

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

CORNELL UNIVERSITY, CORNELL
RESEARCH FOUNDATION, INC., LIFE
TECHNOLOGIES CORPORATION, and
APPLIED BIOSYSTEMS, LLC,

Plaintiffs,

v.

ILLUMINA, INC.,

Defendant.

C. A. No. 10-433-LPS-MPT

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DISTRICT OF DELAWARE
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REPORT AND RECOMMENDATION

I. INTRODUCTION

On May 24, 2010, Cornell University, Cornell Research Foundation, Inc. (collectively, "Cornell"), Life Technologies Corporation ("Life Technologies"), and Applied Biosystems, LLC ("Applied Biosystems") (collectively, "plaintiffs") brought this action against Illumina, Inc. ("Illumina" or "defendant"), alleging infringement of several patents in two patent families: the LDR/PCR Patent family and the Array Patent family.¹

Currently before the court is defendant's motion for leave to amend, pursuant to Federal Rules of Civil Procedure 15(a) and 16(b) and Local Rule 15.1, its Answer and Counterclaims to Plaintiffs' Third Amended Complaint to allege inequitable conduct before the United States Patent and Trademark Office ("PTO") with respect to the

¹ D.I. 1. Plaintiffs filed a First Amended Complaint on August 19, 2011 (D.I. 63), a Second Amended Complaint on April 28, 2015 (D.I. 274), and a Third Amended Complaint on August 7, 2015 (D.I. 298).

prosecution of the LDR/PCR Patent family.² The patents at issue from the LDR/PCR Patent family are: U.S. Patent Nos. 6,797,470 (“the ‘470 patent”), 7,166,434 (“the ‘434 patent”), 7,312,039 (“the ‘039 patent”), 7,320,865 (“the ‘865 patent”), 7,332,285 (“the ‘285 patent”), 7,364,858 (“the ‘858 patent”), 7,429,453 (“the ‘453 patent”), and 8,597,891 (“the ‘891 patent”). The ‘470 patent issued from U.S. Patent Application No. 09/918,156 (“the ‘156 Application”). The ‘434, ‘039, ‘865, ‘285, ‘858, ‘453, and ‘891 patents are continuations of the ‘470 patent.

Defendant alleges discovery revealed that the applicants and prosecuting attorney of the LDR/PCR patents violated their duty of candor to the PTO by filing a false or misleading 37 C.F.R. § 1.131 declaration (“the § 1.131 Declaration”) in prosecuting the ‘156 Application.³

According to defendant, in the § 1.131 Declaration, the applicants knowingly made false or misleading statements regarding the date of their reduction to practice of the claimed LDR/PCR methods in order to swear behind three references—WO 96/15281 (“Carrino”), WO 95/35390 (“Zhang390”), and U.S. Patent No. 5,876,924 (“Zhang924”)—upon which the PTO examiner had rejected the claims of the ‘156 application.⁴ Defendant maintains deposition testimony of the applicants and

² D.I. 405.

³ D.I. 406 at 1.

⁴ *Id.* Carrino is an international application published on May 23, 1996 under the Patent Cooperation Treaty that claims priority to the November 16, 1994 filing of U.S. Patent Application No. 08/344,203. *Id.*, Ex. A (Proposed Amended Answer and Counterclaims to Plaintiffs’ Third Amended Complaint) at ¶ 18(c). Zhang390 is an international application published on December 28, 1995 under the Patent Cooperation Treaty that claims priority to the June 22, 1994 filing of U.S. Patent Application No. 08/263,937. *Id.*, Ex. A at ¶ 19(a). Zhang924 was filed July 31, 1996 and claims priority to the June 22, 1994 filing of U.S. Patent Application No.

prosecuting attorney confirm that the § 1.131 Declaration misrepresented the date of the applicants' reduction to practice and absent the declaration's purportedly false or misleading statement, the LDR/PCR patents would not have issued.⁵

II. FACTS

The '156 Application was filed on July 30, 2001 by patent attorney Michael L. Goldman on behalf of applicants Francis Barany, Matthew Lubin, and Phillip Belgrader.⁶ Successive Requests For Correction Of Inventorship removed Phillip Belgrader as an applicant and added George Barany and Robert Hammer as applicants.⁷ The '156 Application issued as the '470 patent on September 28, 2004.⁸ The '434, '039, '865, '285, 858, '453, and '891 patents issued as continuations of, and claim priority to, the '156 Application and the '470 patent.⁹

The '470 patent "relates to the detection of nucleic acid sequence differences using couple ligase detection reaction ('LDR') and polymerase chain reaction ('PCR')." ¹⁰ Claim 1 of the '470 patent, claims "[a] method for identifying one or more different target nucleotide sequences comprising," among other things, "one or more oligonucleotide probe sets," one or more ligase detection reaction [LDR] cycles," "one or a plurality of oligonucleotide primer sets," one or more polymerase chain reaction [PCR] cycles," and "detecting the extension products to identify one or more target nucleotide sequences in

08/263,937. *Id.*, Ex. A at ¶ 19(b).

⁵ *Id.* at 1.

⁶ *Id.*, Ex. A at ¶ 17.

⁷ *Id.*, Ex. A at ¶¶ 17(c), 17(e).

⁸ *Id.*, Ex. A at ¶ 21(i).

⁹ *Id.*, Ex. A at ¶ 22.

¹⁰ *Id.*, Ex. A at ¶ 17(a); '470 patent, 1:18-20.

the sample.”¹¹ The ‘434, ‘039, ‘865, ‘285, 858, ‘453, and ‘891 patents claim similar or related LDR/PCR methods.¹²

Michael Goldman prosecuted the ‘156 Application on behalf of applicants Francis Barany, Matthew Lubin, George Barany, and Robert Hammer.¹³ The PTO issued an initial Notice of Allowance of the ‘156 Application on April, 21, 2003.¹⁴ On August 8, 2003, Michael Goldman entered a Request For Continued Examination and a 37 C.F.R. §§ 1.97-1.98 Information Disclosure Statement on behalf of applicants Francis Barany, Matthew Lubin, George Barany, and Robert Hammer.¹⁵ The Information Disclosure Statement included the Carrino, Zhang390, and Zhang924 references.¹⁶

On September 11, 2003, the PTO rejected the claims in the ‘156 Application pursuant to 35 U.S.C. §§ 102(a), 102(e), and 103(a) as anticipated by, or obvious in light of, Carrino, Zhang390, and Zhang924.¹⁷ Among other things, the PTO found that particular pages and figures in Carrino, Zhang390, and Zhang924 anticipated independent claim 1 as well as dependent claims 3 and 4 because the references “clearly disclose[] the claimed method” of “carrying out a ligation detection reaction using probes containing primer binding sites at the appropriate ends, and then carrying out a polymerase chain reaction on the ligated products using primers targeting said

¹¹ ‘470 patent, claim 1.

¹² D.I. 406, Ex. A at ¶ 22.

¹³ *Id.*, Ex. A at ¶¶ 17, 17(e), 18, 18(a), 20.

¹⁴ *Id.*, Ex. A at ¶ 17(f); *id.*, Ex. D (‘470 Patent File History) at C001094-96.

¹⁵ *Id.*, Ex. A at ¶¶ 18, 18(a); *id.*, Ex. D at C001099-1146.

¹⁶ *Id.*, Ex. A at ¶¶ 18(b), 18(c); *id.*, Ex. D at C001099-1141; D.I. 429 at 1.

¹⁷ D.I. 406, Ex. A at ¶¶ 19-19(c); *id.*, Ex. D at C001147-54.

primer binding sites.”¹⁸

On November 14, 2003, Michael Goldman filed an “Amendment” to overcome the PTO’s rejection of the ‘156 Application by traversing Carrino, Zhang390, and Zhang924 based on a 37 C.F.R. § 1.131 declaration signed by each of the applicants: Francis Barany, Matthew Lubin, George Barany, and Robert Hammer.¹⁹

The Manual of Patent Examining Procedure (“MPEP”) is published by the PTO for use by patent attorneys, agents, and examiners.²⁰ The MPEP details the laws and regulations followed during patent examination, and is based on Chapter 37 of the Code of Federal Regulations.²¹ Chapter 715 of the 2003 version of the MPEP sets forth the guidelines for swearing behind a reference under 37 C.F.R. § 1.131.²² Pursuant to Section 715.07 an applicant may swear behind a reference through a § 1.131 declaration establishing either the applicant’s (1) reduction to practice prior to the effective date of the reference, or (2) conception prior to the effective date of the reference coupled with due diligence from prior to the reference date to either actual or constructive reduction to practice.²³ Therefore, to swear behind a reference under the first method, the MPEP does not require a showing of diligence; but to swear behind a reference under the second method, the MPEP states that “the actual dates of acts relied on to establish diligence must be provided.”²⁴

¹⁸ *Id.*, Ex. A at ¶ 19(c); *id.*, Ex. D at C001149-50.

¹⁹ *Id.*, Ex. A at ¶ 20; *id.*, Ex. D at C001257-75.

²⁰ *Id.*, Ex. A at ¶ 21.

²¹ *Id.*, Ex. A at ¶ 21.

²² *Id.*, Ex. A at ¶ 21(b).

²³ *Id.*, Ex. A at ¶ 21(b).

²⁴ *Id.*, Ex. A at ¶¶ 21(c), 21(d).

In preparing the Amendment, Michael Barany conferred, at least, with applicant Francis Barany.²⁵ Neither the Amendment nor the declaration attempted to distinguish the '156 Application from Carrino, Zhang390, and Zhang924.²⁶ The § 1.131 Declaration submitted by the applicants included no "actual dates of acts relied on to establish diligence."²⁷ Rather, the declaration stated: "[p]rior to June 22, 1994, we conceived *and* diligently reduced to practice, in the United States, the invention claimed in the above-identified patent application."²⁸ As a consequence, the Amendment asserted that Carrino, Zhang390, and Zhang924 "cannot be prior art."²⁹ Following the submission of the § 1.131 Declaration, the PTO withdrew the rejections based on Carrino, Zhang390, and Zhang924.³⁰

Francis Barany and Matthew Lubin were the applicants principally responsible for developing the claimed LDR/PCR method.³¹ At deposition, Francis Barany and Matthew Lubin testified that the claimed LDR/PCR method had not been reduced to practice "[p]rior to June 22, 1994" and that laboratory work relating to the claimed

²⁵ *Id.*, Ex. A at ¶ 20(a).

²⁶ *Id.*, Ex. A at ¶ 20(b); *id.*, Ex. D at C001257-75.

²⁷ *Id.*, Ex. A at ¶ 21(f); *id.*, Ex. D at C001261-68.

²⁸ *Id.*, Ex. A at ¶¶ 20(c), 21(e); *id.*, Ex. D at C001261 (emphasis added). The § 1.131 Declaration also stated that "[e]vidence of this conception prior to June 22, 1994, is provided in attached Exhibit 1" and that "[w]e hereby declare that all statements made herein of our own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statements may jeopardize the validity of the application or any patent issued thereon." *Id.*, Ex. D at C001261-62.

²⁹ *Id.*, Ex. A at ¶ 20(d); *id.*, Ex. D at C001259.

³⁰ *Id.*, Ex. A at ¶ 21(g); *id.*, Ex. D at C001276-84.

³¹ *Id.*, Ex. A at ¶ 20(e); *id.*, Ex. M (Deposition of Matthew Lubin) at 39:19-40:3; *id.*, Ex. N (Deposition of Francis Barany) at 137:6-23.

LDR/PCR methods did not begin until July 11, 1994.³² Michael Goldman testified that at the time he filed the Amendment and § 1.131 Declaration, he knew that the claimed LDR/PCR methods had not been reduced to practice “[p]rior to June 22, 1994.”³³

III. LEGAL STANDARDS

“If a party moves for leave to amend the pleadings after a deadline imposed by a Scheduling Order, Rule 16 of the Federal Rules of Civil Procedure is also implicated.”³⁴ Under Rule 16, “[a] schedule may be modified only for good cause and with the judge’s consent.”³⁵ “After a pleading deadline has passed, the Third Circuit requires a showing of good cause in order to amend.”³⁶ “Good cause” exists if the Schedule “cannot reasonably be met despite the diligence of the party seeking the extension.”³⁷ “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.”³⁸

Pursuant to Federal Rule of Civil Procedure 15(a)(2), “party may amend its pleading only with the opposing party’s written consent or the court’s leave. The court should freely give leave when justice so requires.”³⁹ “The Third Circuit has adopted a

³² *Id.*, Ex. A at ¶ 21(e); *id.*, Ex. A at ¶ 20(e); *id.*, Ex. M at 74:7-13, 206:9-207:4; *id.*, Ex. N at 195:3-7, 524:14-17.

³³ *Id.*, Ex. A at § 21(e); *id.*, Ex. A at ¶ 20(f); *id.*, Ex. L (Deposition of Michael Goldman) at 108:18-25.

³⁴ *ICU Med., Inc. v. Ryemed Techs., Inc.*, 674 F. Supp. 2d 574, 577 (D. Del. 2009).

³⁵ FED. R. CIV. P. 16(b)(4).

³⁶ *ICU Med.*, 674 F. Supp. 2d at 577 (citing *E. Minerals & Chems. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000)).

³⁷ FED. R. CIV. P. 16(b)(4) Advisory Committee’s Notes (1983 Amendments).

³⁸ *ICU Med.*, 674 F. Supp. 2d at 577-78 (quoting *Roquette Freres v. SPI Pharma. Inc.*, C.A. No. 06-540-GMS, 2009 WL 1444835, at *4 (D. Del. May 21, 2009)).

³⁹ FED. R. CIV. P. 15(a)(2).

liberal policy favoring the amendment of pleadings to ensure that claims are decided on the merits rather than on technicalities.”⁴⁰ The United States Supreme Court has stated that although:

the grant or denial of an opportunity to amend is within the discretion of the District Court . . . , [i]n the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, . . . undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the amendment, etc.—the leave sought should, as the rules require, be “freely given.”⁴¹

Because defendant seeks leave to amend its affirmative defenses and counterclaims to assert inequitable conduct and unenforceability of the LDR/PCR patents, the heightened pleading standard of Federal Rule of Civil Procedure 9(b) applies to its allegations.⁴² Rule 9(b) requires that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.”⁴³ “[I]nequitable conduct, while a broader concept than fraud, must be pled with

⁴⁰ *Leader Techs., Inc. v. Facebook, Inc.*, C.A. No. 08-862-LPS, 2010 WL 2545959, at *3 (D. Del. June 24, 2010) (citing *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990)). Whether to grant or deny “a motion to amend a pleading under Rule 15(a) is a procedural matter governed by the law of the regional circuit.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009) (citing *Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1357 (Fed. Cir. 2009)).

⁴¹ *Foman v. Davis*, 371 U.S. 178, 182 (1962).

⁴² “Whether inequitable conduct has been pleaded with particularity under Rule 9(b) is a question governed by Federal Circuit law.” *Exergen Corp.*, 575 F.3d at 1318 (citing *Cent. Admixture*, 482 F.3d at 1356); see also *id.* at 1327 (“[W]e apply our own law, not the law of the regional circuit, to the question of whether inequitable conduct has been pleaded with particularity under Rule 9(b).”).

⁴³ FED. R. CIV. P. 9(b).

particularity” under Rule 9(b).⁴⁴

[T]o plead the “circumstances” of inequitable conduct with the requisite “particularity” under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. Moreover, although “knowledge” and “intent” may be averred generally, a pleading of inequitable conduct under Rule 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 PTO.⁴⁵

IV. DISCUSSION

A. Rule 16(b)

The deadline for the parties to move to amend the pleadings was August 7, 2015.⁴⁶ Fact discovery concluded on December 4, 2015, except for certain depositions, including the deposition of plaintiffs’ patent attorney, that could not be completed, despite the parties’ best efforts, prior to December 4, 2015.⁴⁷ Pursuant to Rule 16(b), defendant must demonstrate “good cause” to modify the Scheduling Order to permit its proposed amendment. “The good cause element requires the movant to demonstrate that, despite diligence, the proposed claims could not have been reasonably sought in a timely manner.”⁴⁸

Defendant maintains it has shown good cause to amend its Answer and

⁴⁴ *Exergen*, 575 F.3d at 1326 (quoting *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003)).

⁴⁵ *Id.* at 1328-29.

⁴⁶ D.I. 291.

⁴⁷ D.I. 398.

⁴⁸ *Roquette Freres v. SPI Pharma, Inc.*, C.A. No. 06-540-GMS, 2009 WL 144835, at *4 (D. Del. May 21, 2009) (citing *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)).

Counterclaims to add an inequitable conduct affirmative defense and a counterclaim for a declaratory judgement of unenforceability because it worked diligently to discover and confirm the facts underlying its inequitable conduct claim through depositions, principally of Francis Barany, Matthew Lubin, and Michael Goldman, that occurred after the August 7, 2015 deadline to amend pleadings in this case.

The depositions of Matthew Lubin, Francis Barany, and Michael Goldman did not occur until after the August 7, 2015 deadline for amending pleadings.⁴⁹ On May 11, 2015, defendant subpoenaed Francis Barany, Matthew Lubin, George Barany, and Robert Hammer to appear for depositions and produce relevant documents.⁵⁰ Plaintiffs' counsel represented the applicants and responded to the subpoenas on their behalf.⁵¹ Defendant deposed Robert Hammer on July 17, 2015, George Barany on August 20, 2015, Matthew Lubin on September 8, 2015, and Francis Barany on September 20 and 21, 2015. It was through those depositions that defendant learned the applicants had not reduced to practice the LDR/PCR method claimed in the '156 Application prior to June 22, 1994 and that Michael Goldman had prepared the § 1.131 Declaration signed by the applicants.⁵² Defendant received the final transcripts of Matthew Lubin's and Francis Barany's depositions on September 16, 2015 and October 2, 2015.

Between October 5 and 7, 2015, defendant served third-party subpoenas on plaintiffs' prosecution counsel, Michael Goldman, and his law firm.⁵³ Following

⁴⁹ D.I. 406 at 10.

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.* at 11.

responses and objections to the subpoenas, defendant sought a deposition date prior to the December 4, 2015 close of fact discovery but scheduling conflicts prevented that from occurring.⁵⁴ On December 7, 2015, the parties entered into a stipulation to extend the time to take certain depositions, including that of Michael Goldman, that could not be completed, “despite the parties’ best efforts,” prior to the December 4, 2015 close of fact discovery.⁵⁵ Thereafter, on December 16, 2015, defendant deposed Michael Goldman during which he confirmed that both the applicants and the prosecuting attorney knew, at the time of signing the § 1.131 Declaration, that the applicants had not reduced to practice the claimed LDR/PCR method prior to June 22, 1994.⁵⁶ He also confirmed the absence of any ground for overcoming Carrino, Zhang390, and Zhang924 other than the applicants’ statement in the § 1.131 Declaration.⁵⁷ Defendant received the final transcript of Michael Goldman’s deposition on December 29, 2015.⁵⁸

On January 13, 2016, defendant sent a draft of its proposed Amended Answer and Counterclaim adding inequitable conduct allegations to plaintiffs, along with a request for plaintiffs’ consent to defendant’s filing of the Amended Answer and Counterclaims.⁵⁹ On January 19, 2016, plaintiffs indicated they would not consent.⁶⁰ Defendant then filed its motion on January 25, 2016.⁶¹

Plaintiffs do not address the good cause requirement of Rule 16(b) to amend

⁵⁴ *Id.*

⁵⁵ *Id.* (quoting D.I. 398).

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 11-12.

⁶¹ *Id.* at 12; D.I. 405.

pleadings after the deadline to amend has passed. The court determines defendant has met that requirement because it “pleads a new legal theory—inequitable conduct—based on a new set of facts obtained and confirmed during discovery which took place after the Scheduling Order’s deadline for amending pleadings.”⁶² Based on the deposition time lines set for above, the court finds defendant worked diligently to obtain and confirm facts to support its inequitable conduct affirmative defense and counterclaim; particularly through the depositions of Francis Barany, Matthew Lubin, and Michael Goldman which occurred after the August 7, 2015 deadline to amend pleadings in this case. After obtaining and confirming those facts, defendant “filed its amendment soon after it was able to satisfy the pleading requirements of Rule 9(b).”⁶³

B. Rule 15(a)

The court should grant leave to amend “[i]n the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, . . . undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the amendment, etc.”⁶⁴

Plaintiffs do not argue that defendant unduly delayed in seeking leave to amend. Defendant argues that it is pleading inequitable conduct without undue delay. “[T]he question of undue delay requires that [the court] focus on the movant’s reasons for not

⁶² *ICU Med., Inc. v. Rymed Techs., Inc.*, 674 F. Supp. 2d 574, 578 (D. Del. 2009); see also, e.g., *Enzo Life Sciences, Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 488 (D. Del. 2003).

⁶³ *Enzo Life Sci.*, 270 F. Supp. 2d at 490; *id.* at 489 (Because Rule 9(b) must be plead with particularity, defendant was “prudent and possibly required to confirm the factual allegations through discovery.”).

⁶⁴ *Foman v. Davis*, 371 U.S. 178, 182 (1962).

amending sooner.”⁶⁵ As the court found, above, defendant diligently worked to obtain and confirm facts supporting its proposed amendment and filed its motion soon after obtaining and confirming those facts and plaintiffs’ refusal to agree to that amendment. Therefore, the court finds there was no undue delay on defendant’s part. Likewise, plaintiffs do not argue bad faith on the part of defendant in seeking to amend. The court agrees with defendant that it demonstrated its good faith in seeking leave to amend to add an affirmative defense and counterclaim of inequitable conduct by waiting until after completion of the applicants’ and patent prosecution counsel’s depositions in confirming the relevant facts.⁶⁶ “[P]rejudice to the non-moving party is the touchstone for the denial of an amendment.”⁶⁷ Plaintiffs’ do not argue allowing defendant to amend would cause them undue prejudice, therefore, the court finds there would be none.

Plaintiffs’ basis for its argument that the court deny defendant’s motion is that its amended pleading is futile for failure to adequately plead inequitable conduct. Defendant contends its amended counterclaim is not futile as it properly pleads inequitable conduct.

⁶⁵ *Cureton v. Nat’l Collegiate Athletic Ass’n*, 252 F.3d 267, 273 (3d Cir. 2001) (citing *Adams v. Gould Inc.*, 739 F.2d 858, 864 (3d Cir. 1984) *cert. denied*, 469 U.S. 1122 (1985)).

⁶⁶ See, e.g., *Intervet v. Boehringer Ingelheim Vetmedica, Inc.*, C.A. No. 11-595-LPS, 2002 WL 4808427, at *1 (D. Del. Oct. 9, 2012) (“[U]nsupported charges of inequitable conduct are disfavored by the Federal Circuit.”) (quoting *Probert v. Clorox Co., Inc.*, 258 F.R.D. 491, 494 (D. Utah 2009)).

⁶⁷ *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006) (quoting *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993)).

“An amendment is deemed futile if it could not withstand a motion to dismiss.”⁶⁸
“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.”⁶⁹ “The fact that plaintiffs disagree with the factual representations made . . . [in the pleading] is irrelevant, as the court is not required to judge the merits of the parties’ respective positions at this stage of the proceedings.”⁷⁰ In fact, at this stage, “the court does not and cannot weigh the facts, nor determine whether a party will ultimately prevail.”⁷¹

Because inequitable conduct allegations must be plead with particularity pursuant to Federal Rule of Civil Procedure 9(b), “the pleading must identify the specific who, what, when, where and how of the material misrepresentation or omission committed before the PTO.”⁷² Defendant maintains its proposed Amended Answer and Counterclaim of inequitable conduct satisfies these pleading requirements.

The pleading identifies applicants Francis Barany, Matthew Lubin, George Barany, and Robert Hammer, and their prosecution counsel Michael Goldman as the individuals *who* signed and filed the § 1.131 Declaration.⁷³ It also identifies Francis Barany, Matthew Lubin, and Michael Goldman as the individuals *who* knew the applicants had not reduced to practice the claimed LDR/PCR method “[p]rior to June

⁶⁸ *Enzo Life Sci.*, 270 F. Supp. 2d at 489 (citing *Satellite Fin. Planning Corp. v. First Nat’l Bank*, 646 F. Supp. 118, 120 (D. Del. 1986)).

⁶⁹ *Roquette Freres v. SPI Pharma, Inc.*, C.A. No. 06-540-GMS, 2009 WL 1444835, at *3 (D. Del. May 21, 2009).

⁷⁰ *Cot’n Wash, Inc. v. Henkel Corp.*, 56 F. Supp. 3d 613, 626 (D. Del. 2014).

⁷¹ *Roquette Freres v. SPI Pharma, Inc.*, C.A. No 06-540-GMS, 2009 WL 1444835, at *3 (D. Del. May 21, 2009).

⁷² *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009).

⁷³ D.I. 406, Ex. A at ¶ 20.

22, 1994" as attested in the § 1.131 Declaration.⁷⁴

The pleading identifies *what* information—the date of the applicants' reduction to practice of the claimed LDR/PCR method—the applicants purportedly misrepresented to the PTO through the § 1.131 Declaration.⁷⁵ The amended pleading also demonstrates *when* the purported misrepresentation was made to the PTO by setting out the specific dates of the applicants' § 1.131 Declaration as well as the actions the PTO took before and after the filing of that declaration.⁷⁶ It identifies *where* the misrepresentation—the purportedly false or misleading assertion of reduction to practice prior to June 22, 1994—occurred in the § 1.131 Declaration, and that misrepresentation's relation to the priority dates of Carrino, Zhang390, and Zhang924, which the PTO had previously found to anticipate the claimed LDR/PCR method.⁷⁷

Lastly, defendant maintains its pleading demonstrates *how* the § 1.131 Declaration resulted in the PTO's allowance of the '470 patent over Carrino, Zhang390, and Zhang924:

The Examiner found that Carrino, Zhang390, and Zhang924 "clearly disclose[d]" and anticipated the LDR/PCR method set forth in independent claim 1 and dependent claims 3 and 4 of the '156 Application;⁷⁸

To swear behind the June 22, 1994 priority date of Zhang390 and Zhang924, the applicants and Michael Goldman submitted the § 1.131 Declaration attesting that, "[p]rior to June 22, 1994, [the applicants] conceived and diligently reduced to practice, in the United States, the invention claimed in the above-identified patent application,"⁷⁹

⁷⁴ *Id.*, Ex. A at ¶¶ 20(c), 20(e), 20(f).

⁷⁵ *Id.*, Ex. A at ¶¶ 20-20(f), 21(b)-21(f).

⁷⁶ *Id.*, Ex. A at ¶¶ 17, 18, 19, 20, 21(i).

⁷⁷ *Id.*, Ex. A at ¶¶ 18, 18(b), 18(c), 19-19(c), 20(b)-20(d), 21(f).

⁷⁸ *Id.*, Ex. A at ¶¶ 18(c), 19-19(c).

⁷⁹ *Id.*, Ex. A at ¶¶ 20(c), 21(e).

As a consequence of the declaration, the applicants' Amendment asserted that Carrino, Zhang390, and Zhang924 "cannot be prior art,"⁸⁰

The § 1.131 Declaration and the accompanying Amendment neither distinguished Carrino, Zhang390, and Zhang924 from the claimed LDR/PCR method nor provided "actual dates" of the applicants' diligence as required to swear behind Zhang390 and Zhang924 in the absence of actual reduction to practice prior to June 22, 1994,⁸¹ and

The Examiner necessarily relied on the attested date of reduction to practice prior to June 22, 1994 in issuing the '470 patent despite Carrino, Zhang390, and Zhang924.⁸²

Additionally, to meet the requirements of Rule 9(b):

[A] pleading of inequitable conduct under Rule 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 PTO.⁸³

Plaintiffs argue defendant's proposed amendment is futile because it fails to adequately plead that the § 1.131 Declaration was material, fails to adequately plead specific intent to deceive the PTO, and thus, fails to state a claim on which relief can be granted.

Defendant argues its amended pleadings allege sufficient facts from which the court can reasonably infer that the § 1.131 Declaration's alleged misrepresentation of the applicants' date of reduction to practice was material to issuance of the LDR/PCR patents. "[A]s a general matter, the materiality required to establish inequitable conduct

⁸⁰ *Id.*, Ex. A at ¶ 20(d).

⁸¹ *Id.*, Ex. A at ¶¶ 20(b), 21(b)-21(f).

⁸² *Id.*, Ex. A at ¶ 21(h).

⁸³ *Exergen Corp.*, 575 F.3d at 1328-29 (Fed. Cir. 2009).

is but-for materiality.”⁸⁴ However, “[w]hen a patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.”⁸⁵

The court determines the § 1.131 Declaration was material to the issuance of the ‘470 patent. The Examiner found that Carrino, Zhang390, and Zhang924 “clearly disclose[d]” and anticipated the LDR/PCR method of independent claim 1 and dependent claims 3 and 4 of the ‘156 Application. In response, the applicants submitted the § 1.131 Declaration stating “[p]rior to June 22, 1994, [the applicants] conceived and diligently reduced to practice, in the United States, the invention claimed in the above-identified patent application.” As a consequence of the declaration, the Amendment asserted the Carrino, Zhang390, and Zhang924 references “cannot be prior art.” No attempt was made to distinguish those references from the claimed LDR/PCR method. After receiving the § 1.131 Declaration and the Amendment the Examiner issued the ‘470 patent despite the references previously cited in rejecting the claims. It is reasonable, therefore, that but for those submissions the patent would not have issued; there are no other apparent materials on which the Examiner could have based his reversal on patentability.

Plaintiffs, however, contend the statement in the § 1.131 Declaration was not

⁸⁴ *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011) (*en banc*).

⁸⁵ *Id.* at 1292 (citing *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983) (“there is no room to argue that submission of false affidavits is not material”); *Refac Int’l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1583 (Fed. Cir. 1996) (finding the intentional omission of declarant’s employment with inventor’s company rendered the affidavit false and that “[a]ffidavits are inherently material”)).

false or misleading.

The court finds that defendant's proposed amended pleading alleges plausible facts that the § 1.131 Declaration contained false or misleading information. As discussed above, to antedate alleged prior art the applicant must declare that the invention was reduced to practice prior to the date of the prior art in question or conceived of the invention prior to the date of the prior art in question, and then diligently acted from before the date of the prior art through actual or constructive reduction to practice.

Plaintiffs' rely on the use of the word "conception" and "diligent" in the § 1.131 Declaration statement attesting that "[p]rior to June 22, 1994, we conceived and diligently reduced to practice, in the United States, the invention claimed in the above-identified patent application" as evidence that the applicants were relying on the second part of Rule 1.131, i.e., not representing actual reduction to practice prior to June 22, 1994. Significantly, however, is the MPEP requirement that when relying on the second part of Rule 1.131 "the actual dates of acts relied on to establish diligence must be provided."⁸⁶ No such dates were provided. That no such information was provided, and the applicants' use of the conjunctive "conceived *and* diligently reduced to practice" "[p]rior to June 22, 1994," it is plausible that the Examiner understood that statement as a representation the applicants had actually reduced to practice the LDR/PCR methods. That plausibility is bolstered by the fact that the Examiner did not request information confirming "the actual dates of acts relied on to establish diligence."

⁸⁶ *Id.*, Ex. A at ¶¶ 21(c), 21(d).

The court agrees with defendant that much of plaintiffs' argument is based on pointing to other evidence they believe is inconsistent with defendant's allegations and reading of the § 1.131 Declaration. At the pleading stage, plaintiffs' evidence is irrelevant and the court can not address the merits of that evidence.⁸⁷ The court, therefore, finds defendant has sufficiently alleged the § 1.131 Declaration contains a material false or misleading misrepresentation.

Plaintiffs also allege defendant's proposed amended pleading fails to adequately plead specific intent to deceive the PTO. "Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence."⁸⁸ To meet the pleading standard, defendant "need only allege facts from which the Court could *reasonably infer* that the patent applicant made a deliberate decision to deceive the PTO."⁸⁹

Plaintiffs argue there can be no finding of deceptive intent, nor a reasonable inference of deceptive intent because Francis Barany and Matthew Lubin testified they believed the declaration to be true at the time of filing and that Michael Goldman also

⁸⁷ See *Cot'n Wash, Inc. v. Henkel Corp.*, 56 F. Supp. 613, 626 (D. Del. 2014) ("The fact that the plaintiffs disagree with the factual representation made by [the defendant] is irrelevant, as the court is not required to judge the merits of the parties' respective positions at this of the proceedings."); *Bayer Cropscience AG v. Dow Agrosciences LLC*, C.A. No. 10-1045-RMB-JS, 2012 WL 1253047, at *3 (D. Del. Apr. 12, 2012) ("[I]n this context the Court must accept as true [the defendant's] well-pleaded facts. The Court may not weight the facts and address the merits of [the plaintiff's] averments.").

⁸⁸ *Therasense*, 649 F.3d at 1290 (citing *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009)).

⁸⁹ *Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 WL 600715, at *7 (D. Del. Feb. 3, 2012) (emphasis in original); see also *id.* at *14 (noting that inequitable conduct claims are rarely disallowed "at the pleading stage due to the failure to adequately allege scienter").

testified he took steps to ensure that the inventors understood what the declaration, and the specific sentence at issue, meant before they signed the declaration.⁹⁰ Goldman also testified he would not have submitted a declaration that relied on a conception and a diligent reduction to practice if there had been an actual reduction to practice.⁹¹

Again, plaintiffs' argument relies on assertions of fact requiring the court to address the merits of the evidence which the court may not do at this stage of the proceedings.⁹² The court determines defendant has adequately plead specific intent to deceive the PTO. The Examiner had rejected the proposed claims. The applicants submitted the § 1.131 Declaration (without evidence demonstrating diligence) that the court determined plausibly could have been understood by the Examiner as attesting to an actual reduction to practice prior to June 22, 1994. The Examiner then allowed the claims. Francis Barany and Matthew Lubin testified the claimed LDR/PCR methods had not been reduced to practice prior to that date and Michael Goldman testified he knew at the time of filing the § 1.131 Declaration that there had not been actual reduction to practice. The court, therefore, rejects plaintiffs' argument that defendant did not adequately allege specific intent⁹³ and grants defendant's motion with respect to the '470 patent.

Finally, plaintiffs contend defendant failed to adequately plead the applicants'

⁹⁰ D.I. 429 at 8.

⁹¹ *Id.* at 10.

⁹² The court notes the cases addressing inequitable conduct relied on by plaintiffs are either on summary judgment or after trial.

⁹³ See, e.g., *eSpeed, Inc. v. Brokertec USA, LLC*, 417 F. Supp. 2d 580, 591 (D. Del. 2006) ("Intent need not be proven by direct evidence; it is most often proven by a showing of acts, the natural consequences of which are presumably intended by the actor.") (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995)).

and prosecuting attorney's purported misconduct with regard to the '156 Application and resulting '470 patent infects the continuation patents, i.e., the '434, '039, '865, '285, '858, '453, and '891 patents.

"[I]nequitable conduct 'early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application.'"⁹⁴ The court determines defendant has adequately plead that the those patents are also infected by the alleged misconduct in prosecuting the '470 patent. Defendant alleges those patents issued as continuations of, and claim priority to, the '156 Application and similarly claim LDR/PCR methods relating to the detection of nucleic acid sequence differences using coupled LDR and PCR.⁹⁵ Defendant also alleges that in prosecuting the continuation patents, the applicant largely relied on terminal disclaimers over prior art patents in the LDR/PCR family, such as the '470 patent, in response to obvious-type double patenting rejections.⁹⁶ According to defendant's pleading, those terminal disclaimers indicated the Examiner had found the continuation patents were closely related to the '470 patent and, therefore, could have been rejected over the Carrino, Zhang390, and Zhang924 references but for the purportedly false § 1.131 Declaration.⁹⁷ Accordingly, the court also grants defendant's motion with respect to the continuation patents.

⁹⁴ *Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006) (quoting *Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801, 804 (Fed. Cir. 1990)).

⁹⁵ D.I. 406, Ex. A at ¶¶ 17(a), 22.

⁹⁶ *Id.*, Ex. A at ¶ 22(b); see, e.g., *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998) ("If the application claim is not patentably distinct, in order to overcome the double patenting rejection, the applicant must file a 'terminal disclaimer,' forgoing that portion of the term of the second patent that extends beyond the term of the first.") (citing *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993)).

⁹⁷ D.I. 406, Ex. A at ¶ 22(b).

V. CONCLUSION

Consistent with the findings contained in the Report and Recommendation, IT IS RECOMMENDED that defendant's motion to amend (D.I. 405) be GRANTED.

Pursuant to 28 U.S.C. § 636(b)(1)(B), FED. R. CIV. P. 72(a) and D. DEL. LR 72.1, any objections to the Report and Recommendation shall be filed within fourteen (14) days limited to ten (10) pages after being served with the same. Any response is limited to ten (10) pages.

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 November 16, 2009, a copy of which is available on the court's website, www.ded.uscourts.gov.

Dated: May 27, 2016

/s/ Mary Pat Thyng
UNITED STATES MAGISTRATE JUDGE