

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

ROQUETTE FRÈRES,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C. A. No. 06-540-GMS
	:	
SPI PHARMA, INC., et. al.	:	
	:	
Defendants.	:	

**MEMORANDUM ORDER**

**Procedural Background**

Plaintiff, Roquette Frères (“Roquette”), a French company, filed this patent infringement action against SPI Pharma, Inc. (“SPI”), a Delaware corporation, on August 31, 2006, alleging that SPI’s MANNOGEM™ EZ spray-dried mannitol product infringes United States Patent No. 5,573,777 (the “777 patent”). On October 20, 2006, Roquette filed a first amended complaint adding Drytec Ltd., a British corporation, as an infringing defendant.<sup>1</sup> SPI filed its answer on November 6, 2006. Drytec Ltd. moved to dismiss for lack of personal jurisdiction on December 6, 2006. The first scheduling order was entered on March 13, 2007. That order provided that the deadline for amendments to pleadings was May 18, 2007. On May 20, 2007, Roquette moved for leave to file a second amended complaint to add three entities as co-defendants, specifically Drytec Contract Processing Ltd. (“Drytec CP”), Anhydro U. K. and Anhydro Holding A/S (“Anhydro Holding”). As a result of conferences with the court, Roquette’s

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<sup>1</sup> According to defendants, Drytec Ltd. changed its name to Anhydro U.K., Ltd. (“Anhydro U.K.”) on January 1, 2007.

motion was granted on June 25, 2007 and Drytec Ltd.'s motion was withdrawn with leave to file another motion to dismiss on behalf of all Drytec related entities. That motion to dismiss was filed on July 10, 2007.<sup>2</sup>

In response to Roquette's second amended complaint, SPI filed its answer which included defenses and counterclaims on July 13, 2007. Roquette responded to SPI's counterclaim on July 31, 2007.

On September 14, 2007 at the request of the parties, the scheduling order was amended primarily to extend the time for discovery.

On December 28, 2007, SPI filed the present motion under consideration, that is, to amend its answer to include a fifth affirmative defense and third counterclaim based on inequitable conduct claiming that Roquette and/or its agents or representatives knowingly and intentionally misled the PTO regarding the content of prior art described in the '777 patent specification, and withheld material information. Paragraph 22 of the proposed first amended answer is the fifth affirmative defense: paragraphs 30 through 51 also address the alleged inequitable conduct. Roquette opposes the motion and filed, not only, an answering brief in opposition, but also, a motion for leave to file a sur-reply brief, along with the sur-reply brief. Not surprisingly, Roquette's motion to file a sur-reply brief is opposed.

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<sup>2</sup> On November 2, 2007 and again on April 15, 2008, Roquette moved to file sur-reply briefs in opposition to the Drytec entities' motion to dismiss based on recent discovery. Those motions were opposed by all defendants. In response to Roquette's first motion to file a sur-reply brief, SPI filed its motion to dismiss for lack of personal jurisdiction which incorporated the briefing and responses of the Drytec related entities. The parties consented to the jurisdiction of Magistrate Judge Thyng to decide the motion to dismiss which is the subject of another opinion.

On January 22, 2008, the schedule order was amended again as to the deadlines for the disclosure of expert testimony.

This Report and Recommendation addresses SPI's motion to amend (D.I. 147) and Roquette's motion for leave to file a sur-reply brief (D.I. 156).

### **Parties' Positions**

SPI contends that its motion to amend is properly and timely filed pursuant to Fed. R. Civ. P. 15(a) since it is seeking to amend in good faith, without undue delay or dilatory motive. It further maintains that the proposed amendment will not prejudice Roquette since the inequitable conduct allegations are based, in part, on testimony elicited from the '777 patent inventors, whose depositions did not occur until mid-November 2007, approximately six months after the deadline for amendments to the pleadings. SPI argues that its amendment is not futile, particularly in light of the '777 inventors' deposition testimony because:<sup>3</sup>

- The data in Table 1 of the '777 patent is misleading because of the failure to use appropriate comparators of which the patent applicants were aware. As a result, the data in Table 1 is flawed and misleading because the invention is not compared with the spray-dried mannitol products prepared in accordance with the prior art, specifically JP 61-85331, JP 55-36646 and the Lieberman '146 patent.<sup>4</sup>
- Alternatively, if the applicants did not conduct tests on the spray-dried

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<sup>3</sup> Whether discussed or not, all arguments raised by the parties were reviewed and considered. The overview of the arguments is not intended to be an exhaustive analysis of their positions on the motions.

<sup>4</sup> It is not disputed that those publications are prior art.

mannitols of the aforementioned prior art, then SPI maintains that their statements to the PTO to the contrary are intentional and highly material misrepresentations.

- The materiality of the data contained in Table 1 is highly relevant since it was the basis to argue novelty and nonobviousness of the alleged invention.
- The evidence shows that Roquette intentionally withheld compressibility data which demonstrated that the invention did not impart any advantage for tableting applications. SPI contends that Roquette had data which refuted its representation in the '777 patent that the compressibility of mannitol under the invention was an advantage, and further withheld unfavorable compressibility data from Table 2 of the patent.
- Roquette's interpretation of the particle size data in JP 61-85331 and JP 61-85330 is contrary to the convention utilized in the '777 patent and inconsistent with the inventors' testimony on sieving. Under this argument, apparently the parties disagree regarding the interpretation that each attaches to the tables of data contained in those patents.<sup>5</sup> In support of its position, SPI primarily references the data contained in the tables which it claims is the only information related to particle size.

SPI notes that delay is an insufficient basis to deny an amendment. Moreover, contrary to Roquette's argument, SPI represents that it did not have all of the

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<sup>5</sup> The parties appear to have dueling translations of those Japanese patents.

information on which it presently relies to support its charge of inequitable conduct. It asserts by citation to deposition testimony of the inventors, that their testimony confirms that neither was the source for the data in Table 1 of the '777 patent; and, that they failed to verify any of that data, as well as, certain affirmative statements made to the PTO which distinguished the prior art from the patent-in-issue. As a result of the inventors' deposition testimony, SPI argues that Roquette failed to verify anything and misrepresented that it had, and made affirmative misrepresentations about the content of the prior art. Until the inventors' depositions, the misrepresentations and omissions in the '777 patent, which included incomplete and unsupported data, were unknown. SPI posits that the inventors' depositions support its proposed contentions.

SPI emphasizes that Roquette knew of the present motion more than four months before discovery closed. Further, since this matter is not scheduled for trial, there has been and is ample time for Roquette to prepare its rebuttal. It contends that Roquette's reliance on *Inline Connections Corp v. Earthlink, Inc.* is misplaced.<sup>6</sup> Roquette's allegation of bad faith, according to SPI, is essentially non-existent and unsupported. Under Third Circuit law, as noted by SPI, bad faith requires more than a party's mere disagreement with the merits of a motion.<sup>7</sup>

It asserts that Roquette has not established futility since SPI has proffered "several examples in the '777 patent of highly material misrepresentations and omissions concerning test date and the prior art." It argues that Roquette's futility

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<sup>6</sup> 237 F.R.D. 361, 368 (D. Del. 2006).

<sup>7</sup> See *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-93 ( 3d Cir. 1994) (holding that a finding of bad faith requires more than mere lack of diligence, but willful and deliberate conduct).

argument under the law is misplaced.

Similarly, the above arguments show that Roquette would not be prejudiced by the amendment.

In opposing SPI's motion, Roquette recites a litany of factual disputes with SPI's representations. It maintains that because a copy of the JP61-85331 patent was provided to the examiner and the '777 patent specification accurately described the relevant portions of that document, SPI cannot prove inequitable conduct. It claims that SPI's recitation of the data contained in the JP61-85331 referenced in the '777 patent is incorrect. It also contends that the '777 patent disclosures of the JP 55-36646 and the Lieberman '146 patent are proper and that because SPI twists the information contained in the '777 patent, it thereby misrepresents its content.

It argues that since SPI's motion was filed more than a year after the filing of its answer and over seven months after the deadline to amend, and because all information upon which SPI's inequitable conduct allegations are based is found in the '777 patent specification or certain prior art references cited therein, SPI's amendment should be denied as unduly delayed. It further contends that the deposition excerpts referenced by SPI do not contradict the disclosures in the '777 patent or other information submitted by the applicants to the PTO. Because SPI's inequitable conduct claim fails to show misrepresentations regarding the '777 patent or improper analysis of the disclosures of the prior art and contains insufficient facts, the amendment should be denied on the basis of bad faith or dilatory motive.

Roquette maintains that it would be "significantly prejudiced" if the amendment was permitted because it would require it "to engage in new, substantial and costly

rework of its case.”

In its sur-reply brief, Roquette performs a similar factual analysis of the “new” information allegedly contained in SPI’s reply brief.<sup>8</sup>

## **Discussion**

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

The court ordinarily considers motions to amend the pleadings under Rule 15(a) which provides that “leave shall be freely given when justice so requires.” Although the determination of whether to grant or deny a motion to amend is within the discretion of the court, under *Foman v. Davis*,<sup>9</sup> the Supreme Court has instructed that leave to amend should be freely granted “in the absence of . . . undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the amendment, etc.”<sup>10</sup>

Generally, “[d]elay alone is not sufficient to justify denial of leave to amend.”<sup>11</sup>

The more dispositive factor in determining whether leave should be granted is prejudice

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<sup>8</sup> The court has doubts that SPI’s reply brief contains, as argued by Roquette, new interpretation of data Tables in the Japanese prior art, new allegations concerning Table 1 of the ‘777 patent or a new allegation that Table 2 of the ‘777 patent omitted the compressibility data. Although those contentions were not discussed in similar detail in SPI’s opening brief, they are alleged in the proposed amended answer. See D.I. 147, Ex. B ¶¶ 31-51.

<sup>9</sup> 371 U.S. 178 (1962).

<sup>10</sup> *Foman*, 371 U.S. at 182. See also *Arthur v. Maersk, Inc.*, 434 F.3d 196, 203 (3d Cir. 2006).

<sup>11</sup> *Arthur*, 434 F.3d at 204 (wherein the Third Circuit noted that “only one appellate court . . . has approved . . . denial of leave to amend based on a delay of less than one year.”).

to the non-moving party.<sup>12</sup> In proving prejudice, the non-moving party “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 amendments been timely.”<sup>13</sup> Moreover, in assessing futility of a proposed amendment, the same standard of legal sufficiency as under Rule 12(b)(6) is applied.<sup>14</sup> An amendment is futile when it fails to state a claim upon which relief may be granted.<sup>15</sup> The analysis is the same as under Rule 12(b)(6) in that all factual allegations and all reasonable inferences therefrom are accepted as true. Under Rule 12(b)(6), the court does not and cannot weigh the facts, nor determine whether a party will ultimately prevail.<sup>16</sup> “Only where it is clear to the court . . . that a claim has *no* possibility of succeeding on the merits, will the court disallow it by denying leave to amend.”<sup>17</sup>

Balanced with Rule 15(a) is Rule 16(b), which governs modification to the court’s scheduling order. Under Rule 16(b), a more stringent standard is applied which requires a showing of good cause by the movant, and consent of the judge. This jurisdiction recognizes that motions to amend which, in effect, operate to change the scheduling order, are controlled by Rule 16(b).<sup>18</sup> The good cause element requires the movant to demonstrate that, despite diligence, the proposed claims could not have

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

<sup>13</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>14</sup> *See Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997).

<sup>15</sup> *See In re Merck & Co., Inc.*, 493 F.3d 393, 400 (3d Cir. 2007).

<sup>16</sup> *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974).

<sup>17</sup> *Agere Systems Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 736 (D. Del. 2002) (emphasis added).

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

been reasonably sought in a timely manner.<sup>19</sup> In contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party.<sup>20</sup>

### **Rules 8 and 9(b) and the Standard for Inequitable Conduct<sup>21</sup>**

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 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 application.<sup>22</sup> Information is deemed material if there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to issue the application as a patent.<sup>23</sup> Breach of the duty of candor may render a patent unenforceable for inequitable conduct.<sup>24</sup> To *prove* unenforceability by inequitable conduct, “the alleged infringer must provide clear and convincing evidence of (1) affirmative misrepresentations of a material fact, the failure to disclose material information, or submission of false

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<sup>19</sup> *Samick Music Corp. v. Delaware Music Indus., Inc.*, No. 91cv 23-CMW, 1992 WL 39052, at \* 6-7 (D. Del. Feb. 12, 1992).

<sup>20</sup> *Slip Track Sys., Inc. v. Metal Lite, Inc.*, 304 F.3d 1256, 1270 (Fed. Cir. 2002).

<sup>21</sup> Roquette makes a passing reference to both Rule 9(b) and Rule 16(b)(4) in its briefs, but does not present any argument regarding those rules.

<sup>22</sup> *Elk Corp. of Dallas v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 30 (Fed. Cir. 1999).

<sup>23</sup> *Elk Corp.*, 168 F.3d at 31.

<sup>24</sup> *M. Eagles Tool Warehouse, Inc. v. Fisher Tolling Co.*, 439 F.3d 1335, 1339 (Fed. Cir. 2006); 37 CFR § 1.56.

material information and (2) an intent to deceive.”<sup>25</sup> When analyzing whether inequitable conduct occurred, the court balances the levels of materiality and intent.

Since inequitable conduct is a claim sounding in fraud, Rule 9(b) applies. Under that rule, the elements of inequitable conduct must be pled with particularity. The purpose of the heightened pleadings requirements of Rule 9(b) is to “deter the filing of charges of fraud as a pretext for discovery of unknown wrongs.”<sup>26</sup> Inequitable conduct allegations, however, “remain subject to the liberal pleading standard of Rule 8, which requires only a ‘short and plain’ statement of a claim or defense,” the purpose of which is to place the opposition on notice of the misconduct charged.<sup>27</sup> Therefore, “pleadings that disclose the name of [the allegedly withheld] relevant prior art and disclose the acts of the alleged fraud fulfill the requirements of Rule 9(b).”<sup>28</sup> Further, the particularity requirement does not mandate that a party plead the date, time, or place of the alleged fraud, if that party uses “an alternative means of injecting precision and some measure of substantiation into [its] allegations of fraud.”<sup>29</sup> Thus, “courts still must apply Rule 9(b) with some flexibility so that a party is not required to plead issues which may have been

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<sup>25</sup> *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006).

<sup>26</sup> *Stowe Woodward L.L.C. v. Sensor Products, Inc.*, 230 F.R.D. 463, 466 (W.D. Va. 2005).

<sup>27</sup> *McKesson Information Solutions LLC v. The Trizetto Group, Inc.*, 2005 WL 914776, at \*3 (D. Del. Apr. 20, 2005); *TruePosition, Inc. v. Allen Telecom, Inc.*, 2003 WL 151227, at \*5 (D. Del. Jan. 21, 2003).

<sup>28</sup> *France Telecom, S.A. v. Novell, Inc.*, 2002 WL 31355255, at \*3 (D. Del. Oct. 17, 2002) (quoting *EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261, 1263 (D. Del. 1996)).

<sup>29</sup> *Martek Biosciences Corp. v. Nutrinova Inc.*, 2004 WL 2297870, at \*3 (D. Del. Oct. 8, 2004).

concealed by an adverse party.”<sup>30</sup>

## **Analysis**

### **Rules 8(a), 9(b), 15(a) and 16(b)(4)**

On the record presented, the court finds that SPI is pleading a new legal theory, inequitable conduct, based on additional information that was provide and confirmed through the depositions of the inventors. Although Roquette maintains that SPI possessed all necessary information which forms the basis of its proposed inequitable conduct contentions prior to the scheduling deadline for amendment to the pleadings, in light of the pleading with particularity requirement under Rule 9(b), it was appropriate for SPI to confirm the factual allegations through discovery. There is no dispute that the inventors’ depositions did not occur until mid-November 2007, six months after the cut-off date for amendment to pleadings. In support of its proposed amendment, SPI emphasizes that testimony.

Further, SPI did not unduly delay the filing of its motion to amend because: the inventors’ depositions occurred in November 2007; Roquette was aware of the motion before the close of discovery; and SPI filed its motion to amend on December 28, 2007. Roquette’s reliance on *Inline Connection Corp.* is misplaced. There, the defendants admittedly had all the information necessary to plead with particularity new inequitable conduct allegations at least *three years* before the proposed amendments were filed. Further, the defense waited until long after discovery had been completed (more than

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<sup>30</sup> *Mars Inc. v. JCM American Corp.*, 2006 WL 1704469, at \*5 (D.N.J. June 14, 2006) (citing *Rolo v. City Investing Co. Liquidation Trust*, 155 F.3d 644, 658 (3d Cir. 1998)).

two years) to propose the amendment. In the instant matter, the motion was initiated four months before the close of discovery in April 2008.

As noted previously herein, prejudice to the non-moving party is the “touchstone for the denial of an amendment.” Roquette’s alleged prejudice is that it would have to address a new issue and rework its case, thereby incurring additional costs. Such concerns are not sufficient to show prejudice. Information regarding the inventors’ knowledge and what they did or did not do regarding the patent specification and their representations to the PTO would primarily be within the control of Roquette. Such information certainly was not within the possession or control of SPI.

Nothing Roquette has presented suggests willful or deliberate conduct, the elements necessary for bad faith, on the part of SPI in bringing the motion. Clearly, Roquette disagrees with the merits of the inequitable conduct allegations, but that is not enough to show bad faith.

Regarding Roquette’s argument that the amendment is futile, as discussed herein, the assessment of futility is based on a Rule 12(b)(6) analysis. Although Roquette clearly disagrees with SPI’s characterization of the inventors’ deposition testimony and its interpretation and application of the prior art, those are factual disputes which would require an analysis of the evidence and go to the issue of whether SPI would ultimately prevail. Roquette’s focus challenges the meaning and interpretation of specific factual allegations raised by SPI. Roquette’s argument does not address whether SPI fails to allege any set of facts that could support a finding of inequitable conduct. Rather, it seeks to argue the merits of SPI’s factual allegations. At this juncture, the court cannot conclude that the proposed amendment would be futile

since the allegations are sufficient to “raise a right to relief above the speculative level, on the assumption that all the allegations in the [proposed amendment] are true,”<sup>31</sup> and SPI provided the “‘grounds’ of [its] ‘entitle[ment] to relief’” beyond “labels and conclusions,”<sup>32</sup> with “enough facts to state a claim to relief that is plausible on its face.”<sup>33</sup>

Roquette makes a cursory reference to Rules 9(b) and 16(b)(4), without any developed argument. The history in this matter shows that the scheduling order has been modified several times to serve the interests of the parties. In the analysis above, the court finds that SPI did not unduly delay in bringing the motion; to meet its obligations of pleading with particularity, SPI needed the depositions of the inventors and was justified in taking certain discovery before filing the motion; the proposed amendment is not futile; and, there is no evidence of bad faith or improper motive. In so concluding, the court determines that SPI has satisfied the good cause requirement of Rule 16. Accordingly, SPI’s motion for leave to amend should be granted.

THEREFORE, for the reasons contained herein, IT IS ORDERED that SPI’s motion to amend (D.I. 147) be granted. Since the arguments raised in Roquette’s motion for a sur-reply brief were considered, its motion for leave (D.I. 156) is granted.

This Memorandum Order 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 ten (10) days after being served with a copy of this Memorandum

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<sup>31</sup> *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1965 (2007) (outlining the standard for a motion to dismiss under Rule 12(b)(6)); see also *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007).

<sup>32</sup> *Twombly*, 127 S. Ct. at 1965.

<sup>33</sup> *Id.* at 1974.

Order. Fed. R. Civ. P. 72(a).

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 April 7, 2008, a copy of which is available on the court's website, [www.ded.uscourts.gov](http://www.ded.uscourts.gov).

May 21, 2009

/s/ Mary Pat Thyng  
UNITED STATES MAGISTRATE JUDGE