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**The Federal Circuit's Inequitable Conduct Standard after  
*Exergen v. Wal-Mart*:  
A Step in the Right Direction, but Will It Really  
Change Anything?**

*Benjamin Johnson*



# The Federal Circuit's Inequitable Conduct Standard after *Exergen v. Wal-Mart*: A Step in the Right Direction, but Will It Really Change Anything?

By Benjamin Johnson\*

## I. INTRODUCTION

¶1 The current patent system in the United States, which provides patent holders with twenty-year monopolies on their inventions, is designed to balance the interests of inventors with those of the general public.<sup>1</sup> In exchange for a twenty-year monopoly, a patent holder is required to publicly disclose the details of his or her invention.<sup>2</sup> An important requirement of this disclosure is that it be made candidly and in good faith.<sup>3</sup> In order to help ensure candor and good faith, an affirmative defense of “inequitable conduct” is available to defendants in patent infringement cases.<sup>4</sup>

¶2 A finding of inequitable conduct, as has been firmly established in the Federal Circuit, requires a finding of both a material omission/misrepresentation and deceptive intent.<sup>5</sup> The remedy associated with this finding, unenforceability of the original patent, has been referred to by some as an “atomic bomb.”<sup>6</sup> Since the payout of a successful inequitable conduct defense is so significant, defendants in patent infringement cases habitually plead this defense in almost every case.<sup>7</sup> The use of this defense has become so pervasive that it prompted Judge Nichols in *Burlington Industries* to refer to it as an “absolute plague . . . [whose proponents] destroy the respect for one another’s integrity.”<sup>8</sup>

¶3 In August 2009, the Federal Circuit took a step toward fixing this situation in its *Exergen Corp. v. Wal-Mart Stores, Inc.* decision.<sup>9</sup> This Note will examine whether the decision in this case, which established the “who, what, when, where, and how” standard

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<sup>1</sup> Craig Allen Nard, David W. Barnes & Michael J. Madison, *THE LAW OF INTELLECTUAL PROPERTY* 10 (2d ed. 2008).

<sup>2</sup> *Id.* at 655–61.

<sup>3</sup> 37 C.F.R. § 1.56 (2009) (stating that “[t]he public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the [U.S. Patent and Trademark] Office is aware of and evaluates the teachings of all information material to patentability”).

<sup>4</sup> *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008).

<sup>5</sup> *Astrazeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583 F.3d 766, 770 (Fed. Cir. 2009) (citing *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988)).

<sup>6</sup> *Aventis*, 525 F.3d at 1349 (Rader, J., dissenting) (“The threat of inequitable conduct, with its ‘atomic bomb’ remedy of unenforceability, ensures . . . candor and truthfulness”).

<sup>7</sup> *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

<sup>8</sup> *Id.*

<sup>9</sup> 575 F.3d 1312 (Fed. Cir. 2009).

for inequitable conduct,<sup>10</sup> will have any substantive effect on the widespread use of inequitable conduct as a defense to patent infringement claims.<sup>11</sup>

¶4 Section II will examine recent developments in the Federal Circuit regarding inequitable conduct prior to *Exergen*. Section III will take a closer look at the *Exergen* decision itself to determine the standard that it lays out. Section IV will give a quick reaction to the new standard and outline what defendants in patent infringement cases should do when considering an inequitable conduct defense. Section V will apply the *Exergen* standard to a previous case to see whether the ruling would have come out differently. Section VI will look at the parallels between the standard and philosophy of the *Exergen* decision and the language used in Congress during the debates over the recently-proposed Patent Reform Acts. Finally, Section VII concludes that, at a minimum, the *Exergen* decision sent a clear signal to the patent law community that the Federal Circuit is aware of the current trend of over-pleading inequitable conduct and will be applying heightened scrutiny to its inequitable conduct analyses.

## II. RECENT DEVELOPMENTS IN THE FEDERAL CIRCUIT INEQUITABLE CONDUCT STANDARD

### A. *Recognizing the Danger of Over-Asserting Inequitable Conduct Defenses*

¶5 Efforts have been made by the Federal Circuit in the past to combat the flood of inequitable conduct pleadings. Notably, the Federal Circuit held in *Burlington Industries, Inc. v. Dayco Corp.* that a “summary judgment that a reputable attorney has been guilty of inequitable conduct, over his denials, ought to be, and can properly be, rare indeed.”<sup>12</sup> In *Burlington Industries*, the patent in question involved the manufacture of an improved V-belt cover fabric.<sup>13</sup> The controversy in the case centered on the use of the words “fiber” and “bundles.”<sup>14</sup> The inventor understood that he had formulated a process that allowed a rubber polymer solution to impregnate individual fibers, while the patent attorney who prosecuted the patent understood that the process involved impregnating fiber bundles and encapsulating the individual fibers.<sup>15</sup> The patent attorney claimed that he never knew that the application could be read as claiming an ability to impregnate individual fibers.<sup>16</sup> In fact, the attorney had used the terms “fiber” and “bundles” interchangeably throughout the patent application.<sup>17</sup> The distinction between the terms was material, because a claim of impregnating individual fibers avoided a prior art rejection which had occurred after the first application.<sup>18</sup>

¶6 After reviewing the facts in the case, the Federal Circuit held that the patent attorney’s explanation “[w]hile not compelling, [does] represent the version of the facts

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<sup>10</sup> *Id.* at 1327.

<sup>11</sup> See, e.g., Steven Seidenberg, *Pleading Precedent: Inequitable Conduct Ruling May Alter the Patent Infringement Litigation Landscape*, INSIDE COUNS., Nov. 2009, at 26; Charles A. Bieneman, *What to Do About McKesson?*, INTELL. PROP. TODAY, Sept. 2009, at 14.

<sup>12</sup> 849 F.2d 1418, 1422 (Fed. Cir. 1988) (emphasis in original).

<sup>13</sup> *Id.* at 1419.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

most favorable to the nonmoving party,” thus making it inappropriate to find inequitable conduct on a summary judgment motion.<sup>19</sup> This holding was further supported by the finding that the patent examiner, upon reading the interchangeable terms in the patent application, “ought to have been given pause by some of the claim language.”<sup>20</sup>

¶7 Though the court did not wholeheartedly endorse the explanation provided by the prosecuting attorney, it did not hesitate to express its view on the use of inequitable conduct as a defense to a charge of infringement. Maintaining that the use of inequitable conduct defenses had “become an absolute plague,” the court went on to charge that patent litigants who make unsupported charges of “inequitable conduct in the Patent Office” should view their actions as “a negative contribution to the rightful administration of justice.”<sup>21</sup>

¶8 Later in 1988, the Federal Circuit handed down a decision in *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*<sup>22</sup> The controversy in this case revolved around the resubmission of a previously rejected claim in a continuation application filed by Kingsdown.<sup>23</sup> The device in question was a “two-piece ostomy appliance for use by patients with openings in their abdominal walls for release of waste.”<sup>24</sup> In response to a 35 U.S.C. § 112 rejection by the patent examiner, Kingsdown’s original patent prosecutor amended a claim in the patent application.<sup>25</sup> When Hollister manufactured a similar two-piece ostomy appliance, the original patent prosecutor engaged an outside counsel to file a continuation application.<sup>26</sup> The outside counsel incorrectly resubmitted the previously rejected claim in the continuation application, renumbering it as another claim.<sup>27</sup>

¶9 The Federal Circuit found that the mistake made by the outside counsel, though negligent, did not exhibit the required intent to justify a finding of inequitable conduct on the part of the attorney.<sup>28</sup> The Federal Circuit also rejected the trial court’s conclusion that the outside counsel’s gross negligence justified a finding of the requisite intent for inequitable conduct.<sup>29</sup> The court adopted the view that “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive.”<sup>30</sup> Instead, they held that in order to find the requisite intent, “the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.”<sup>31</sup> The *Kingsdown* court, like the court in *Burlington*, recognized “the present proliferation of inequitable conduct”<sup>32</sup> as an “absolute plague” on the patent system.<sup>33</sup>

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<sup>19</sup> *Id.* at 1422.

<sup>20</sup> *Id.* at 1421.

<sup>21</sup> *Id.* at 1422.

<sup>22</sup> 863 F.2d 867 (Fed. Cir. 1988).

<sup>23</sup> *Id.* at 870–71.

<sup>24</sup> *Id.* at 869.

<sup>25</sup> *Id.* at 870.

<sup>26</sup> *Id.*

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

<sup>28</sup> *Id.* at 873.

<sup>29</sup> *Id.* at 876.

<sup>30</sup> *Id.*; see also *Rothman v. Target Corp.*, 556 F.3d 1310, 1323 (Fed. Cir. 2009) (holding that gross negligence is not sufficient to show deceptive intent on the part of the patent owner).

<sup>31</sup> *Kingsdown Med.*, at 876.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.* at 876 n.15.

B. *Recent Federal Circuit Cases That Have Found Inequitable Conduct on Questionable Grounds*

¶10

Despite its apparent recognition of the abuse of the inequitable conduct defense and the severity of the consequences associated with this abuse, the Federal Circuit has issued a number of opinions that would seem to encourage widespread use of this defense.<sup>34</sup> Because of this, there has been a great deal of criticism of the current inequitable conduct doctrine in the Federal Circuit, with many calling for a complete overhaul of the doctrine.<sup>35</sup> Much of this criticism is warranted given many of the court's recent decisions.<sup>36</sup> Because the remedy associated with inequitable conduct—unenforceability of the patent—is so significant, courts should be very hesitant to find inequitable conduct unless there is a very strong case for it. Therefore, there is a need for a strict standard for determining the existence of inequitable conduct. In the *Aventis* and *Hoffman-La Roche* cases,<sup>37</sup> the Federal Circuit did not hesitate to find inequitable conduct when faced with evidence of mistakes in the patent prosecution process.<sup>38</sup> With its recent decision in *Exergen*, the Federal Circuit seems to be trying to solidify the standards for a finding of inequitable conduct in order to rein in the pleading of this defense.<sup>39</sup>

### III. EXERGEN AND ITS IMPLICATIONS

#### A. *District Court Decision*

¶11

The three patents at issue in this case are owned by Exergen and relate to infrared thermometers used to measure human body temperature.<sup>40</sup> These were U.S. Patents No. 5,012,813 (“813”), No. 6,047,205 (“205”), and No. 6,292,685 (“685”).<sup>41</sup> Exergen sued

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<sup>34</sup> See Matthew M. Peters, *The Equitable Inequitable: Adding Proportionality and Predictability to Inequitable Conduct in the Patent Reform Act of 2008*, 19 DEPAUL J. ART TECH. & INTEL. PROP. L. 77 (2008) (citing, among other cases, *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1348–49 (Fed. Cir. 2008) (finding intent to deceive the Patent and Trademark Office through omission of material dosage information in a comparison between two compounds, though the raw dosage information was included in a separate table); *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1357–58 (Fed. Cir. 2003) (finding unenforceable a patent purchased by a third party when the court found that an experiment had been referred to in the past tense with some out-of-order steps in the patent application, despite the experiment working as written).

<sup>35</sup> See, e.g. Peters, *supra* note 34, at 117–18 (maintaining that the ultimate decision as to whether inequitable conduct has occurred should rest with the U.S. Patent and Trademark Office, which will determine appropriate penalties more creative than unenforceability of the patent in question); Benjamin Brown, Note, *Inequitable Conduct: A Standard in Motion*, 19 FORDHAM INTEL. PROP. MEDIA & ENT. L.J. 593, 628 (2009) (maintaining that attorney's fees should be awarded the patent holder upon a ruling of summary judgment against a party bringing an inequitable conduct charge); Nicole M. Murphy, Note, *Inequitable-Conduct Doctrine Reform: Is the Death Penalty for Patents Still Appropriate?*, 93 MINN. L. REV. 2274, 2297 (2009) (developed a categorical approach to determining culpability in inequitable conduct cases, each with a different remedy for the associated level of inequitable conduct); Melissa Feeney Wasserman, *Limiting the Inequitable Conduct Defense*, 13 VA. J.L. & TECH 7 (2008) (maintaining that the draconian penalties associated with a finding of inequitable conduct should be limited to only those cases where there is a finding of behavior that rises to the level of common law fraud).

<sup>36</sup> See Peters, *supra* note 34.

<sup>37</sup> See discussion of these cases *infra* note 92.

<sup>38</sup> See Peters, *supra* note 34; see also discussion of both cases *infra* note 92.

<sup>39</sup> *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 (Fed. Cir. 2009).

<sup>40</sup> *Id.* at 1316.

<sup>41</sup> *Id.*

SAAT (Wal-Mart's codefendant), a manufacturer of thermometers that detect radiation from the skin that covers the temporal artery, for infringement of its patents related to infrared thermometers.<sup>42</sup> SAAT answered Exergen's infringement claim by asserting affirmative defenses and counter-claims of both noninfringement and invalidity.<sup>43</sup>

¶12 SAAT initially neglected to assert an affirmative defense and counterclaim of inequitable conduct, but motioned to add this defense and counterclaim late in the litigation pursuant to Federal Rule of Civil Procedure 15(a).<sup>44</sup> The district court denied this motion, maintaining that the inequitable conduct pleading "failed to allege inequitable conduct with particularity under Federal Rule of Civil Procedure 9(b)."<sup>45</sup> Federal Rule of Civil Procedure 9(b) states that, when "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake . . . [while] [m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally."<sup>46</sup> The case proceeded to a jury trial on literal infringement, and the jury found for Exergen on every count, awarding damages of over \$2.5 million.<sup>47</sup> SAAT's motion for judgment as a matter of law (JMOL) on the grounds of noninfringement, invalidity, and absence of lost profits was denied.<sup>48</sup> SAAT appealed the denial of its motion for JMOL and the awarded damages to Exergen.<sup>49</sup> Additionally, SAAT "appeal[ed] the denial of its motion for leave to amend its answer to allege that '813 and '685 patents [were] unenforceable due to inequitable conduct."<sup>50</sup>

## B. Federal Circuit Opinion

### 1. Development of Standards for Inequitable Conduct Pleadings Prior to *Exergen*

¶13 SAAT argued that the pleading standard for allegations of inequitable conduct should conform to the First Circuit's "time, place, and content" test for the Federal Rule of Civil Procedure 9(b).<sup>51</sup> The Federal Circuit specifically rejected this argument, noting that it applies its own law when determining whether an inequitable conduct charge has been plead with sufficient specificity.<sup>52</sup> The court also indicated that there was some disagreement within the First Circuit as to the applicability of the "time, place, and content" test.<sup>53</sup> The Federal Circuit recognized that, although inequitable conduct is a broader concept than fraud or mistake (which are both governed by Federal Rule of Civil

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<sup>42</sup> *Id.* at 1317.

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

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

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

<sup>46</sup> FED. R. CIV. P. 9(b).

<sup>47</sup> *Exergen*, 575 F.3d at 1317.

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

<sup>49</sup> *Id.* at 1316.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* at 1326 (SAAT cited *McGinty v. Beranger Volkswagen, Inc.*, 633 F.2d 226, 228 (1st Cir. 1980) (holding that "[t]he clear weight of authority is that Rule 9 requires specification of the time, place, and content of an alleged false representation, but not the circumstances or evidence from which fraudulent intent could be inferred").

<sup>52</sup> *Id.* (citing *Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356 (Fed. Cir. 2007)).

<sup>53</sup> *Id.* (citing *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004)).

Procedure 9(b)), it is still governed by Rule 9(b) and therefore must be plead with particularity.<sup>54</sup> In the end, the Federal Circuit in *Exergen* decided to apply the Seventh Circuit standard for a fraud allegation under Federal Rule of Civil Procedure 9(b) to the inequitable conduct pleading requirements.<sup>55</sup>

¶14 In *DiLeo v. Ernst & Young*, the Seventh Circuit held that, in order to plead the circumstances of a fraud claim under Federal Rule of Civil Procedure 9(b) with sufficient specificity, the pleading must include the “who, what, when, where, and how” of the circumstances surrounding the alleged fraud.<sup>56</sup> The Federal Circuit adopted this standard in *Exergen* to determine whether the material omission/misrepresentation prong of an inequitable conduct claim has been pled with sufficient specificity.<sup>57</sup>

¶15 The *Exergen* court also set forth standards for pleading and succeeding on the intent element of inequitable conduct. Again, the court based its standard in part on the Seventh Circuit *DiLeo* case, holding that, under Federal Rule of Civil Procedure 9(b), a complaint “must still afford a basis for believing that plaintiffs could prove scienter.”<sup>58</sup> The *Exergen* court provided a cogent example of the strict standard that should be applied to the intent aspect of inequitable conduct pleadings when it described the holding in *King Auto., Inc. v. Speedy King Muffler King, Inc.*<sup>59</sup>

¶16 In the *King Automotive* case, a trademark registrant filed a petition with the U.S. Patent and Trademark Office claiming that, “to the best of its knowledge,” no one had the right to use the trademark “SPEEDY MUFFLER KING.” The case centered on an effort by that registrant’s competitor to cancel the mark. The competitor alleged that the registrant’s statement about the use of the trademark was “known . . . to be untrue.”<sup>60</sup> The *King Automotive* court held that the competitor’s bald assertion that the registrant knew the trademark was confusing did not set forth the requisite underlying facts to support a finding of belief on the part of the registrant that the trademark was confusing.<sup>61</sup>

¶17 After considering the standard set forth in Federal Circuit precedents as well as the *DiLeo* Seventh Circuit decision, the *Exergen* court held that

a pleading of inequitable conduct under [Federal Rule of Civil Procedure] 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a *specific individual* (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a *specific* intent to deceive the [U.S. Patent and Trademark Office].<sup>62</sup>

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<sup>54</sup> *Id.* (citing *Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003)).

<sup>55</sup> *Id.* at 1327 (citing *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990)).

<sup>56</sup> *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990); *see supra* Section § III(B)(2)(b) for a detailed explanation of the test.

<sup>57</sup> *Exergen*, 575 F.3d at 1327.

<sup>58</sup> *Id.* at 1327 n.4 (quoting *Dileo*, 901 F.2d at 629).

<sup>59</sup> *Id.* at 1327 (citing *King Auto., Inc. v. Speedy Muffler King, Inc.*, 667 F.2d 1008, 1011 (C.C.P.A. 1981)).

<sup>60</sup> *King Auto., Inc. v. Speedy Muffler King, Inc.*, 667 F.2d 1008, 1009 n.3 (C.C.P.A. 1981).

<sup>61</sup> *Id.* at 1011.

<sup>62</sup> *Exergen*, 575 F.3d at 1328–29 (emphasis added).

In order to prevail on the merits of an inequitable conduct charge, the *Exergen* court held that an “accused infringer must prove both materiality and intent by clear and convincing evidence.”<sup>63</sup> Furthermore, the *Exergen* court, referring to the *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.* Federal Circuit decision, held that the “reasonable inference” mentioned above must be “the *single most reasonable* inference able to be drawn from the evidence to meet the clear and convincing standard.”<sup>64</sup>

## 2. Application of the New Standards to the *Exergen* Facts

### a) *Anticipation, Infringement, and Inducement to Infringe*

¶18 The Federal Circuit, while taking a hard stance on its standard for inequitable conduct, actually reversed the jury’s findings of inducement to infringe<sup>65</sup> and actual infringement on the part of SAAT.<sup>66</sup> The court noted that in order to find inducement to infringe, it would first have to find actual infringement.<sup>67</sup> In addition to reversing the jury’s determinations on infringement, the Federal Circuit also reversed the jury’s finding that claims 1–5 of the ‘205 patent were not anticipated by U.S. Patent No. 4,602,642.<sup>68</sup> The court found that claim 1 was anticipated and that claims 2–5 were also anticipated, even though Exergen failed to present any separate argument as to the validity of these claims.<sup>69</sup>

### b) *Application of the “who, what, when, where, and how” Materiality Standard*

¶19 The most significant aspect of the Federal Circuit’s holding in *Exergen* is the new standard that it imposed for findings of both the requisite materiality and intent elements of an inequitable conduct charge. The court found SAAT’s pleadings regarding inequitable conduct were insufficient in that they failed to provide the “who, what, when, where, and how” of the alleged inequitable conduct.<sup>70</sup>

¶20 With regard to the “who” of the new inequitable standard, the court found that SAAT failed to “name the specific individual associated with the filing or prosecution of the application issuing as the ‘685 patent, who both knew of the material information and deliberately withheld or misrepresented it.”<sup>71</sup> The inadequate pleading to which this statement referred to were ¶¶ 40 and 43 of SAAT’s pleading:

40. The ‘685 patent is unenforceable due to inequitable conduct by Exergen, its agents and/or attorneys during the prosecution of the application for the ‘685 patent before the PTO.

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<sup>63</sup> *Id.* at 1328 n.5 (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008)).

<sup>64</sup> *Id.* (quoting *Star Scientific*, 537 F.3d at 1366) (emphasis in original).

<sup>65</sup> *Id.* at 1324–25.

<sup>66</sup> *Id.* at 1320.

<sup>67</sup> *Id.* at 1321.

<sup>68</sup> *Id.* at 1318.

<sup>69</sup> *Id.* at 1319–20.

<sup>70</sup> *Id.* at 1329–31.

<sup>71</sup> *Id.* at 1329.

....

43. Because *Exergen* was aware of the ‘808 patent and the ‘998 patent prior to the issuance of the ‘685 patent, *Exergen* had an opportunity to disclose each of these patents to the PTO during the prosecution of the ‘685 patent. Moreover, because the ‘808 patent and the ‘998 patent were material to the patentability of the ‘685 patent, *Exergen* had an obligation to disclose each of these patents to the PTO. Nevertheless, *Exergen* failed to cite either of these patents to the PTO during the prosecution of the ‘685 patent. SAAT is informed and believes, and therefore alleges, that *Exergen, its agents and/or attorneys* intentionally withheld the ‘808 patent and the ‘998 patent from the PTO with the intent to deceive the PTO to issue the ‘685 patent.<sup>72</sup>

As the court pointed out, these two allegations merely pointed to Exergen as a party and “its agents and/or attorneys” without naming any individuals. The court also noted that in order “to protect those whose reputation[s] would be harmed as a result of being subject to fraud charges,” the filings would be made under seal or other safeguards would be imposed to protect the identity of the individual.<sup>73</sup>

¶21

With regard to the “what” and “where” of the new inequitable conduct standard, the court found that the pleading “fail[ed] to identify which claims, and which limitation in those claims, the withheld references are relevant to, and where in those references the material information is found.”<sup>74</sup> The inadequate pleading to which the court referred to was found in ¶¶ 41–42 of SAAT’s pleading:

41. Prior to the filing of the ‘685 patent application, Exergen filed a patent application that ultimately issued as U.S. Patent No. 4,566,808 (hereinafter referred to as “the ‘808 patent”) on January 28, 1986. Thus, Exergen was aware of the ‘808 patent well before the ‘685 patent issued on September 18, 2001. The ‘808 patent was material to the patentability of the ‘685 patent because it discloses a technique of scanning a radiation detector across a target to measure the maximum emitted radiation, and it is not cumulative to the information already of record in the prosecution history of the ‘685 patent.

42. In addition, U.S. Patent No. 4,317,998 (hereinafter referred to as “the ‘998 patent”) was cited in a Supplemental Information Disclosure Statement filed by Exergen on October 17, 1997 in connection with the prosecution of the ‘205 patent. Thus, Exergen was aware of the ‘998 patent well before the ‘685 patent issued on September 18, 2001. The ‘998 patent was material to the patentability of the ‘685 patent because it discloses a technique of swiping a radiation detector across a target, and it is not cumulative to the information already of record in the prosecution history of the ‘685 patent.<sup>75</sup>

Because ¶¶ 41–42 referred only to the patents in general, and not to the specific claims contained within them, they failed to meet the specificity requirements of the Federal

<sup>72</sup> *Id.* at 1325–26 (emphasis added).

<sup>73</sup> *Id.* at 1329 n.6 (citing *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009)).

<sup>74</sup> *Id.* at 1329.

<sup>75</sup> *Id.* at 1325.

Circuit's new standard. This standard is, as the court notes, supported in Title 37 of the Code of Federal Regulations, which states that "[t]he duty disclose information exists with respect to each pending *claim* until the *claim* is cancelled or withdrawn from consideration."<sup>76</sup>

¶22 With regard to the "how" of the new inequitable conduct pleading standard, the court found that SAAT failed in ¶¶ 41–42 and the rest of its pleading to "explain both 'why' the withheld information is material and not cumulative, and 'how' an examiner would have used this information in assessing the patentability of the claims."<sup>77</sup> This failure was due to a lack of specificity as to which claims SAAT was alleging were "material" and "not cumulative" as stated in ¶¶ 41–42.<sup>78</sup>

*c) Application of the Standard for Intent in Inequitable Conduct Proceedings.*

¶23 Despite the fact that the Federal Circuit found SAAT's pleadings of inequitable conduct to be factually deficient, which alone would be fatal under Rule 9(b) of the Federal Rules of Civil Procedure, the court went on to examine whether the facts alleged established the intent requirement for inequitable conduct.<sup>79</sup> Applying the standards taken from *King Automotive, DiLeo*, and *Star Scientific*, the *Exergen* court found that SAAT's pleadings in ¶¶ 41–43, 46 were insufficient.<sup>80</sup> Paragraph 46 of SAAT's inequitable conduct pleading reads as follows:

46. Thus, while Exergen acknowledged on its website that the temporal artery has a long history of temperature measurement, Exergen misrepresented to the PTO that no such history existed and omitted any reference to the website. The misrepresentation and omission were material to the patentability of the '685 patent because the information was not cumulative to the information already of record in the prosecution history of the '685 patent, and it refutes, or is inconsistent with, a position taken by Exergen in asserting an argument of patentability. SAAT is informed and believes, and therefore alleges, that the misrepresentation and omission were made with the intent to deceive the PTO to issue the '685 patent.<sup>81</sup>

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<sup>76</sup> 37 C.F.R. § 1.56(a) (2009) (emphasis added).

<sup>77</sup> *Exergen*, 575 F.3d at 1329–30.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.* at 1330.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.* at 1326. ¶¶ 44–45 are provided here for context:

44. In addition, during the prosecution of the '685 Patent application, Exergen made a number of arguments to the PTO to overcome rejections of the pending claims based upon various prior art references related to tympanic temperature detectors. For example, in an Amendment filed on July 31, 2000, the following statements were made to the PTO:

What was nonobvious . . . was that reliable temperature measurements could be obtained from the forehead by extending techniques initially developed for the tympanic membrane. What had not been generally appreciated by those skilled in the art of temperature measurement was that the superficial temporal artery . . . provides an exceptionally reliable temperature reading.

When combined with ¶ 43, ¶ 46 bases its allegation of intent on mere “information and belief,” which is insufficient to pass the Federal Rule of Civil Procedure 9(b) standards set forth by the Federal Circuit.<sup>82</sup>

¶24

Because SAAT merely alleged that Exergen was aware of the previous patents, without providing any factual basis for an inference “that any specific individual, who owed a duty of disclosure in prosecuting the ‘685 patent, knew of the specific information in the ‘808 and ‘998 patents,” the *Exergen* court found that the pleading did not meet the two-pronged standard<sup>83</sup> for intent in an inequitable conduct charge.<sup>84</sup> The court maintains this standard in order to prevent “inequitable conduct [from devolving] into ‘a magic incantation to be asserted against every patentee’ and its ‘allegation established upon a mere showing that art or information having some degree of materiality was not disclosed.’”<sup>85</sup>

#### IV. AFTER *EXERGEN*

##### A. *Reactions to Exergen*

¶25

It is still unclear what effect the *Exergen* decision will have on the future of inequitable conduct pleadings in patent cases. One effect that can be predicted with some clarity is that alleged infringers will no longer be able to plead inequitable conduct in general terms.<sup>86</sup> The new “who, what, when, where, and how” materiality standard, combined with the affirmation of a two-pronged intent standard, should make general pleadings obsolete. Thus, defendants in infringement suits will have to be very careful to base their inequitable conduct charges on specific facts. In some cases, this would require a great deal of discovery.<sup>87</sup> Also, “the commonly held practice of pleading deceptive intent ‘on information and belief’ may not pass muster unless the pleader states the ‘information’ on which it relies and the reasons for its ‘belief.’”<sup>88</sup> The question remains, however, whether the newly required specificity will actually reduce the number of inequitable conduct pleadings.

¶26

It is possible, as has been pointed out by some scholars, that defendants will merely push back their inequitable conduct charges until later in the litigation, after a great deal of discovery has been conducted.<sup>89</sup> It is also possible that litigants will accelerate their

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45. These arguments made to the PTO were contradicted by statements from Exergen's own website, such as the following statement which appeared on the website at the time of the July 31, 2000 Amendment:

The temporal artery area has a long history of temperature measurement, dating back to the early centuries before Christ with the first recorded references to palpation of the head for fever assessment.

<sup>82</sup> *Id.* at 1330.

<sup>83</sup> *See supra* § III(B)(1).

<sup>84</sup> *Exergen*, 575 F.3d at 1330.

<sup>85</sup> *Id.* at 1331 (quoting *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987)).

<sup>86</sup> Seidenberg, *supra* note 11; Richard H. Brown, Jonathan B. Tropp & Catherine Dugan O'Connor, *Federal Circuit Closely Scrutinizes Inequitable Conduct Charges*, THE METROPOLITAN CORP. COUNS., Sept. 2009, at 26; *Exergen*, 575 F.3d at 1329.

<sup>87</sup> Brown, *supra* note 35.

<sup>88</sup> Brown, *supra* note 35.

<sup>89</sup> Seidenberg, *supra* note 11.

discovery processes in order to gather the needed information to satisfy the Federal Circuit's new standard for pleading inequitable conduct.<sup>90</sup>

¶27 What seems most likely is that, at a minimum, defendants in patent infringement cases will be considerably more conservative in their use of the inequitable conduct charges. The Federal Circuit has made it abundantly clear that it frowns upon frivolous use of inequitable conduct as a defense to infringement,<sup>91</sup> despite some decisions that seem to indicate otherwise.<sup>92</sup>

### B. How Should Accused Infringers Proceed?

¶28 The Federal Circuit sent a clear message to defendants in patent infringement cases when it raised the standard for pleading inequitable conduct: Don't plead it unless you have a factual basis for doing so. Otherwise, such defendants risk annoying or even angering the court with charges of inequitable conduct that will likely fail anyway.<sup>93</sup>

¶29 The counterpoint to this assertion is that there remains the enormous incentive for defendants in patent infringement cases to bring charges of inequitable conduct—the potential for a finding of unenforceability of the patent. In the case of inequitable conduct based upon fraudulent behavior, this remedy seems fair.<sup>94</sup> In other cases, where inequitable conduct has been found when seemingly benign mistakes were made during patent prosecution,<sup>95</sup> this remedy can be devastating and disproportionately harmful to patent holders. Thus, it would be useful to examine a questionable decision that the Federal Circuit has made in this area in order to determine whether the *Exergen* standard would have prevented any of the court's seemingly poor decisions.

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<sup>90</sup> Seidenberg, *supra* note 11.

<sup>91</sup> See, e.g., *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (maintaining that inequitable conduct should only be found in the most extreme cases of fraud and deception); *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (finding that the use of inequitable conduct as a defense to charges of patent infringement had become a plague on the system).

<sup>92</sup> See, e.g., *Aventis*, 525 F.3d. at 1348–49 (finding intent to deceive the Patent and Trademark Office through omission of material dosage information in a comparison between two compounds, though the raw dosage information was included in a separate table); *Hoffmann-La Roche, Inc. v. Promega Corp.* 323 F.3d 1354, 1357–58 (Fed. Cir. 2003) (finding unenforceable a patent purchased by a third party when the court found that an experiment had been referred to in the past tense with some out-of-order steps in the patent application, despite the experiment working as written).

<sup>93</sup> *Burlington Indus.*, 849 F.2d at 1422 (stating that only a small percentage of cases “get anywhere” with the accusation of inequitable conduct).

<sup>94</sup> See, e.g., Wasserman, *supra* note 35 (maintaining that the draconian penalties associated with a finding of inequitable conduct should be limited to only those cases where there is a finding of behavior that rises to the level of common law fraud).

<sup>95</sup> *Aventis*, 525 F.3d at 1351–52 (maintaining that the oversight made by a scientist assisting with the patent application process did not “rise to the level of intent to deceive” that would warrant an award of unenforceability of the patent).

V. *EXERGEN* ANALYSIS OF A RECENT, QUESTIONABLE INEQUITABLE CONDUCT DECISION:  
*AVENTIS PHARMA S.A. v. AMPHASTAR PHARMS. INC.*

A. *Application of the Exergen Pleading Standard*

¶30 This case was chosen for analysis due to popular recognition that it was poorly reasoned with regard to its inequitable conduct ruling.<sup>96</sup> The controversy in this case centers on U.S. Patent No. 5,389,618 (“618”), a patent for a drug called Lovenox®.<sup>97</sup> This drug is used to prevent blood clotting while minimizing the possibility of hemorrhaging.<sup>98</sup> Amphastar and Teva (the codefendants) filed an Abbreviated New Drug Applications with the FDA, hoping to obtain approval for marketing a generic version of Lovenox®.<sup>99</sup> Aventis sued Amphastar and Teva for patent infringement.<sup>100</sup> Amphastar filed a counterclaim of inequitable conduct and moved for summary judgment on this counterclaim.<sup>101</sup>

¶31 Amphastar’s counterclaim met the “who” requirement of the *Exergen* test by identifying Dr. André Uzan, a French chemist who had contributed his expertise in the patent application process.<sup>102</sup> The counterclaim averred that Dr. Uzan had misrepresented the results of a half-life analysis of the Lovenox® drug by failing to state the dosage information used in the tests.<sup>103</sup> This was especially pertinent in that the half-life comparison made between Lovenox® and the prior art was done using different dosages of each compound.<sup>104</sup>

¶32 In making this accusation, Amphastar also appeared to meet the “what” and “where” standards of the *Exergen* test, identifying the specific claim that was at issue and the reference which should have been disclosed (the actual dosage information). It should be noted, as Judge Rader points out in his dissent that the relevant dosage information was included in the patent application, just not in the half-life table. Therefore, it can be argued that Amphastar failed to plead correctly.<sup>105</sup> Regardless of this discrepancy, it would appear that for the pleading stage, Amphastar had indeed met the “what” and “where” requirements.

¶33 While it is clear that Amphastar met the “when” standard of the *Exergen* test by identifying Dr. Uzan’s specific “omission,”<sup>106</sup> it is less clear whether Amphastar met the “how” requirement of the *Exergen* test. If the dosage information had been completely withheld from the patent examiner, it is clear that this would have prevented the examiner from making a fully-informed determination as to the patentability of the half-life claim.<sup>107</sup> Because the information was included in the attachments to the patent

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<sup>96</sup> See Peters, *supra* note 34; see also discussion of both cases *supra* note 92.

<sup>97</sup> *Aventis*, 525 F.3d at 1337.

<sup>98</sup> *Id.*

<sup>99</sup> *Id.* at 1340.

<sup>100</sup> *Id.* at 1341.

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.* at 1352.

<sup>106</sup> *Id.* at 1341.

<sup>107</sup> *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1329–30 (Fed. Cir. 2009) (setting forth that the “how” requirement applies to the way in which “an examiner would have used [the omitted] information in

application, it could be argued that Amphastar failed to meet the specificity requirement of the *Exergen* standard. It is likely, however, that this discrepancy would not be fatal to meeting the *Exergen* standard for materiality in inequitable conduct pleadings. Instead, this issue would be more appropriately addressed in the analysis of culpable intent.

¶34 Thus, having concluded that Amphastar met the *Exergen* pleading requirements for materiality in an inequitable conduct charge, it is necessary to examine Amphastar's justification for culpable intent on the part of Dr. Uzan. Again, in order to meet the pleading requirements of the *Exergen* standard, the party alleging inequitable conduct must show that "a *specific individual* (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a *specific* intent to deceive the [U.S. Patent and Trademark Office]."<sup>108</sup> Amphastar clearly identified a specific individual, Dr. Uzan. It also showed that Dr. Uzan knew of the allegedly omitted dosage information in that he was the one who produced and compiled the data.<sup>109</sup>

¶35 Less clear, however, is whether Amphastar "include[d] sufficient allegations of underlying facts from which a court may reasonably infer that [Dr. Uzan] . . . (2) withheld or misrepresented this information with a *specific* intent to deceive the [U.S. Patent and Trademark Office]."<sup>110</sup> The district court found that the cumulative evidence relevant to deceptive intent outweighed Dr. Uzan's testimony that he did not intend to deceive the U.S. Patent and Trademark Office.<sup>111</sup> This evidence of deceptive intent was 1) that the dosage information was only included in raw data compilations, 2) the difference in half-life values for different dosages was not significant except in the case in which Dr. Uzan omitted the dosage information, and 3) that Dr. Uzan's justifications for using certain dosages for half-life comparisons.<sup>112</sup> As pointed out by Judge Rader in his dissent, the omission of dosage was "blatantly obvious," making it much less likely that Dr. Uzan intended to deceive the patent examiner because he could have omitted the information in a much more subtle manner.<sup>113</sup> Despite this point, it is likely that, at the pleading stage, Amphastar provided enough evidence with sufficient specificity to allow this issue to proceed in litigation.

### B. Application of *Exergen's* Merit Standards

¶36 Having shown that it is likely that Amphastar met the pleading standards set forth in *Exergen*, it is now necessary to determine whether Amphastar would have prevailed on the merits of its inequitable conduct charge. With regard to materiality, it seems reasonable to conclude that the dosage information was material to the patentability of the '618 patent. Aventis attempted to use the half-life results obtained by Dr. Uzan to show that the Lovenox® was different in structure from the prior art introduced by the patent examiner in his rejection of the initial patent application.<sup>114</sup> The dosage associated

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assessing the patentability of the claim[>").

<sup>108</sup> *Id.* at 1328–29 (emphasis added).

<sup>109</sup> *Aventis*, 525 F.3d at 1341.

<sup>110</sup> *Exergen*, 575 F.3d at 1328–29 (emphasis added).

<sup>111</sup> *Aventis*, 525 F.3d at 1347–49.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.* at 1352.

<sup>114</sup> *Id.* at 1338.

with both Lovenox® and the prior art had a direct effect on the half-life of each substance which, in turn, would call for different conclusions depending on the dosages compared between the two substances.<sup>115</sup>

¶37 What is less clear is whether the *Aventis* court came to the proper conclusion regarding its finding of culpable intent on the part of Dr. Uzan. As mentioned earlier, the *Exergen* court held that, in order for a charge of culpable intent to prevail, the reasonable inference suggested by the circumstances pled must be “the *single most reasonable* inference able to be drawn from the evidence to meet the clear and convincing standard.”<sup>116</sup> The *Aventis* court seemed to base its finding of culpable intent on the overall materiality of the dosage omission, noting that the district court did take into consideration Dr. Uzan’s testimony when determining culpable intent.<sup>117</sup>

¶38 Yet, as Judge Rader pointed out in his dissent, there was another, very plausible explanation for the omission of dosage information—inadvertent oversight.<sup>118</sup> Judge Rader pointed out that the omission of the dosages was “blatantly obvious,” which should have immediately drawn the attention of the patent examiner.<sup>119</sup> In addition, Dr. Uzan had an excellent reputation over the course of his fifty-year career, which should have created more skepticism regarding the conclusion that he intentionally misled the patent examiner.<sup>120</sup> Because he was not even involved with the invention of Lovenox®, it seems very unlikely that he would have risked his reputation and career by purposely omitting relevant and material data from his work.<sup>121</sup> It is difficult to determine whether the “innocent omission” explanation is more convincing than the conclusion reached by the *Aventis* court. The *Exergen/Star Scientific* standard seems, however, to weigh against a finding of culpable intent when the issue is in doubt.

## VI. RECENT LEGISLATIVE DEVELOPMENTS

¶39 Congressional efforts to reform the inequitable conduct standard in the modern patent system began in earnest when Senator Orrin Hatch introduced the Patent Reform Act of 2006.<sup>122</sup> The Act would have restricted the use of inequitable conduct defenses to situations where at least one claim was found invalid.<sup>123</sup> Though this bill failed to pass in the Senate, it was revived in 2007 as the Patent Reform Act of 2007 and is still alive as the Patent Reform Act of 2009.<sup>124</sup>

¶40 In his address to the Committee on the Judiciary regarding the Patent Reform Act of 2007, Senator Patrick Leahy noted some of the changes to the system that were present in the Act. One such change was that the U.S. system would conform to the first-to-file

<sup>115</sup> *Id.* at 1349.

<sup>116</sup> *Exergen*, 575 F.3d at 1329 n.5 (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008) (emphasis in original)).

<sup>117</sup> *Aventis*, 525 F.3d at 1347–48.

<sup>118</sup> *Id.* at 1351–52 (Rader, J., dissenting).

<sup>119</sup> *Id.* at 1352.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> Murphy, *supra* note 35, at 2290–91.

<sup>123</sup> *Id.* at 2290.

<sup>124</sup> *Id.* at 2291.

system already in place in the rest of the world.<sup>125</sup> Senator Leahy also noted that the Patent Reform Act of 2007 backed down from the language of the 2006 Act regarding inequitable conduct. The Senator recognized that the Patent Reform Act of 2006 would have weakened the inequitable conduct doctrine and that, due to political opposition, this was dropped from the 2007 Act.<sup>126</sup>

¶41 During the same proceedings, Senator Hatch expressed his “disappoint[ment] that the inequitable conduct provision from [the Patent Reform Act of 2006] was removed.”<sup>127</sup> He noted that it was universally recognized by attorneys that “the inequitable conduct defense has been overpleaded [sic] and has become a drag to the litigation process.”<sup>128</sup> Recognizing that there should be a remedy for inequitable conduct, Senator Hatch noted that “reforms to the inequitable conduct defense should focus on the nature of the misconduct and not permit the unenforceability of a perfectly valid patent on a meritorious invention.”<sup>129</sup> Senator Hatch also criticized the way the materiality prong of inequitable conduct analysis had “become so inclusive that virtually anything now is portrayed as material.”<sup>130</sup>

¶42 When introducing the Patent Reform Act of 2009 as a cosponsor, Senator Hatch again expressed his belief that the inequitable conduct doctrine must “sanction true misconduct and . . . do so in a proportional and fair manner,” which he believed was the original purpose of the doctrine.<sup>131</sup> He noted that the other sponsors of the bill, Senators Leahy and Conyers, had agreed to incorporate changes into the inequitable conduct doctrine through the Patent Reform Act of 2009.<sup>132</sup> These changes, according to Senator Hatch, have “the potential to single-handedly revolutionize the manner in which patent applications are prosecuted.”<sup>133</sup>

¶43 At this point, potential acceptance of these changes seems promising, even if they don’t occur in the 111th Congress. Senator Hatch seems optimistic that the changes will occur despite strong opposition from big pharmaceutical manufacturers.<sup>134</sup> At the least, significant attention has been drawn to the issue, which will hopefully facilitate change through future reform acts if the Patent Reform Act of 2009 fails to pass. As Senator Hatch said about the current system, “there is virtually no downside for the infringer to raise [inequitable conduct as a defense].”<sup>135</sup> Real reform to the patent laws needs to occur to change this environment.

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<sup>125</sup> 153 CONG. REC. S4678, 4685 (2007).

<sup>126</sup> *Id.*

<sup>127</sup> *Id.* at 4691.

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* at 4691–92.

<sup>130</sup> *Id.* at 3692.

<sup>131</sup> 155 CONG. REC. 2706, 2715 (2009).

<sup>132</sup> *Id.* at 2716.

<sup>133</sup> *Id.*

<sup>134</sup> Diane Bartz, *Sen. Hatch Says U.S. Patent Bill Will Pass*, REUTERS, Mar. 18, 2009, available at <http://www.reuters.com/article/smallBusinessNews/idUSTRE52H7W620090318>.

<sup>135</sup> 155 CONG. REC. 2706, 2715 (2009).

## VII. CONCLUSION

¶44 While the precise scope and effect of the *Exergen* inequitable conduct standard remains to be seen, it is clear that it will force defendants in patent infringement cases to be more thorough in their pleadings of inequitable conduct. This may ultimately help stem the “absolute plague” of inequitable conduct pleadings that has been the norm in patent proceedings.<sup>136</sup> On the other hand, as observed earlier in this note, it may merely accelerate the discovery process in patent cases, further increasing the expense of patent litigation.<sup>137</sup> After evaluating the *Aventis* decision, however, it would appear that at least some of the Federal Circuit’s findings of inequitable conduct would not have occurred with the *Exergen* standard in place.

¶45 In addition, if Congress is able to come through with a significant reform of the Patent Act and its inequitable conduct doctrine, the scope of the *Exergen* standard will no longer matter. Either way, reform needs to take place as soon as possible. Considering that the remedy for inequitable conduct is so extreme, courts need to be very careful and conservative in its approach toward the issue, reserving inequitable conduct findings for “only the most extreme cases of fraud and deception.”<sup>138</sup>

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<sup>136</sup> *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

<sup>137</sup> Seidenberg, *supra* note 11 (stating that the heightened pleading standard may merely push inequitable conduct pleadings into later stages of litigation, after significant discovery and fact-finding has occurred).

<sup>138</sup> *Aventis Pharma, S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008).