

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PFIZER INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C. A. No. 12-654-GMS/MPT
	:	
SANDOZ INC.,	:	
	:	
Defendant.	:	

**REPORT AND RECOMMENDATION**

**I. INTRODUCTION**

**A. Procedural Background**

On May 24, 2012, Pfizer, Inc., Wyeth LLC, and Wyeth Pharmaceuticals Inc. (collectively, “plaintiff”) filed suit against Sandoz Inc. (“defendant”) for infringement of U.S. Patent No. 8,026,276 (“the ‘276 patent”).<sup>1</sup> Defendant answered on June 21, 2012, denying infringement of the ‘276 patent and asserting various defenses, including invalidity and preserving the potential for “additional defenses or counterclaims . . . including unenforceability.”<sup>2</sup> A Rule 16 Scheduling Conference occurred on August 1, 2012.<sup>3</sup> Under that scheduling order, fact discovery was to be completed on April 26, 2013,<sup>4</sup> which was extended to June 25, 2013,<sup>5</sup> with expert discovery ending on October

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<sup>1</sup> D.I. 1.  
<sup>2</sup> D.I. 8.  
<sup>3</sup> D.I. 17.  
<sup>4</sup> *Id.*  
<sup>5</sup> D.I. 84.

18, 2013.<sup>6</sup> A final pretrial conference is scheduled for November 13, 2013 with trial to follow on December 2, 2013.<sup>7</sup> The deadline to amend pleadings to add claims of inequitable conduct was March 22, 2013.<sup>8</sup>

On February 4, 2013, defendant noticed depositions for the four inventors of the '276 patent.<sup>9</sup> Three of those depositions occurred after the March 22, 2013 deadline to amend pleadings.<sup>10</sup> Specifically, defendant's depositions of Ms. Gandhi and Dr. Rubino occurred on April 18, 2013 and May 22, 2013, respectively.<sup>11</sup> After a grant of a motion to extend expert report deadlines,<sup>12</sup> defendant did not serve opening expert reports until August 20, 2013.<sup>13</sup> Defendant first raised its theory of inequitable conduct in its opening expert reports<sup>14</sup> and subsequently, one month later, moved for leave to amend its answer, defenses and counterclaims on September 20, 2013.<sup>15</sup>

## **B. Factual Background**

Plaintiff is the assignee of the '276 patent describing parenteral formulations of rapamycin.<sup>16</sup> Defendant is a generic manufacturer that is seeking approval of a generic formulation of plaintiff's product.<sup>17</sup> During prosecution of the '276 patent, plaintiff

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<sup>6</sup> D.I. 103.

<sup>7</sup> D.I. 17.

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

<sup>9</sup> D.I. 48-51.

<sup>10</sup> D.I. 112 at 2.

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

<sup>12</sup> D.I. 93.

<sup>13</sup> D.I. 112 at 4; D.I. 103.

<sup>14</sup> See D.I. 112 at 4. Despite purportedly reserving a right to amend its answer to add enforceability, defendant remained silent regarding this defense for fourteen months after filing its original answer.

<sup>15</sup> D.I. 111.

<sup>16</sup> D.I. 1, Ex. A, Abstract.

<sup>17</sup> D.I. 122 at 3.

submitted Rule 131 and Rule 132 declarations to overcome prior art and obviousness rejections, respectively.<sup>18</sup> The Rule 131 declaration was made by the four named inventors of the '276 patent, while the Rule 132 declaration was made by inventor Dr. Rubino.<sup>19</sup>

### **C. Legal Standard**

#### **i. Rules 15(a) and 16(b)**

Under Fed. R. Civ. P. 15(a), leave to amend pleadings is “freely give[n] when justice so requires.”<sup>20</sup> Whether to grant leave to amend is up to the discretion of the court.<sup>21</sup> In weighing whether to grant leave to amend, the court should consider: (1) whether the movant has unduly delayed; (2) whether the amendment would unfairly prejudice the nonmovant; (3) whether the amendment is brought for an improper purpose; and (4) whether the amendment is futile.<sup>22</sup>

Generally, “[d]elay alone is not sufficient to justify denial of leave to amend.”<sup>23</sup> The more dispositive factor is whether the nonmovant would suffer prejudice if leave to amend is granted.<sup>24</sup> To prove prejudice, the nonmovant “must do more than merely claim prejudice; it must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the

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<sup>18</sup> D.I. 112 at 2-3.

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

<sup>20</sup> FED. R. CIV. P. 15(a)(2).

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

<sup>22</sup> *Foman v. Davis*, 371 U.S. 178, 182 (1962).

<sup>23</sup> *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006).

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

amendments been timely.”<sup>25</sup>

However, in addition to the requirements under Rule 15(a), Rule 16(b) governing scheduling orders must also be satisfied.<sup>26</sup> Under Rule 16(b), the movant must satisfy a more stringent standard by demonstrating “good cause” subject to the judge’s consent.<sup>27</sup> This jurisdiction recognizes motions to amend function to alter the scheduling order and are, thus, controlled by Rule 16(b).<sup>28</sup> In order to satisfy the good cause requirement of Rule 16(b), the movant must demonstrate that, despite diligence, the amendment could not have been reasonably sought in a timely manner.<sup>29</sup> Unlike the analysis under Rule 15(a), which depends on prejudice to the nonmovant, the good cause standard hinges on the diligence of the movant.<sup>30</sup>

**ii. Rule 9(b) and the Standard for Inequitable Conduct**

Because the patent application process is *ex parte*, patent applicants and their counsel, or those involved in the preparation and prosecution of patent applications, owe a duty of candor, honesty and good faith to the Patent & Trademark Office (“PTO”). The duty of candor, good faith and honesty includes the obligations to submit truthful information and to disclose to the PTO information known to the patent applicants or their attorneys which is material to the examination of the patent

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<sup>25</sup> *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989) (internal citations omitted); *Kiser v. Gen. Elec. Co.*, 831 F.2d 423, 427-28 (3d Cir. 1987).

<sup>26</sup> FED. R. CIV. P. 16(b).

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

<sup>28</sup> *E. Minerals & Chems. Co. v. Mahan*, 225 F.3d 330, 340 & n. 18 (3d Cir. 2000).

<sup>29</sup> *Samick Music Corp. v. Delaware Music Indus., Inc.*, C/A No. 91-23-CMW, 1992 WL 39052, at \*6-7 (D. Del. Feb. 12, 1992).

<sup>30</sup> *Slip Track Sys., Inc. v. Metal Lite, Inc.*, 304 F.3d 1256, 1270 (Fed. Cir. 2002).

application.<sup>31</sup> Information is deemed material if the PTO would not have allowed the claim otherwise—“but-for materiality.”<sup>32</sup> An exception to the requirement of but-for materiality is the filing of an unmistakably false affidavit which renders the misconduct material.<sup>33</sup> To *prove* unenforceability by inequitable conduct, “the accused infringer must prove both elements—intent and materiality—by clear and convincing evidence.”<sup>34</sup> “Intent and materiality are separate requirements.”<sup>35</sup> The accused infringer must prove not only materiality, but also *specific* intent to deceive the PTO which may not be inferred solely from materiality.<sup>36</sup>

Since inequitable conduct is a claim sounding in fraud, Rule 9(b) applies. Under that rule, the elements of inequitable conduct must be plead with particularity. To satisfy this requirement, the accused infringer “must identify the specific who, what, when, where and how of the material misrepresentation or omission committed before the PTO.”<sup>37</sup> Further, the accused infringer must also allege sufficient facts to permit a reasonable inference “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 PTO.”<sup>38</sup>

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<sup>31</sup> *Elk Corp. of Dallas v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 30 (Fed. Cir. 1999).

<sup>32</sup> *Therasense, Inc. v. Becton Dickinson and Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011) (adopting a but-for materiality standard for inequitable conduct).

<sup>33</sup> *Id.* at 1292 (citing *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983)).

<sup>34</sup> *Id.* at 1287.

<sup>35</sup> *Id.* at 1290.

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

<sup>37</sup> *Exergen Corp. v. Wal-mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009).

<sup>38</sup> *Id.* at 1328-29.

#### **D. Positions of the Parties**

Defendant argues its motion should be granted because all relevant factors weigh in favor of granting leave to amend and good cause has been demonstrated.<sup>39</sup> Defendant argues the “tortuous” and voluminous document production during discovery, coupled with key depositions after the deadline to amend, support the proposition that the deadline for amendment could not have reasonably been met.<sup>40</sup> Specifically, defendant points to what it considers key admissions during the depositions of Dr. Rubino and Ms. Gandhi as necessary to support its assertion of inequitable conduct.<sup>41</sup> Further, defendant asserts that it diligently reviewed the evidence and its experts’ opinions to confirm it had sufficient basis to allege inequitable conduct.<sup>42</sup> Defendant indicates its delay was necessary to establish, with the requisite particularity, the facts underlying its defense to satisfy the pleading standard for inequitable conduct and support a motion for leave to amend.<sup>43</sup>

Plaintiff contends defendant unduly delayed in filing its motion for leave to amend.<sup>44</sup> Plaintiff asserts all documents relied upon by defendant in formulating its inequitable conduct defense were produced in discovery prior to the deadline to amend pleadings.<sup>45</sup> Specifically, plaintiff claims the facts underlying defendant’s defense are obvious from the documents alone regardless of subsequent depositions.<sup>46</sup> Further,

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<sup>39</sup> D.I. 112 at 7.

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

<sup>41</sup> *Id.* at 8-9.

<sup>42</sup> *Id.* at 10.

<sup>43</sup> *Id.* at 12.

<sup>44</sup> D.I. 122 at 5.

<sup>45</sup> *Id.* at 6.

<sup>46</sup> *Id.* at 7.

plaintiff points out defendant delayed until September 20, nearly four months after the final deposition, to file the motion for leave to amend.<sup>47</sup> Plaintiff also argues defendant failed to adequately plead inequitable conduct as to both materiality and specific intent.<sup>48</sup> Plaintiff asserts the misrepresentations alleged by defendant are not material as they are based on conjecture and are taken out of context.<sup>49</sup> Plaintiff opines that awareness of contrary facts does not give rise to a reasonable inference of intent to deceive.<sup>50</sup> Lastly, plaintiff indicates the proposed amendment would impose undue prejudice.<sup>51</sup> Although defendant seeks no additional discovery and points out plaintiff is in possession of the documents, plaintiff emphasizes it was not made aware of the bases for defendant's inequitable conduct defense until the exchange of expert reports, and further investigation and preparation will be required to address these allegations in the short window of time remaining prior to trial.<sup>52</sup>

## II. ANALYSIS

The court has inherent discretion whether to grant leave to amend after the deadline for amendment of pleadings.<sup>53</sup> In considering whether to grant the motion under Rule 15(a), the court considers the four elements previously discussed, that is, undue delay by the movant, unfair prejudice to the nonmovant, improper purpose and futility.<sup>54</sup> The movant, however, must also satisfy the good cause requirement of Rule

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<sup>47</sup> *Id.* at 8.

<sup>48</sup> *Id.* at 10.

<sup>49</sup> *Id.* at 14-15.

<sup>50</sup> *Id.* at 11.

<sup>51</sup> *Id.* at 16.

<sup>52</sup> *Id.* at 16-17.

<sup>53</sup> *Foman*, 371 U.S at 182.

<sup>54</sup> *Arthur*, 434 F.3d at 204.

16(b) by demonstrating that the amendment could not have been reasonably sought in a timely manner despite diligence.<sup>55</sup>

**A. Undue Delay and Rule 16(b)**

With respect to the nearly six month delay from the deadline to amend until the date of its motion, defendant maintains it did not unduly delay.<sup>56</sup> Defendant asserts it diligently pursued its claims, but the prosecution history of the '276 patent was extensive, compounded by significant document production by plaintiff, and some of the necessary documents were not produced until after the deadline to amend.<sup>57</sup> Defendant argues the depositions of Dr. Rubino and Ms. Gandhi and the opinions of its experts were necessary to establish the required particularity to support allegations of specific intent and materiality.<sup>58</sup> Defendant relies on *Roquette Frères v. SPI Pharma, Inc.*, *Leader Techs., Inc. v. Facebook, Inc.* and *Enzo Life Sci., Inc. v. Digene Corp.* for the proposition that, when pleading inequitable conduct, the defendant may be required to confirm facts through discovery including inventor depositions despite having documents in its possession.<sup>59</sup>

Plaintiff counters defendant possessed all necessary documents prior to the deadline to amend pleadings.<sup>60</sup> Plaintiff alleges the basis for defendant's claims was

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<sup>55</sup> *Samick Music Corp.*, 1992 WL 39052, at \*6-7.

<sup>56</sup> D.I. 112 at 7

<sup>57</sup> *Id.* at 7-8.

<sup>58</sup> *Id.* at 8-10.

<sup>59</sup> *Id.* at 11-12; C.A. No. 06-540-GMS, 2009 WL 1444835 (D. Del. May 29, 2009); C.A. No. 08-862-LPS, 2010 WL 2545959 (D. Del. Jun. 24, 2010); 270 F.Supp.2d 484, 487-90 (D. Del. 2010).

<sup>60</sup> D.I. 122 at 6-7.

facially obvious, and defendant failed to demonstrate the necessity for depositions.<sup>61</sup> Specifically, plaintiff points to the four month delay from the time of the final deposition until the filing of the motion as evidence that the delay was undue.<sup>62</sup> Differentiating the present action, plaintiff claims the cases relied upon by defendant are inapposite.<sup>63</sup> In specific terms, plaintiff points out *Roquette Frères* and *Leader Techs.* involved delays of roughly a month from the time of the depositions until the filing for the motion to amend.<sup>64</sup> Plaintiff also asserts it was unaware of defendant's claims until receipt of its opening expert reports in August, as well as its intent to move until nearly a month later.<sup>65</sup>

Generally, "[d]elay alone is not sufficient to justify denial of leave to amend."<sup>66</sup> Where delay is undue, however, it weighs in favor of a denial of leave to amend.<sup>67</sup> The focus of such an inquiry is appropriately placed on the diligence of the movant and, at some point, the delay becomes undue.<sup>68</sup> This court has previously found a delay of six months from the deadline to amend and after the close of fact discovery may be improper.<sup>69</sup> In the present case, defendant asserts diligence by citing its efforts, including depositions, consultation with experts and review of the prosecution history of

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<sup>61</sup> *Id.* at 7-8.

<sup>62</sup> *Id.* at 8.

<sup>63</sup> *Id.* at 8-9.

<sup>64</sup> *Id.* at 9.

<sup>65</sup> *Id.* at 9.

<sup>66</sup> *Arthur*, 434 F.3d at 204.

<sup>67</sup> *See Foman*, 371 U.S. at 182.

<sup>68</sup> *ICU Med., Inc. v. RyMed Techs., Inc.*, 674 F.Supp.2d 574, 577-78 (D. Del. 2009); *Adams v. Gould Inc.*, 739 F.2d 858, 868 (3d Cir. 1984).

<sup>69</sup> *Asahi Glass Co., Ltd. v. Guardian Indus. Corp.*, 276 F.R.D. 417, 420 (D. Del. 2011).

the '276 patent before filing its motion. The timing of defendant's motion, however, strongly suggests the delay is improper. Defendant had the requisite documents in its possession, at the latest, within a few weeks of the deadline to amend pleadings. In addition, defendant delayed four months from the final deposition to file the present motion. Defendant's reliance on *Roquette Frères*, *Leader Techs., Inc.*, and *Enzo Life Sci., Inc.* is misplaced. Those cases involved motions to amend filed shortly after the depositions, where notice was given of the defendant's intent to move thereafter.<sup>70</sup> Defendant's only explanation for the delay is the volume of the record and concurrent litigation. Thus, under Rule 15, defendant's delay is undue and weighs against granting leave to amend.

Good cause under Rule 16(b) may be established upon showing that the movant acted with diligence and could not reasonably have met the deadline for amending.<sup>71</sup> Defendant maintains its diligence is evident by sifting through the record to establish its inequitable conduct allegations with particularity. However, other than bare assertions that the record was "tortuous," defendant has failed to satisfactorily explain its substantial delay of nearly four months from the final deposition until the filing of the

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<sup>70</sup> *Roquette Frères*, C.A. No. 06-540-GMS, 2009 WL 1444835, at \*5 (motion to amend filed approximately one month after the relevant depositions and nonmovant was aware of the motion before the close of discovery); *Leader Techs., Inc.*, C.A. No. 08-862-LPS, 2010 WL 2545959, at \*5 (motion to amend filed approximately one month after the relevant depositions with notice to nonmovant); *Enzo Life Sci., Inc.*, 270 F. Supp. 2d at 489 (motion to amend filed nearly two months after the relevant depositions with notice to the nonmovant prior to filing).

<sup>71</sup> *Samick Music Corp. v. Delaware Music Indus., Inc.*, C/A No. 91-23-CMW, 1992 WL 39052, at \*6-7 (D. Del. Feb. 12, 1992).

present motion when it knew of both the pretrial and trial dates.<sup>72</sup> Further, defendant never notified plaintiff until after the close of fact discovery and only a month before the instant motion. For these reasons, defendant has failed to demonstrate good cause for leave to amend.

### **B. Unfair Prejudice**

Defendant claims plaintiff will suffer no unfair prejudice if leave to amend is granted.<sup>73</sup> Specifically, defendant highlights that the relevant documents lie within plaintiff's control and the deposed inventors are employees or former employees of plaintiff.<sup>74</sup> Defendant cites several cases in this district where the court held that no prejudice exists when the evidence lies within the control of the plaintiff.<sup>75</sup>

Plaintiff counters defendant should not be permitted to justify its delay on the basis of the extensive prosecution history of the '276 patent and significant discovery, but at the same time require plaintiff address inequitable conduct allegations raised only a couple months before trial.<sup>76</sup> Plaintiff further notes that three of the four inventors are no longer in its employ, and it was completely unaware of the basis for any inequitable conduct allegations at the time of their depositions.<sup>77</sup>

Although plaintiff was not made aware of the bases for inequitable conduct until August 20, the allegations are based on documents in its control. The prejudice to

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<sup>72</sup> Defendant apparently was considering filing a motion to amend as evidenced by its "reservation" in its original answer.

<sup>73</sup> D.I. 112 at 13-15.

<sup>74</sup> *Id.* at 14.

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

<sup>76</sup> D.I. 122 at 16.

<sup>77</sup> *Id.*

plaintiff is the significantly compressed time frame for developing a response to the allegations prior to trial, while defendant used approximately fourteen months to develop its inequitable conduct defense.

**C. Improper Purpose**

Defendant alleges it has not brought its motion for an improper purpose.<sup>78</sup> In fact, it posits public interest is served by granting its motion.<sup>79</sup> Specifically, defendant points out an invalid patent may be used to stifle competition, and resolving questions of patent validity benefits the public.<sup>80</sup> According to defendant, if the motion is denied, the patent-at-issue will be listed in the FDA's Orange Book and will deter further invention and innovation.<sup>81</sup>

Plaintiff does not directly challenge defendant's purpose for bringing this motion.<sup>82</sup>

**D. Futility and Rule 9(b)**

Defendant contends its amendment would not be futile,<sup>83</sup> claiming it has met the standard for pleading inequitable conduct.<sup>84</sup> Specifically, defendant alleges its amendment satisfies both the but-for materiality and specific intent requirements of *Therasense*.<sup>85</sup> Arguing that plaintiff's Rule 131 and Rule 132 declarations are unmistakably false and the falsehood is both material and evidence of specific intent,

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<sup>78</sup> D.I. 112 at 16.

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

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

<sup>81</sup> *Id.* at 16-17.

<sup>82</sup> See generally D.I. 122.

<sup>83</sup> D.I. 112 at 17.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.* at 18-20.

defendant asserts that it has met the pleading standard.<sup>86</sup> Defendant points out it has pled “the who, what, where, and when of the bases for its inequitable conduct claims and unenforceability counterclaims,” and thereby establishes the requisite particularity under Rule 9(b).<sup>87</sup> With respect to the *Therasense* and *Exergen* standards, defendant propounds specific intent may be inferred from the filing of false declarations, when the inventors knew the declarations were false, and neither accident nor mistake can excuse such falsities.<sup>88</sup> Defendant maintains it need not meet but-for materiality as the affidavits are unmistakably false.<sup>89</sup>

Plaintiff counters that knowledge of falsity is insufficient to establish a reasonable inference of specific intent,<sup>90</sup> arguing defendant’s allegations are conclusory and fail to meet the pleading standard for inequitable conduct.<sup>91</sup> Regarding the two purportedly false declarations, plaintiff contests whether any misrepresentations were, in fact, material.<sup>92</sup> Pointing specifically to the Rule 131 declaration, plaintiff highlights the examiner accepted the Record of Invention which disclosed separate formulations containing tocopherol and citric acid and a combination of the two.<sup>93</sup> In addition, plaintiff suggests the alleged inconsistency in the Rule 132 declaration is the result of misapprehension by defendant.<sup>94</sup> Plaintiff explains the impurities referenced in the

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<sup>86</sup> *Id.*

<sup>87</sup> *Id.* at 20.

<sup>88</sup> D.I. 128 at 7-8.

<sup>89</sup> *Id.* at 9.

<sup>90</sup> D.I. 122 at 10-11.

<sup>91</sup> *Id.* at 12.

<sup>92</sup> *Id.* at 13.

<sup>93</sup> *Id.* Ex. 6 at 2-3.

<sup>94</sup> *Id.* at 14-15.

declaration were nonoxidative in nature, while the impurities referenced by defendant are oxidative impurities.<sup>95</sup> Plaintiff also propounds that since the starting impurity level was constant and the declaration was intended to demonstrate the effect of tocopherol levels on formation of impurities, the exact quantity of starting impurities is not material.<sup>96</sup>

As discussed previously, inequitable conduct is based in fraud, making Rule 9(b) applicable which requires the elements of such a claim be plead with particularity. In addition, sufficient facts must be alleged to allow a reasonable inference of knowledge of the withheld material information or of the falsity of the material misrepresentation, and the withholding or misrepresentation of the information was done with the specific intent to deceive,<sup>97</sup> under a but-for standard.<sup>98</sup> An exception to the but-for materiality standard is the filing of a clearly false affidavit.<sup>99</sup> Intent and materiality are distinct elements that must be separately proven and not inferred.<sup>100</sup>

Turning to defendant's allegations regarding the Rule 131 declaration, it claims Dr. Rubino's deposition testimony demonstrates he "had not conceived or reduced to practice a formulation that included the co-solvent system with ethanol, propylene

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<sup>95</sup> *Id.* at 15.

<sup>96</sup> *Id.* Specifically, plaintiff asserts the purpose of the information was to demonstrate an unexpected result with high levels of tocopherol, rendering the starting impurity levels immaterial with respect to the issuance of the patent.

<sup>97</sup> *Exergen Corp. v. Wal-mart Stores, Inc.*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009).

<sup>98</sup> *Therasense, Inc. v. Becton Dickinson and Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011) (adopting a but-for materiality standard for inequitable conduct).

<sup>99</sup> *Id.* at 1292 (citing *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983)).

<sup>100</sup> *Id.* at 1290.

glycol, Tocopherol and citric acid” before the prior art date, and his failure to execute experiments utilizing both tocopherol and citric acid until after the filing of the provisional application are irrefutable proof of the falsity of the declaration, evidencing plaintiff had the specific intent to deceive the PTO.<sup>101</sup> Defendant’s proposed amendment fails to create a reasonable inference of specific intent to deceive the PTO. Even assuming the statement may have been material, other than alleging that the inventor filed two false affidavits, defendant does no more than argue that information and belief is sufficient to reasonably infer intent. Thus, there is an insufficient factual basis to draw an inference of specific intent to deceive.<sup>102</sup> Similarly, defendant’s allegations regarding the Rule 132 declaration do not provide a sufficient factual basis for an inference of specific intent despite inconsistencies in the statements. The facts, as alleged, do not permit an inference of a pattern to deceive. Thus, defendant has failed to demonstrate that its proposed amendment would not be futile.

### **III. CONCLUSION**

Defendant’s failure to demonstrate good cause coupled with its undue delay resulting in prejudice to plaintiff weigh against granting the motion for leave to amend. Defendant’s motion is also futile, given its inability to establish a reasonable inference of specific intent to deceive the PTO. Even if the proposed amendment is not futile, the failure to demonstrate good cause and inadequately explained delay for filing the motion resulting in prejudice warrant denying the motion.

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<sup>101</sup> D.I. 129 Ex. L; D.I. 111 Ex. B at 56, 58.

<sup>102</sup> See *Bayer Cropscience AG v. Dow Agrosciences LLC*, C.A. No. 10-1045, 2012 WL 1253047, at \*4-5 (D. Del. Apr. 12, 2012) (holding that mere knowledge may not be sufficient to support a reasonable inference of specific intent).

**IV. ORDER & RECOMMENDED DISPOSITION**

For the reasons contained herein, the court recommends:

- (1) Defendant's motion for leave to amend (D.I. 111) be DENIED.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), FED. R. CIV. P. 72(a) and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen days after being served with a copy of this Report and Recommendation. The objections and response to the objections are limited to ten pages each.

The parties are directed to the Court's Standing Order in Non-Pro Se matters for Objections Filed under FED. R. CIV. P. 72, dated October 9, 2013, a copy of which is available on the Court's website, [www.ded.uscourts.gov](http://www.ded.uscourts.gov).

November 4, 2013

/s/ Mary Pat Thyng  
UNITED STATES MAGISTRATE JUDGE