one of which was unanimous.<sup>7</sup>

This article examines the cases from this critical 2008-2010 period, with an eye toward identifying tendencies that may foreshadow how the *en banc* court might decide one or more of the six questions presented in the *Therasense en banc* order.<sup>8</sup> Those questions are:

1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?

2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? If so, what is the appropriate standard for fraud or unclean hands?
3. What is the proper standard for materiality? What role should the US Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that, but for the alleged misconduct, one or more claims would not have issued?
4. Under what circumstances is it proper to infer intent from materiality?
5. Should the balancing inquiry (balancing materiality and intent) be abandoned?<sup>9</sup>
6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context?

The first case, *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, revealed a fundamental split in the Federal Circuit's willingness to accept judgments of inequitable conduct. In that case, affirmance of the district court's finding of inequitable conduct by the majority, Judges Prost and Moore, led dissenting Judge Rader to remark that "my reading of our case law restricts a finding of inequitable conduct to only the most extreme cases of fraud and deception."<sup>10</sup> In *Aventis*, a non-inventor scientist, Dr. Uzan, submitted a declaration comparing the half-life of the claimed compound to the half-life of prior compounds cited by the PTO but did not disclose the doses used in the half-life measurements. In fact, the doses for the two measurements were different.<sup>11</sup> The district court found the declaration to be misleading for, essentially, concealing the fact that it allegedly compared apples to oranges.<sup>12</sup> The applicant argued that: (1) the use of different doses was justified because the comparison was done at clinically relevant doses for each compound, (2) half-lives are dose independent, and (3) the failure to disclose the dose differences was due to inadvertence.<sup>13</sup>

The Federal Circuit affirmed the district court's finding of inequitable conduct, concluding that clear error had not been shown in either the district court's finding of materiality or intent to deceive. Judge Rader took issue with that holding and, in particular, the majority's treatment of the allegation. Referring to the inequitable conduct remedy as the "atomic bomb," he remarked on the litany of litigation tactics made possible through allegations of inequitable conduct.<sup>14</sup> He then repeated the oft-quoted maxim that "inequitable conduct as a litigation strategy had become a 'plague.'"<sup>15</sup> Stating his view that inequitable conduct ought to apply "to

only the most extreme cases of fraud and deception,”<sup>16</sup> Judge Rader invited the court to “revisit occasionally its *Kingsdown* opinion.”<sup>17</sup>

Judge Rader then compared the facts of the instant case to *Kingsdown* and concluded that the actions in the instant case, namely failing to include dosage information, did not threaten the integrity of the patent system even as much as the acts in *Kingsdown*.<sup>18</sup> Explaining how it came to be that the dosage data was omitted, he wrote:

Without question, Dr. Uzan should have disclosed the dosage of [the compound]. Unfortunately, the Foquet study chart that Dr. Uzan used did not show the dosage information. Dr. Uzan neglected to add the information. To make it clear, Dr. Uzan did not attempt to conceal data that were otherwise present. Rather he just submitted the study without adding to the disclosure. This omission, even if negligent, is hardly *Kingsdown*’s culpable intent to deceive. Moreover, this omission strikes less at the integrity of the system than the issuance of a rejected claim, which *Kingsdown* sanctioned.<sup>19</sup>

After further explaining why Dr. Uzan’s failure to include the dosage information due to inadvertence was credible, Judge Rader struck at the core of the why inequitable conduct allegations themselves may be inequitable:<sup>20</sup>

Moreover, I find it difficult to fathom that a scientist of Dr. Uzan’s caliber and reputation would engage in such deception. As the district court points out, Dr. Uzan has had a magnificent fifty year career with Aventis, has published over 350 scientific articles and has received numerous prestigious awards including the Galien Research Prize, France’s highest award for drug discovery. This world-class scientist would hardly risk his reputation and tarnish his brilliant career for a single example in the prosecution of a patent for an invention in which he was not even involved.<sup>21</sup>

The *Aventis* case, therefore, provides insight into how at least Judge Rader might answer the second question in the *Therasense* order. Specifically, Judge Rader’s comment that inequitable conduct should be reserved for “only the most extreme cases of fraud and deception” is illuminating.

The next case, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*,<sup>22</sup> is significant not because of any intra-panel dissension—it was a unanimous opinion—but because of what the panel had to say about inequitable conduct generally and how it moved to curb the “plague.” In that case, the patent at issue related to a curing method for tobacco that would produce lower levels of certain carcinogens. At issue was a letter sent from a consultant of the patentee to the patentee’s original prosecution counsel indicating that prior art methods may also have produced lower levels of the carcinogens.<sup>23</sup> After switching prosecution firms, the letter (the Burton letter) was never discovered by the new firm and was not disclosed to the PTO. The defendants in the suit claimed that the switch of law firms was made to conceal the Burton letter, and the district court agreed, finding deceptive intent and inequitable conduct.<sup>24</sup> The Federal Circuit thought that finding clearly erroneous and reversed.<sup>25</sup>

Judge Michel, writing for a unanimous panel, began much as Judge Rader began his dissent in *Aventis* by positing that the original intent of the inequitable conduct defense was to punish fraud.<sup>26</sup> Then he remarked on the court’s duty to respond to the lessening of that standard, invoking the notion of “equity”:

Subsequent case law has broadened the doctrine to encompass misconduct less egregious than fraud, see for example *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069-70 (Fed. Cir. 1998), 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.<sup>27</sup>

As it turned to the evidence of deceptive intent in the instant case, the court announced what might be considered a new standard to evaluating deceptive intent. Recognizing that deceptive intent is nearly always proven based on an inference, the court required that “the inference must not only be reasonable in light of the 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>28</sup>

The court was not explicit that its single-most-reasonable-inference test was a new standard, but the citation it made for that proposition was not as far-reaching. To support the proposition, the court cited a statement from *Scanner Techs. Corp. v. ICOS Visions Sys. Corp.* that “[w]henver evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”<sup>29</sup> To say that a court should not “overlook” a reasonable inference is one thing. However, what the court said in *Star Scientific* was that courts *must* overlook a reasonable inference if it is not the “single most reasonable inference.” That is quite another thing. The court in the instant case concluded that evidentiary gaps precluded a finding of deceptive intent and reversed the holding of inequitable conduct.

*Star Scientific* reveals how members of the court (at least Judge Dyk, who is the only member of that panel who will be on the *Therasense en banc* panel in November 2010) might answer the second and fourth *Therasense* questions. The unanimous panel opinion stated that inequitable conduct “was originally applied only in cases of ‘fraud on the Patent Office,’” answering the second *Therasense* question.<sup>30</sup> The single-most-reasonable-inference test also suggests how Judge Dyk might approach the fourth *Therasense* question relating to the inference of intent.<sup>31</sup>

In the third case, *Abbott Labs. v. Sandoz, Inc.*,<sup>32</sup> inequitable conduct was a bit player in the overall decision. However, the case presents an interesting contrast with *Aventis* and *Star Scientific*. In those earlier cases, the position was taken that inequitable conduct was (and perhaps should be) properly based only upon egregious conduct such as “fraud” on the Patent Office. Here, the dissent argued for a broader application to conduct that did not reach the level of actual “fraud.” In this case, the majority affirmed the grant of a preliminary injunction, in the process affirming a holding of no inequitable conduct. The conduct in the case centered on a statement in a declaration that certain test results were “statistically significantly lower” than a comparable formulation, despite the fact that the declarant had not analyzed statistical significance.<sup>33</sup> The district court found that, although the misstatement would have been important to a reasonable examiner, it was nevertheless not material.<sup>34</sup> Sandoz, on the other hand, argued for the high materiality of the statement and further argued that deceptive intent should be inferred from materiality of the misstatement.<sup>35</sup> The Federal Circuit did not comment on the materiality issue, but rejected Sandoz’s argument that intent could be inferred solely from

materiality and therefore upheld the finding of no inequitable conduct.<sup>36</sup> In light of the evidence presented and Sandoz's argument, which was clearly contrary to established precedent that materiality and intent need to be proven independently by clear and convincing evidence,<sup>37</sup> the holding was unremarkable.

What was somewhat remarkable was Judge Gajarsa's dissent. Although largely dedicated to disputing the majority's view of preliminary injunction case law and the issue of validity in the case, Judge Gajarsa did remark that the "substantial question of inequitable conduct" presented by the evidence may have been sufficient alone to defeat the preliminary injunction. Similar to Judge Rader's and Judge Michel's earlier statements about the level of "fraud" historically necessary to establish inequitable conduct,<sup>38</sup> Judge Gajarsa stated that "the district court abused its discretion because it created such a high bar for materiality that in essence no statement or withholding of information would be material if it would not change the ultimate outcome of allowing the patent."<sup>39</sup> That comment suggests that at least Judge Gajarsa might conclude that the answer to the third *Therasense* question, namely whether materiality should be a but-for test, is in the negative. However, as noted below, Judge Garjarsa seems to have softened that view.<sup>40</sup>

The fractured nature of the preceding inequitable conduct cases reached a breaking point for at least one judge in *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Prods. Ltd.*<sup>41</sup> In this case, the applicant informed the examiner of several related applications that were pending in the PTO during the prosecution of a reexamination, including several office actions and numerous pieces of art related thereto but failed to disclose particular office actions specifically.<sup>42</sup> The district court found several undisclosed pieces of prior art and particular office actions (the "Third" and "Fourth" office actions) material and found intent to deceive based on the failure to bring all of them to the attention of the PTO during the reexamination.<sup>43</sup> The Federal Circuit determined that the district court had clearly erred as to the materiality of the prior art, but not as to the Third and Fourth office actions.<sup>44</sup> However, it remanded the case for a new determination of deceptive intent because the district court had made its determination based on the non-disclosure of the prior art and the office actions.<sup>45</sup> In so doing, the court cautioned the district court that any inference of deceptive intent must be the "single most reasonable inference," citing *Star Scientific*.<sup>46</sup> It also warned that deceptive intent cannot be inferred simply from the absence of a good faith explanation and that any good faith that militates against deceptive intent

must be considered.<sup>47</sup> The court then identified some of the good faith evidence, including the notification of the co-pending applications.<sup>48</sup> Finally, the court noted that, even if deceptive intent were found, the district court still had to balance materiality and intent to determine if inequitable conduct had occurred, noting that the district court had previously found high materiality based upon the withholding of references that the Federal Circuit determined were simply not material.<sup>49</sup>

If the court's opinion had not served as adequate warning to the district court concerning the Federal Circuit's skepticism over the case, Judge Linn's concurrence placed the opinion in a larger context that cannot be ignored. From the outset, Judge Linn wrote:

I join the opinion of the court, because our precedent so requires. I write separately, however, to express my view that this precedent has significantly diverged from the Supreme Court's treatment of inequitable conduct and perpetuates what was once referred to as a "plague" that our *en banc* court sought to cure in *Kingsdown*.<sup>50</sup>

Judge Linn described this case as symptomatic of the plague: During original prosecution, the PTO considered 143 references, 135 of which the applicant had submitted. The accused infringer nevertheless asserted inequitable conduct. The case was stayed during reexamination in which the applicant submitted another 210 references, including the accused infringer's allegations in the litigation. The applicant also notified the PTO of the co-pending applications and submitted two more information disclosure statements containing all of the references relied on in office actions for the co-pending applications but not the office actions themselves. The patent survived reexamination without substantive change, and the accused infringer again asserted inequitable conduct.<sup>51</sup>

Judge Linn blamed the Federal Circuit for condoning this conduct, saying, "[t]he ease with which inequitable conduct can be pled, but not dismissed, is a problem of our own making."<sup>52</sup> Like Judges Rader and Michel had previously done, Judge Linn compared Federal Circuit jurisprudence to that of the Supreme Court's, remarking that the Supreme Court's inequitable conduct cases "involved overt fraud, not equivocal acts of omission."<sup>53</sup> Then, commenting on the "gross negligence" standard rejected in *Kingsdown*, Judge Linn complained that "a standard even lower than 'gross negligence' has propagated through our case law."<sup>54</sup> Judge Linn noted that prior cases had set a course for inferring deceptive intent that required: (1)

the applicant knew or should have known of the materiality of withheld information, and (2) the applicant has not provided a credible explanation for the withholding.<sup>55</sup> The contradiction with *Star Scientific* was clear.<sup>56</sup> Judge Linn concluded that “the time has come for the court to review the issue en banc.”<sup>57</sup>

Thus, Judge Linn can be counted among the judges that one would expect to answer the second *Therasense* question in favor of a requiring fraud or unclean hands. Perhaps as well, Judge Linn’s frustrations seem to reflect a belief that the current balancing framework (questions one and five) is unworkable.

Judge Linn again voiced concern over the broadening of the inequitable conduct net in *Avid Identification Systems, Inc. v. The Crystal Import Group*.<sup>58</sup> In that case, the issue was whether a non-inventor, non-attorney executive in a closely held company was “substantively involved” in the prosecution of a patent application such that he had a duty to disclose his potential prior art tradeshow activities to the PTO. Answering in the affirmative, the majority (Judges Prost and Mayer) held that the individual was “substantively involved” because:

1. The invention was his idea, even though he had hired the inventors to reduce it to practice;
2. He was involved in all aspects of the company’s research, development, and marketing;
3. He had signed a small entity statement for the patent-in-suit; and
4. He had corresponded with a European patent attorney on matters relating to a European patent.<sup>59</sup>

Having found that the individual had a duty of candor, the court found that he intended to deceive the PTO by not disclosing the tradeshow activities.<sup>60</sup>

Notably, the court did not point to *any* evidence of deceptive intent in its opinion. In fact, the subheadings in the opinion were “Materiality” and “Duty of Candor.” There was no separate section of the opinion directed to intent to deceive. The court’s only discussion relevant to intent was its citation to the witness’s lack of credibility.<sup>61</sup> The sum total of the majority’s intent analysis seems to be a single line in its conclusion paragraph, “Dr. Stoddard acted with deceptive intent.”<sup>62</sup>

Judge Linn dissented in relevant part. Principally, Judge Linn would have imported a materiality standard into the “substantively involved” test, namely, that an individual cannot be deemed “substantively involved” unless he is so apprised of the legal and technical merits of the application that he can assess materiality.<sup>63</sup>



*Avid* reflects two trends apparent (or to become apparent) on the court. First, Judge Linn would take steps to rein in the inequitable conduct defense. Second, Judge Prost is the judge on the court perhaps least hesitant to find inequitable conduct.<sup>64</sup> She seems particularly willing to infer intent from materiality. That position is highly relevant to the fourth *Therasense* question.

Subsequently, the Court denied *en banc* review of its *Avid* decision, over the dissent of Judge Newman.<sup>65</sup> In her dissent, Judge Newman took the side of Judge Linn,<sup>66</sup> but principally dissented on the grounds that analysis of whether the information disclosed at the trade show activities were material could not be fairly made while the third *Therasense* question was pending.<sup>67</sup> Judge Newman encouraged the Court to grant *en banc* review, and then withhold judgment until after *Thersaense* had been decided.<sup>68</sup> Additionally, she strongly indicated that because the jury had found the trade show activities not to be invalidating, they should not have been deemed material to begin with.<sup>69</sup>

If *Avid* allowed one to speculate that Judge Prost approved of inferring intent from materiality, her concurrence in the next case, *Optium Corp. v. Emcore Corp.*,<sup>70</sup> made that approval explicit. In *Optium*, the court considered whether non-disclosure of a highly material reference constituted inequitable conduct. The case came to the court after a grant of summary judgment of no inequitable conduct based on a lack of deceptive intent.<sup>71</sup> In the procedural posture of the case, the high materiality of the undisclosed reference was presumed, and consequently, the focus was on the issue of intent to deceive.

Judge Newman, writing for the majority, noted “some divergence” of Federal Circuit authority on the issue of intent.<sup>72</sup> The case pitted two competing arguments: (1) whether there is a presumption of deceptive intent in cases of high materiality when there is no credible explanation for the nondisclosure, and (2) whether materiality and intent must remain separate inquiries that cannot inform each other.<sup>73</sup> In the instant case, although there may not have been any explanation for the non-disclosure, Optium argued that, if a reference is highly material, then the challenger has a lesser burden in proving intent. The court rejected this argument.<sup>74</sup> Instead, the court pointed to the fact that there was no independent evidence of deceptive intent, and because there is no inference of intent based solely on high materiality, the claim of inequitable conduct must fail.<sup>75</sup>

Judge Prost concurred in the result, also citing the lack of evidence of deceptive intent. However, Judge Prost would have inferred deceptive intent from the non-disclosure of a highly

material reference. She therefore framed the issue not as to whether there was *any* evidence of deceptive intent, but as to whether there was *any other* evidence of deceptive intent besides the inference from the materiality of the nondisclosure.<sup>76</sup> According to Judge Prost:

If a reference is of very high materiality, and it is shown that the patentee knew of the reference, then it is more probable that the reference was withheld from the examiner with deceptive intent, as compared to a reference of low materiality. In other words, framed under our standard for deceptive intent, the more material the withheld reference, the more likely that an inference of deceptive intent is “the single most reasonable inference able to be drawn from the evidence.”<sup>77</sup>

Both Judge Prost’s comments and Judge Newman’s majority opinion directly answer the fourth *Therasense* question, albeit differently.

The second *Therasense* question was front and center in the next case, *Taltech Ltd. v. Esquel Enterprises Ltd.*<sup>78</sup> In that case, the inventor created a drawing during his deposition of his “inspiration” for his patent, which “inspiration” had not been disclosed to the PTO. After determining that the drawing was not cumulative of a disclosed reference and was highly material, the majority opinion (authored by Judge Mayer) inferred deceptive intent. Echoing Judge Prost’s criticism of the majority in *Optium*, the court wrote, “We agree that intent is an element of inequitable conduct requiring support by clear and convincing evidence, but the dissent’s belief that intent requires facts wholly distinct from those establishing materiality is incorrect.”<sup>79</sup>

Judge Gajarsa’s pointed dissent complained of the “ongoing pandemic of baseless inequitable conduct charges that pervade our patent system.”<sup>80</sup> Judge Gajarsa’s dispute concerning materiality reflected a more clearly articulated, and different, position than the one he advanced in *Abbott*. In *Abbott*, Judge Gajarsa was critical of the majority for reading a “but for” standard into materiality.<sup>81</sup> In the present case, however, Judge Gajarsa disputed materiality on the ground that the information was not relevant to the actual claimed invention.<sup>82</sup> The implication, therefore, seems to be that materiality requires something approaching a “but for” analysis that would lead the examiner into allowing the claims. Having disputed materiality, Judge Gajarsa next questioned the majority’s inference of intent that was based solely on

“questionable materiality findings.”<sup>83</sup> In closing, Judge Gajarsa addressed the second *Therasense* question, as well as his view of where the court was headed, saying:

In conclusion, the majority’s opinion affirms a district court judgment that contains no supportable finding of intent, limited materiality findings, and wholly ignored evidence of good faith. In doing so, the majority reverses the road upon which this court’s inequitable conduct is presently traveling. As we recently explained, “[t]he need to strictly enforce . . . [an] elevated standard of proof . . . is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent . . . This penalty was originally applied only in cases of fraud on the Patent Office.”<sup>84</sup>

The final case from spring 2010 again demonstrated Judge Prost’s willingness to infer intent from materiality. In that case, *Leviton Mfg. Co. v. Universal Security Instruments, Inc.*,<sup>85</sup> the district court had found inequitable conduct on summary judgment based on the failure of the prosecuting attorney to disclose to the PTO (1) a co-pending, co-owned (though later filed) application, having different inventorship, from which he had copied claims that issued in the patent-in-suit, and (2) litigation involving the patent-in-suit.<sup>86</sup> Commenting that the Federal Circuit had never “affirmed a grant of summary judgment” of inequitable conduct on similar facts, the court declined to do so in the instant case.<sup>87</sup> Judge Michel, writing for the majority, echoed his *Star Scientific* comment when he criticized the district court for inferring deceptive intent when that inference “was not the only reasonable one based on the record.”<sup>88</sup> The court remanded the case for an evidentiary hearing on deceptive intent.

Judge Prost staked out a, by now, familiar position in her dissent. She acknowledged “this court’s rightful hesitance to allow a finding of inequitable conduct on summary judgment” but stated that “this is a rare case.”<sup>89</sup> In the instant case, Judge Prost went further than in any of her prior opinions. She did not merely infer intent from materiality. Instead, she stated that the prosecuting attorney’s “personal knowledge” of the information, along with his familiarity with his disclosure obligations, “without providing any justification for withholding this information,” meant that he had “all but admitted that he withheld [the information] with intent to deceive.”<sup>90</sup>

That *en banc* review of inequitable conduct law is warranted should be clear from these cases. An intra-circuit split is evident, not only on the issue of “how fraudulent” the conduct must be but also on how district courts should approach the inference of deceptive intent. On the

one hand we find Judges Rader, Newman,<sup>91</sup> Linn, and Gajarsa, who advocate for a more rigorous analysis of deceptive intent and/or a return to the Supreme Court's view of inequitable conduct as a defense based on actual "fraud" on the PTO. On the other hand we have Judge Prost, who would find inequitable conduct much more frequently than many of her colleagues.<sup>92</sup>

Based on the cases discussed in this article, the following summary illustrates possible positions of certain judges of the *en banc* court on the *Therasense* questions. It should be noted that, pursuant to Federal Circuit rules, the following judges are eligible to sit *en banc* (assuming no recusals and no additions to the court prior to argument in November): Chief Judge Rader, Judges Newman, Lourie, Bryson, Gajarsa, Linn, Dyk, Prost, Moore, and Friedman.<sup>93</sup>

***Therasense* Question Nos. 1 and 5:** Should the materiality-intent-balancing framework for inequitable conduct be modified, replaced (Question 1) or abandoned (Question 5)?

Judge Linn: The current balancing test may be unworkable and deviates from *Kingsdown*.<sup>94</sup>

***Therasense* Question No. 2:** In particular, should the standard be tied directly to fraud or unclean hands? If so, what is the appropriate standard for fraud or unclean hands?

Judges Rader,<sup>95</sup> Linn,<sup>96</sup> Gajarsa,<sup>97</sup> and Dyk<sup>98</sup>: Inequitable conduct was originally reserved for cases of actual fraud.

***Therasense* Question No. 3:** What is the proper standard for materiality? What role should the US Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?

Judge Newman<sup>99</sup>: Indicated that materiality should be based on a "but for" standard.

***Therasense* Question No. 4:** Under what circumstances is it proper to infer intent from materiality?

Judges Moore<sup>100</sup> and Prost<sup>101</sup>: It is acceptable to infer intent from materiality in some circumstances, for example, when the reference is "highly material," the more likely it was withheld with deceptive intent; or when the withholder admits of materiality but does not provide any justification for his conduct.

Judges Newman,<sup>102</sup> Linn,<sup>103</sup> Gajarsa,<sup>104</sup> and Moore<sup>105</sup>: Intent and materiality must be proven separately, and one cannot infer one from the other.

**Therasense Question No. 6:** Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context?

Not a significant issue in any of the above cases.

As demonstrated, it is indeed just in time that the court has accepted Judge Linn's invitation, an action it had repeatedly declined to do over the last several years,<sup>106</sup> and clarify its inequitable conduct jurisprudence.

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## Notes

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<sup>1</sup> *Therasense, Inc. v. Becton, Dickinson & Co.*, 2010 WL 1655391 (Fed. Cir. Apr. 26, 2010) (order rehearing the case *en banc*).

<sup>2</sup> *McKesson Information Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir. 2007).

<sup>3</sup> *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334 (Fed. Cir. 2008); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008); *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008).

<sup>4</sup> Other cases from this period involving inequitable conduct that were also denied an *en banc* hearing include: *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229 (Fed. Cir. 2008); *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008); *Scanner Tech. Corp. v. Icos Vision Systems Corp.*, 528 F.3d 1365 (Fed. Cir. 2008); *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008); *Research Corp. Tech., Inc. v. Microsoft Corp.*, 536 F.3d 1247 (Fed. Cir. 2008); *Cohesive Tech., Inc. v. Waters Corp.*, 543 F.3d 1351 (Fed. Cir. 2008) and *Rothman v. Target Corp.*, 556 F.3d 1310 (Fed. Cir. 2009).

<sup>5</sup> *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317 (Fed. Cir. 2009).

<sup>6</sup> This tally does not include the order to rehear *Therasense en banc*, which issued April 26, 2010.

<sup>7</sup> *Avid Identification Sys., Inc. v. The Crystal Import Corp.*, 603 F.3d 967 (Fed. Cir. 2010); *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313 (Fed. Cir. 2010); *Taltech Ltd. v. Esquel Enterprises Ltd.*, 604 F.3d 1324 (Fed. Cir. 2010); *Leviton Mfg. Co. v. Universal Security Instruments, Inc.*, —F.3d—, 2010 WL 2160917 (Fed. Cir. May 28, 2010)

<sup>8</sup> *Therasense*, 2010 WL 1655391, at \*1.

<sup>9</sup> Question 5 simply appears to be an extension of question 1.

<sup>10</sup> *Aventis*, 525 F.3d at 1349 (Rader, J., dissenting).

<sup>11</sup> *Id.* at 1342.

<sup>12</sup> *Id.* at 1343.

<sup>13</sup> *Id.* at 1342.

<sup>14</sup> "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." *Id.* at 1349-1350 (Rader, J., dissenting).

<sup>15</sup> *Id.* at 1350 (Rader, J., dissenting).

<sup>16</sup> *Id.* at 1349 (Rader, J., dissenting).

<sup>17</sup> *Id.* at 1350 (Rader, J., dissenting). In *Kingsdown*, the Federal Circuit *en banc* decided that inequitable conduct required intent to deceive the PTO and that even gross negligence would be insufficient to sustain a finding of inequitable conduct. In that case, the patent attorney had copied a previously rejected claim into an amendment and the patent issued with the previously rejected claim. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.3d

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867, 871 (Fed. Cir. 1988) (*en banc*). The court there determined the actions had been the result of gross negligence and found no inequitable conduct. *Id.* at 877.

<sup>18</sup> *Aventis*, 525 F.3d at 1351 (Rader, J., dissenting).

<sup>19</sup> *Id.*

<sup>20</sup> *See infra*, n.22, citing *Star Scientific*, 537 F.3d at 1366.

<sup>21</sup> *Aventis*, 525 F.3d at 1352 (Rader, J., dissenting).

<sup>22</sup> *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008).

<sup>23</sup> *Id.* at 1361-1362.

<sup>24</sup> *Id.* at 1367-1368.

<sup>25</sup> *Id.* at 1368.

<sup>26</sup> *Id.* at 1365-1366 (“This penalty was originally applied only in cases of ‘fraud on the Patent Office.’”) (citing Supreme Court cases).

<sup>27</sup> *Id.* at 1366.

<sup>28</sup> *Id.* (emphasis added).

<sup>29</sup> *Id.* at 1366-1367, quoting *Scanner Techs. Corp. v. ICOS Visions Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008).

<sup>30</sup> *Id.* at 1365-1366.

<sup>31</sup> In a more recent case, *Ring Plus, Inc. v. Cingular Wireless Corp.*, \_\_ F.3d \_\_, 2010 WL 3064354, at \*6 (Fed. Cir. Aug. 6, 2010), a unanimous panel of Judges Moore, Gajarsa and Lourie relied on the “single most reasonable inference” standard to find a lack of deceptive intent where a material misrepresentation was held to have been not deceptively made because the source for the misrepresentation was ambiguous. The case is perhaps unremarkable in that a unanimous panel simply followed *Star Scientific*. The case is more noteworthy for the tortured path the majority took. It found the misrepresentation concerning the scope of the prior art to be material by clear and convincing evidence, but also found the prior art to be ambiguous enough that the attorney could be credited for not having believed he was making a misrepresentation. *Id.*

<sup>32</sup> *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008).

<sup>33</sup> *Id.* at 1353.

<sup>34</sup> *Id.* at 1354.

<sup>35</sup> *Id.* at 1355.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* (citing *Kingsdown*, 863 F.2d at 872).

<sup>38</sup> *See supra* nn.11 and 21.

<sup>39</sup> *Abbott*, 544 F.3d at 1380.

<sup>40</sup> *See infra*, nn.80-84 and accompanying text.

<sup>41</sup> 559 F.3d 1317 (Fed. Cir. 2009).

<sup>42</sup> *Id.* at 1325.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* at 1342.

<sup>45</sup> *Id.*

<sup>46</sup> *Id.* at 1340.

<sup>47</sup> *Id.* at 1341.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.* at 1341-1342.

<sup>50</sup> *Id.* at 1342 (Linn, J., concurring).

<sup>51</sup> *Id.* at 1342-1343 (Linn, J., concurring).

<sup>52</sup> *Id.* at 1343 (Linn, J., concurring).

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id.* (citing cases).

<sup>56</sup> *Id.* at 1344 (Linn, J., concurring).

<sup>57</sup> *Id.*

<sup>58</sup> 603 F.3d 967 (Fed. Cir. 2010).

<sup>59</sup> *Id.* at 974-975.

<sup>60</sup> *Id.* at 977.

<sup>61</sup> *Id.* at 975.

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<sup>62</sup> *Id.* at 977.

<sup>63</sup> *Id.* at 978 (Linn, J., dissenting in part).

<sup>64</sup> See *supra* n.10, *infra* nn.76, 89-90, and accompanying text.

<sup>65</sup> 2010 WL 2898998 (Fed. Cir. Jul. 16, 2010).

<sup>66</sup> *Id.* at \*3.

<sup>67</sup> *Id.* at \*2.

<sup>68</sup> *Id.* at \*1 (“As applied to *Avid*, it is grievously unjust to eradicate this patent on grounds that may soon be changed by the en banc court.”). Judge Newman voiced the same concerns in her dissent in *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, \_\_\_ F.3d \_\_\_, 2010 WL 3133539, \*12 (Fed. Cir. Aug. 9, 2010). In that case, the majority remanded a case for a determination of intent to deceive. *Id.* at \*11. Judge Newman there faulted the majority for a flimsy materiality determination and appealed again to the impending *Therasense* resolution of the proper standard for materiality in saying that the panel should not have decided the appeal prior to the *Therasense* decision. *Id.* at \*12.

<sup>69</sup> *Id.* at \*2.

<sup>70</sup> 603 F.3d 1313 (Fed. Cir. 2010).

<sup>71</sup> *Id.* at 1320 (“the question of intent frames this appeal”).

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* at 1321 (recognizing the “divergent line of precedent”).

<sup>74</sup> *Id.* at 1322.

<sup>75</sup> *Id.*

<sup>76</sup> *Id.* at 1324 (Prost, J., concurring) (“An accurate description, however, would be that Optium relies on a high level of materiality and no *other* evidence of intent. To the extent that the majority opinion characterizes the level of materiality as per se irrelevant to the intent inquiry, the majority opinion errs.”) (emphasis in original).

<sup>77</sup> *Id.* at 1323, citing *Larson Mfg. Co.*, 559 F.3d, at 1340 and *Star Scientific*, 537 F.3d, at 1366.

<sup>78</sup> 604 F.3d 1324 (Fed. Cir. 2010).

<sup>79</sup> *Id.* at 1334.

<sup>80</sup> *Id.* at 1335 (Gajarsa, J., dissenting).

<sup>81</sup> See *supra* n.38.

<sup>82</sup> *Taltech*, 604 F.3d at 1339-1340 (Gajarsa, J., dissenting).

<sup>83</sup> *Id.* at 1342 (Gajarsa, J., dissenting).

<sup>84</sup> *Id.* (ellipsis in original).

<sup>85</sup> \_\_\_ F.3d \_\_\_, 2010 WL 2160917 (Fed. Cir. May 28, 2010).

<sup>86</sup> *Id.* at \*6-7.

<sup>87</sup> *Id.* at \*9.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.* at \*11 (Prost, J., dissenting).

<sup>90</sup> *Id.* at \*12 (Prost, J., dissenting). See also *id.* at \*16 (“It seems to me that the circumstances surrounding Leviton’s withholding of the Germain application are as egregious as possible short of an explicit admission of intent to deceive the PTO.”).

<sup>91</sup> See also *McKesson Information Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926-927 (Fed. Cir. 2007) (Newman, J., dissenting).

<sup>92</sup> A more complete examination of case law spanning more years might lead to the discovery of other judges in the Prost camp, including potentially Judge Moore, who, together with Judge Prost, formed the majority in *McKesson*, a case that affirmed a finding of inequitable conduct on facts very similar to those of *Larson*.

<sup>93</sup> Although Judge Friedman holds senior status, he is eligible to sit on the *en banc* court because he was a member of the original three judge *Therasense* panel.

<sup>94</sup> *Larson*, 559 F.3d at 1343 (Linn, J., concurring).

<sup>95</sup> *Aventis*, 525 F.3d at 1349 (Rader, J., dissenting).

<sup>96</sup> *Larson*, 559 F.3d at 1343 (Linn, J., concurring).

<sup>97</sup> *Taltech*, 604 F.3d at 1342 (Gajarsa, J., dissenting).

<sup>98</sup> *Star Scientific*, 537 F.3d at 1365-1366 (joining unanimous opinion).

<sup>99</sup> *Avid*, 2010 WL 2898998, at \*2 (Newman, J., dissenting from denial of rehearing *en banc*); *Golden Hour*, 2010 WL 3133539, at \*12 (Newman, J., dissenting).

<sup>100</sup> *Aventis*, 525 F.3d 1334 (Moore joining Prost for the majority).

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<sup>101</sup> *Aventis*, 525 F.3d 1334; *Avid*, 603 F.3d at 977; *Optium*, 603 F.3d at 1323; *Leviton*, \_\_\_ F.3d at \_\_\_, 2010 WL 2160917, at \*12.

<sup>102</sup> *McKesson*, 487 F.3d at 926 (Newman, J., dissenting); *Abbott*, 544 F.3d at 1355; *Optiom*, 603 F.3d at 1322.

<sup>103</sup> *Larson*, 559 F.3d at 1343 (Linn, J., concurring).

<sup>104</sup> *Taltech*, 604 F.3d at 1342 (Gajarsa, J., dissenting).

<sup>105</sup> *Leviton*, \_\_\_ F.3d at \_\_\_, 2010 WL 2160917, at \*9 (joining Chief Judge Michel in the majority).

<sup>106</sup> *See supra* n.3.