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

INVISTA NORTH AMERICA S.À.R.L.,	)
and AURIGA POLYMERS INC.,	)
Plaintiffs	)
	)
v.	) Civil Action No. 11-1007-SLR-CJB
	)
M&G USA CORPORATION and	) DEDACTED MEDGION
M&G POLYMERS USA, LLC,	; REDACTED VERSION
	)
Defendants.	)

#### REPORT AND RECOMMENDATION

In this action by Plaintiffs INVISTA North America S.à.r.l. ("INVISTA") and Auriga Polymers Inc. ("Auriga") (collectively, "Plaintiffs") against Defendants M&G USA Corporation and M&G Polymers USA, LLC (collectively, "M&G" or "Defendants"), Plaintiffs allege infringement of U.S. Patent Nos. 7,943,216 (the "216 Patent"), 7,879,930 (the "930 Patent") and 7,919,159 (the "159 Patent") (collectively, the "patents-in-suit"). Presently pending before the Court is M&G's Motion for Leave to Amend the Pleadings, filed pursuant to Federal Rule of Civil Procedure 15(a), which seeks leave for M&G to amend to add claims and defenses asserting that the patents-in-suit are unenforceable based on inequitable conduct (the "Motion"). (D.I. 91) For the reasons that follow, I recommend that the Motion be DENIED.

Motions for leave to amend pleadings are typically treated as "non-dispositive" motions within the pretrial powers of a Magistrate Judge on referral. *Smith v. Delaware*, Civ. No. 07-600-JJF-LPS, 2009 WL 2175635, at \*1 n.2 (D. Del. July 21, 2009); *The Chase Manhattan Bank v. Iridium Africa Corp.*, No. Civ. A. 00-564 JJF, 2004 WL 725213, at \*1 (D. Del. Mar. 29, 2004). However, given the potential consequences that denial of permission to assert a claim may have on the outcome of a civil action, the Court is treating denial of the Motion as case-dispositive, therefore issuing a Report and Recommendation. *Smith*, 2009 WL 2175635, at \*1 n.2; *Chase Manhattan Bank*, 2004 WL 725213, at \*1.

## I. BACKGROUND

# A. The Parties and the Technology at Issue

Plaintiff INVISTA is a corporation organized and existing under the laws of Luxembourg, with its corporate headquarters located in Wichita, Kansas. (D.I. 7 at  $\P$  2) INVISTA, one of the world's largest integrated producers of polymers, is the owner of the patents-in-suit. (*Id.* at  $\P$  2, 8-10)

Plaintiff Auriga is a Delaware corporation with its principal place of business in Charlotte, North Carolina. (D.I. 37, ex. A at ¶ 3) Auriga, which produces and sells polyethylene terephthalate ("PET") products, is the exclusive licensee for the patents-in-suit. (*Id.*)

Defendant M&G USA Corporation is a Delaware corporation with its principal place of business in Apple Grove, West Virginia. (D.I. 7 at ¶ 3; D.I. 15 at 2, at ¶ 3) Defendant M&G Polymers USA, LLC, a wholly owned subsidiary of M&G USA Corporation, is a Delaware corporation with its principal place of business in Sharon Center, Ohio. (D.I. 7 at ¶ 4; D.I. 15 at 2, at ¶ 4) The M&G corporations are engaged in the business of manufacturing, offering to sell, selling, and/or exporting PET resins in and from the United States, including M&G's PoliProtect APB and PoliProtect JB products. (D.I. 7 at ¶¶ 11-12; D.I. 15 at 3, at ¶¶ 11-12)

The '159 Patent, entitled "Method to Make Single-Layer PET Bottles with High Barrier and Improved Clarity," was issued to INVISTA on April 5, 2011, and is based on Application No. 10/569,614 (the "159 Application"). ('159 Patent at 1) It lists four individuals (Zhenguo Liu, Sanjay Mehta, Xiaoyan Huang and David Schiraldi) as inventors. (*Id.*) According to the '159 Patent, glass and metal beverage bottles were increasingly being replaced by plastic bottles due to the lighter weight of plastic bottles, their decreased breakage compared to glass, and the

potentially lower costs of plastic. (*Id.* at 1:16-18) However, the polyesters used in these plastic bottles had a relatively high gas permeability; this caused a shorter shelf life for carbonated beverages like soda and oxygen-sensitive liquids like beer and fruit juices. (*Id.* at 1:18-21) Multilayer bottles, with inner layers comprised of a low gas permeable polymer and other layers comprised of polyesters, then entered the market, but these bottles had problems of their own, as their materials caused a haze and an increase in the yellowness of the container. (*Id.* at 1:22-26, 35-37) According to the '159 Patent, the prior art did not include a composition that yielded bottles with low gas barrier properties as well as improved color and clarity. (*Id.* at col. 1-2)

The '159 Patent claims compositions of a polyester and a partially aromatic polyamide with an ionic compatibilizer and a cobalt salt—a combination that purports to solve these problems. (*Id.* at Abstract) The claimed compositions are used in containers that have a long shelf life, such as beer bottles. (*Id.* at col. 2:48-52, 5:62-64) Compared to the prior art, the patent claims that these compositions yield greatly improved gas barrier properties and can be processed into containers with improved haze and reduced yellowness. (*Id.* at Abstract; col. 1:10-11; 2:58-60; 5:22-25)

The '216 Patent is a divisional of the '159 Patent; both patents share the same title and specification. The '216 Patent issued to INVISTA on May 17, 2011, and is based on Application No. 12/768,541 (the "'216 Application"). ('216 Patent at 1) The '216 Patent lists the same four individuals as inventors as does the '159 Patent. (*Id.*) Like the '159 Patent, the '216 Patent claims compositions used as gas barrier resins in containers requiring a long shelf life. (*Id.* at col. 1:17-22, 2:55-59)

The '930 Patent, entitled "Colored Oxygen Scavenging Polymers," issued to INVISTA on

February 1, 2011, and is based on Application No. 11/659,053 (the "930 Application"). ('930 Patent at 1) It lists Zhenguo Liu as the sole inventor. (*Id.*) The '930 Patent claims a melt blend resin of a base polymer, an oxidizable organic polymer, a transition metal salt catalyst and a colorant that is used for food packaging articles. ('930 Patent at Abstract; col. 1:7-20; 30-38) This patent explains that in the food packaging business, oxygen scavenging polymers are a well-known solution to the problem of oxygen entering into a food package and affecting the odor and taste of the food contained therein, as the polymers react with oxygen to reduce or eliminate these effects. (*Id.* at col. 1:30-38) While some colorants deactivate the catalyst, thus making them less effective as a barrier against the permeation of oxygen into the package, the '930 Patent teaches certain colorants that do not completely deactivate the catalyst, thus obviating the need for a costly process to separate the colorant and catalyst into different layers of the package. (*Id.* at 1:34-48, 2:25-43)

### B. Procedural Background

On October 21, 2011, INVISTA commenced this action, asserting that M&G infringes certain claims of the '216 Patent and the '930 Patent. (D.I. 1) On November 11, 2011, before M&G had answered, INVISTA amended its Complaint to add an additional claim of infringement of the '159 Patent. (D.I. 7 at ¶¶ 10, 36-45) INVISTA alleged that M&G infringed the patents-in-suit by (1) "making, using, selling, offering to sell, and/or importing PET products, including without limitation their PoliProtect APB and PoliProtect JB resins, covered by [certain claims of the '216 and '159 Patents]" and (2) by inducing their customers to infringe, or by contributing to their customers' infringement of certain claims of the patents-in-suit. (*Id.* at ¶¶ 22, 27, 32-33, 38, 43)

On December 1, 2011, M&G filed its answer to INVISTA's Amended Complaint, asserting eight defenses and six counterclaims, none of which included allegations of inequitable conduct.<sup>2</sup> (D.I. 15) On December 19, 2011, INVISTA filed its Answer to M&G's Counterclaims. (D.I. 17) On April 26, 2012, the parties filed a joint stipulation joining Auriga as a co-plaintiff in this action, (D.I. 52), which the Court entered on April 30, 2012.

On January 10, 2012, Judge Sue L. Robinson entered the Scheduling Order in this case, which required any motions to amend the pleadings relating to inequitable conduct to be filed on or before sixty days prior to October 5, 2012, the deadline for the close of fact discovery (i.e., by August 6, 2012). (D.I. 18 at ¶¶ 2(c), 4) On the same date, the Court was referred this case by Judge Robinson for the purposes of discovery and exploring alternative dispute resolution; this referral was later expanded to include referral of dispositive and nondispositive motions up to claim construction. (D.I. 45)

On August 6, 2012, the final day of the deadline set by the Scheduling Order, M&G filed the instant Motion. (D.I. 91) M&G's Motion was fully briefed as of September 17, 2012. (D.I. 114)

### II. STANDARD OF REVIEW

Rule 15(a) provides that, other than in certain circumstances where a party may amend a pleading as a matter of course, a party may do so "only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). The rule further explains that a court should "freely give leave [to amend the pleadings] when justice so requires." *Id.* In line with the

M&G later amended its Answer to add an additional defense and counterclaim of double patenting on March 29, 2012. (D.I. 42)

requirements of the Rule, the Third Circuit has adopted a liberal approach in allowing amendments under Rule 15, in order to ensure that "claim[s] will be decided on the merits rather than on technicalities." *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990); *see also Aerocrine AB v. Apieron Inc.*, Civ. No. 08-787-LPS, 2010 WL 1225090, at \*7 (D. Del. Mar. 30, 2010).

In accordance with the considerations set forth above, the "factors [that a court should] consider in weighing a motion for leave to amend are well-settled: (1) whether the amendment has been unduly delayed; (2) whether the amendment would unfairly prejudice the non-moving party; (3) whether the amendment is brought for some improper purpose; and (4) whether the amendment is futile." *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, Civ. No. 11-54-SLR, 2012 WL 2365905, at \*2 (D. Del. June 21, 2012) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)); *see also Grayson v. Mayview State Hosp.*, 293 F.3d 103, 108 (3d Cir. 2002).

#### III. DISCUSSION

M&G's proposed Second Amended Answer to Amended Complaint and Counterclaims pleads inequitable conduct in its ninth and tenth affirmative defenses, and in its seventh, eighth and ninth Counterclaims (collectively, M&G's "proposed inequitable conduct defense"). (D.I. 92, ex. A (hereinafter "Amended Answer")) Plaintiffs oppose M&G's motion on the sole basis that its proposed amendments would be futile—that M&G has failed to properly plead inequitable conduct. (*See* D.I. 103) Accordingly, the only Rule 15(a) factor that the Court must assess here is futility of amendment.

An amendment is considered futile if it could not withstand a motion to dismiss. *SRI*Int'l Inc., v. Internet Sec. Sys., Inc., 817 F. Supp. 2d 418, 423 (D. Del. 2011); Enzo Life Scis., Inc.

v. Digene Corp., 270 F. Supp. 2d 484, 489 (D. Del. 2003). Thus, the standard for assessing futility of amendment is the same standard of legal sufficiency that applies under Fed. R. Civ. P. 12(b)(6). In re Burlington Coat Factory Sec. Litig, 114 F.3d 1410, 1434 (3d Cir. 1997); Bayer Cropscience AG v. Dow Agrosciences LLC, Civil No. 10-1045 (RMB/JS), 2012 WL 1253047, at \*2 (D. Del. Apr. 12, 2012). A proposed amendment is futile when it fails to state a claim upon which relief may be granted, even after the court has accepted as true all well-pleaded allegations in the proposed amendment and reasonable inferences drawn from those allegations. In re Merck & Co., Inc. Sec., Derivative & ERISA Litig., 493 F.3d 393, 400 (3d Cir. 2007); Roquette Frères v. SPI Pharma, Inc., C.A. No. 06-540-GMS, 2009 WL 1444835, at \*3 (D. Del. May 21, 2009). In order for the proposed amendment to be permitted, the factual allegations therein must be enough, when taken as true, to state a claim for relief plausible on its face. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007); Bayer Cropscience, 2012 WL 1253047, at \*2. Determining whether a claim is plausible is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Ashcroft v. Igbal, 556 U.S. 662, 679 (2009). The Court may not weigh the facts nor address the merits of the case at this stage. Bayer Cropscience, 2012 WL 1253047, at \*3; Roquette Frères, 2009 WL 1444835, at \*3. When evaluating a proposed amendment for futility (just as when evaluating a motion to dismiss), the Court may generally only consider "the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993); TransWeb, LLC v. 3M Innovative Props. Co., Civil Action No. 10-4413 (FSH), 2011 WL 2181189, at \*10 (D.N.J. June 1, 2011).

It is well-settled that during the patent prosecution process, patent applicants and their

attorneys owe a duty of candor, good faith and honesty to the United States Patent Office ("PTO"). Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999) (citing 37 C.F.R. § 1.56(a)). "A breach of this duty may constitute inequitable conduct." Elk Corp. of Dallas, 168 F.3d at 30. "The substantive elements of inequitable conduct are: (1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the PTO." Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1327 n.3 (Fed. Cir. 2009) (citations omitted). A finding of inequitable conduct renders the entire patent unenforceable. Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988); Robert Bosch, LLC v. Pylon Mfg. Corp., 775 F. Supp. 2d 739, 744 (D. Del. 2011).

Although inequitable conduct is conceptually broader than fraud, any such allegations must be pled in accordance with Fed. R. Civ. P. 9(b), which requires that "the circumstances constituting fraud or mistake shall be stated with particularity." *Exergen*, 575 F.3d at 1326 (quoting *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003)). The Federal Circuit established the standard for evaluating the sufficiency of inequitable conduct allegations in *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009).<sup>3</sup> The *Exergen* Court held that:

[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

Whether a claim of inequitable conduct has been adequately pled is a question unique to patent law, and is therefore governed by Federal Circuit law. *Exergen*, 575 F.3d at 1318; *Bayer Cropscience*, 2012 WL 1253047, at \*2.

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.

*Id.* at 1328-29. Thus, "[a] pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation" is insufficient. *Id.* at 1326-27.

Following the Exergen decision, upon observing that claims of inequitable conduct had become a "plague" on the courts—indeed, on the entire patent system—the Federal Circuit again addressed inequitable conduct claims, this time in the context of the review of a district court's decision following a bench trial. Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276, 1289 (Fed. Cir. 2011). The *Therasense* Court established a stricter standard of proof for inequitable conduct claims. For one, the *Therasense* Court rejected the "sliding scale" approach to proving inequitable conduct utilized by a series of decisions, "where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa." Therasense, 649 F.3d at 1290. Instead, *Therasense* made clear that "[i]ntent and materiality are separate requirements." Id. Additionally, as to the first prong regarding materiality, Therasense held that absent evidence of "affirmative egregious misconduct," this prong requires a "but-for" showing. Id. at 1291-92. In other words, the party making an inequitable conduct claim must show that but for an omission or misrepresentation by the patent applicant, the PTO would not have allowed a patent claim to issue. Id. at 1291. And to satisfy the intent prong, Therasense held that a deliberate decision to make the misrepresentation or omission would be required. Id. at

1290 (emphasis added). "Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence." *Id.* However, to successfully prove inequitable conduct, *Therasense* reiterated that "the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence." *Id.* (quoting *Star Scientific, Inc.* v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

Therasense did impact the pleading of an inequitable conduct claim, in that, for example, its decision emphasized that intent and materiality must be viewed separately, and that a party must plead facts allowing for the reasonable inference that the information withheld from or misrepresented to the PTO was "but for" material. See, e.g., Evonik Degussa GmbH v. Materia Inc., Civil Action No. 09-cv-636, 2012 WL 4503771, at \*5-6 (D. Del. Oct. 1, 2012); Wyeth Holdings Corp. v. Sandoz, Inc., Civ. Action No. 09-955-LPS-CJB, 2012 WL 600715, at \*6 (D. Del. Feb. 3, 2012), report and recommendation adopted, 2012 WL 749378 (D. Del. Mar. 1, 2012). However, although Therasense also emphasized that specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence, that is a requirement to be met at the proof stage; at the pleading stage, pursuant to Federal Circuit precedent, a party must plead facts "from which the [c]ourt could reasonably infer that the patent applicant made a deliberate decision to deceive the PTO." Wyeth Holdings Corp., 2012 WL 600715, at \*6-9 (citing cases); see also XpertUniverse, Inc. v. Cisco Sys., Inc., 868 F. Supp. 2d 376, 379 & n.1 (D. Del. 2012) (same).

# A. M&G's Proposed Inequitable Conduct Defense Relating to the '159 and '216 Patents

The thrust of M&G's proposed inequitable conduct defense relating to the '159 and '216

Patents is that those responsible for the prosecution of these patents submitted incomplete and misleading internal test data to the PTO, and that they did so in order to bolster a false argument of synergy (i.e., that the claimed combination yields results in permeation, haze and yellowness values that would be unexpected), upon which patentability depended. (*See* Amended Answer) M&G argues that had the correct, complete test data been disclosed, the claims of the patents would not have issued, as this data showed that the compositions did *not* possess the unexpected results that the applicants had repeatedly touted to the PTO. (D.I. 92 at 5; Amended Answer at ¶73, 104-106)

During prosecution of the '159 Application, a PTO Examiner initially rejected all pending claims in that application for obviousness.<sup>4</sup> (Amended Answer at ¶ 78) The Examiner based her rejection on her belief that, at the time of filing, it would have been obvious for a person of ordinary skill in the art to combine certain prior art references—teaching compatibilization by use of a sulfonated copolyester to reduce gas permeation, haze and yellowing and that the addition of cobalt salts reduces the transmission of oxygen in polyester/MXD6 compositions—to arrive at the inventions with the same results. (*Id.*) In response, the applicants argued that the claimed combination was not obvious because it yielded unexpected results in the form of permeation, haze and yellowness values. (*Id.* at ¶ 79) Furthermore, the applicants asserted that the claimed combinations were not just additive of expected individual effects of a cobalt salt or an ionic compatibilizer in a polyester/nylon combination, but that when acting together, the combinations created a type of "super-additive, synergistic effect." (*Id.*)

M&G's proposed inequitable conduct defense relating to the '159 and '216 Patents, which share a common specification, focuses on the '159 Patent prosecution history.

In the course of attempting to overcome the Examiner's rejection, the applicants submitted various test data that measured variables including permeation, haze and yellowness of bottle preforms and bottles. (Amended Answer at ¶¶ 79, 82) These data related to the singular examples disclosed in the patents that support the patent claims. (*Id.* at ¶ 73) As to specific data that the applicants allegedly withheld or misrepresented, M&G identifies the following:

- Applicants submitted an incomplete subset of test data for eight combinations of four different components, despite possessing complete test data (id. at ¶ 83);
- The test data that applicants submitted with the applications failed to include many of the starting conditions necessary to reproduce the experiments (such as the amount of the many additives used in each PET base resin), which are important, because varying amounts of these additives can drastically alter the material characteristics of the resulting resin (id. at ¶¶ 84-85);
- Applicants disclosed regarding the raw test data, resulting in a greater purported difference than the test actually produced, and selectively cobbled together a portion of the disclosed values from the raw test data to make those values appear "as super-additive as possible" (id. at ¶ 87);
- Applicants failed to disclose the standard deviations associated with disclosed averages, (id. at ¶ 88);
- Applicants failed to disclose internal test data, including many similar test runs, that did not support their synergy argument and showed an "opposite effect" (id. at ¶ 90);
- Applicants' synergy argument was based on an alleged super-additive effect on the lowering of yellowness, measured by a "b\* value." (*Id.* at ¶ 91) In Example 2 (the results of which are provided in Table 4 of the '159 Application), the applicants deliberately inserted only the lowest value for both its preform b\* and bottle b\* values for Run 11 of Resin S1, in order to make a stronger argument for synergy. (*Id.* at ¶¶ 94-102) Although the internal test data reports preform and bottle \*b values for a masterbatch and a copolymer, Resin S1 is never identified as either. (*Id.*)

M&G alleges that the withheld information was material and had it been disclosed, the

'159 and '216 Patents would not have issued. (*Id.* at ¶¶ 72-73, 81, 104-106) M&G rests its argument that the applicants acted with specific intent to deceive the PTO on the materiality of the information, and on

. (*Id.* at ¶¶ 112-116) In sum,

M&G alleges that "[t]he highly material nature of Applicant's omission, combined with Applicant's repeated opportunities to cure the omission, and Applicant's motive to deceive" provide sufficient basis to reasonably infer that "Applicant failed to disclose the internal test data . . . because they had the specific intent to deceive the PTO." (*Id.* at ¶ 116)

# 1. Materiality

# a. Who, What, When, Where, and How

As an initial matter, the Court must examine whether M&G has adequately identified the "specific who, what, when, where, and how" of the alleged material omissions and misrepresentations. *See generally Exergen*, 575 F.3d at 1328; *Wyeth Holdings*, 2012 WL 600715, at \*9; *Aerocrine AB*, 2010 WL 1225090, at \*9. Analyzing M&G's allegations in the context of these categories, the "what" in this case refers to the internal test data outlined above, some of which was allegedly withheld from the PTO and some of which was allegedly misrepresented to the PTO, all (it is alleged) to craft the best possible synergy argument upon which patentability depended. (*Id.* at ¶¶ 82-106) The "when" refers to the duration of the prosecution of the patents, throughout which time the applicants are alleged to have repeatedly made material omissions and misrepresentations regarding synergy. (*Id.* at ¶¶ 72, 79, 81, 90, 104, 108-109, 112) The "where"—meaning where in the documents and test materials at issue the allegedly material information is found—is detailed in M&G's proposed Amended Answer,

which describes the data that was (or was not, but allegedly should have been) part of the asserted misrepresentations. (*Id.* at ¶¶ 83-84, 87-88, 94-103) As for the "how" element—how a reasonable examiner would have used the information allegedly concealed or misrepresented by the applicants—M&G asserts that the patents would not have been issued but-for the applicants' misrepresentations and omissions of internal test data, as that test data contradicted the synergy argument, and the patents were ultimately allowed because the Examiner accepted this argument. (*Id.* at ¶¶ 72-73, 104-106)

Of the categories above, the "when" element is sufficiently pled, in light of the nature of the allegations, which allege failure to disclose over the entirety of the patents' prosecution. As to the "what," "where" and "how," on the one hand, other than with respect to allegations regarding the data relating to Table 4, the allegations of misrepresented or withheld test data do have a generalized quality about them. That is, they are not particular to any test run; instead they appear alleged to relate to all testing that was eventually submitted regarding the '159 Application that measured variables including permeation, haze and yellowness. (*See, e.g.*, Amended Answer at ¶ 82) On the other hand, M&G's allegation is that the results of *all* of that test data was relevant to INVISTA's argument as to the unexpected synergistic effect of the claimed combinations on these variables, which was the basis for overcoming the Examiner's objections. (*Id.* at ¶ 78-80)

Assuming, however, that M&G has adequately pled the "what," "when," "where," and "how" of inequitable conduct, its pleading still clearly fails to sufficiently allege the "who." In order to do so, the accuser must "name the *specific individual* associated with the filing or prosecution of the application issuing as the [patent-in-suit], who both knew of the material

information and deliberately withheld or misrepresented it." Exergen, 575 F.3d at 1329 (emphasis added). This requirement is not satisfied by simply identifying individuals in a general averment, such as one that simply makes broad reference to all of the inventors and/or prosecuting attorneys. This is because a "broadly cast net around the inventors and those acting on their behalf... does not allow the court to reasonably infer that a specific individual both knew of the invalidating information and had specific intent to deceive the PTO." Senju Pharm. Co., Ltd. v. Apotex, Inc., Civ. No. 12-159-SLR, 2013 WL 444928, at \*7 (D. Del. Feb. 6, 2013) (finding that defendant failed to satisfy the Exergen pleading standard regarding "who" deceived the PTO where defendant alleged generally that "Senju [Pharma], Kyorin, the inventors and/or those acting on their behalf made the alleged misrepresentations and omissions before the PTO") (internal quotation marks and citation omitted); see also XpertUniverse, Inc., 868 F. Supp. 2d at 381 ("Dropping [inventor] Zelkin's name into the scrum of 'XU personnel including at least Abraham Zelkin or one or more of the other individuals listed as an inventor' fails to meet the pleading standard for 'who' deceived the PTO."); Sepracor Inc. v. Teva Pharm. USA, Inc., Civil Action No. 09-cv-01302 (DMC) (MF), 2010 WL 2326262, at \*6 (D.N.J. June 7, 2010) (finding that defendant failed to describe the specific "who" of inequitable conduct where it "generally referred to 'the patent applicants' and 'Sepracor' in its Amended Answer when discussing the materiality/intent of the alleged misrepresentation throughout its submission").5

See also Aevoe Corp. v. AE Tech. Co., Ltd., No. 2:12-cv-00053-GMN-NJK, 2013 WL 876036, at \*6 (D. Nev. Mar. 7, 2013) (finding that defendant's inequitable conduct counterclaim failed to adequately identify the "who" where defendant's allegations referred only to "the Applicants" and thus failed to identify any specific individual that knew of material information and deliberately withheld or misrepresented it); Everlight Elecs. Co., Ltd. v. Nichia Corp., Civil Action No. 12-cv-11758, 2012 WL 5389696, at \*4 (E.D. Mich. Nov. 2, 2012) (finding identification of four named inventors "and/or other persons who were substantially

Here, at the outset of its proposed inequitable conduct defense, M&G sets the stage by making the general allegation that:

As explained in detail below, Invista, and those responsible for prosecution of . . . the applications which issued as the '159 and '216 Patents [], specifically (collectively, "Applicant"), knowingly, and with an intent to deceive the PTO, repeatedly failed to disclose material information which related to the absence of synergistic, unexpected results, and upon which patentability hinged.

(Amended Answer at ¶ 72) In support of its assertion that it has sufficiently pled the "who" of inequitable conduct, (D.I. 114 at 2), M&G points to its above allegation, and to an allegation that states:

The '159 and '216 Patents name four inventors: Zhenguo Liu, Sanja Mehta, Xiaoyan Huang, and David A. Schiraldi. The attorneys who prosecuted the United States applications leading to the issuance of the '159 and '216 Patents were Gregory Clements, Charles E. Krukiel, and Craig M. Sterner, each engaged or employed by Invista at the time of prosecution. At all times during the prosecution of the applications, the Applicant and their agents and attorneys owed a duty of candor and good faith to the PTO with respect to the prosecution of the applications.

(Amended Answer at ¶ 77) M&G's remaining allegations of inequitable conduct, while referring generally to "Applicant," use pronouns that generically convey the involvement of multiple individuals. (See, e.g., id. at ¶ 88 ("Applicant chose not to report the standard deviations associated with the averages they did disclose.") (emphases added))

involved in the preparation or prosecution of the" patent application was insufficient to identify the "who," as an "all-encompassing identification of the entire universe of actors" was "precisely the type of overbroad allegation that the *Exergen* court ruled insufficient as a matter of law"); *Mitsubishi Heavy Indus., Ltd. v. Gen. Elec. Co.*, No. 6:10-cv-812-Orl-28KRS, 2012 WL 831525, at \*2 (M.D. Fla. Mar. 12, 2012) (finding that defendant's inequitable conduct counterclaim failed to adequately identify the "who," where "[l]ooking at the [proposed inequitable conduct defense allegations], it is impossible to determine who is alleged to have been engaged in deceptive conduct—one or more of the named or unnamed Applicants").

None of M&G's allegations tie specific conduct to any specific individual; instead, as to "who" engaged in misconduct before the PTO, every allegation is pled generally, with reference to "Invista," "Applicant," "they," and "their." (See Amended Answer) Therefore, for each allegation, it is impossible to discern exactly which individual or individuals M&G intends to implicate as having knowledge of the material information and to have had a deliberate intent to deceive. It is also notable that even in its briefing, M&G does no better at connecting specific conduct to specific people. (See, e.g., D.I. 114 at 3-4 ("M&G alleges that despite Invista's knowledge that internal test data was inconsistent and contradictory to the data presented to the PTO, and the arguments of synergy which accompanied it, Invista failed to disclose this information to the Examiner" . . . . [and] Invista failed to disclose this information with an intent to deceive the PTO.") (emphases added))

As noted above, in one instance at the outset of its proposed inequitable conduct defense, M&G identifies as the specific individual "responsible for prosecution" of the '159 and '216 applications. (Amended Answer at ¶ 72) However, the way in which M&G then proceeds to plead its proposed defense generally—relying exclusively on catch-all wording and plural pronouns—still leaves the Court guessing as to exactly who is said to have known and done what. Throughout the allegations, M&G alleges nothing specific to (or to anyone else). M&G's failure to "set forth the requisite factual allegations as to 'who' had actual knowledge of the false testing and misrepresented this to the PTO" is a fatal flaw of its proposed inequitable conduct defense. *Everlight Elecs. Co., Ltd. v. Nichia Corp.*, Civil Action No. 12-cv-11758, 2012 WL 5389696, at \*6 (E.D. Mich. Nov. 2, 2012); *see also Senju Pharm.*, 2013 WL 444928, at \*8 (stating that failing to meet the *Exergen* pleading standard as to who deceived the

PTO "is fatal under Rule 9(b)"); *Mitsubishi Heavy Indus., Ltd. v. Gen. Elec. Co.*, No. 6:10-cv-812-Orl-28KRS, 2012 WL 831525, at \*2 (M.D. Fla. Mar. 12, 2012) (explaining defendant's failure to meet the "who" requirement of pleading inequitable conduct, because it had "broadly referr[ed] to all those involved in the preparation and prosecution of the [] patent" as "Applicants", instead of "attribut[ing] a particular act or statement to a specific individual," and finding that the defense must be stricken "[o]n this ground alone"). This is because, due to M&G's general allegations in regard to *who* engaged in the conduct asserted, "there are *no facts* from which the [C]ourt can reasonably infer that *any individual* with knowledge of [the misrepresentations and omissions] *also* had knowledge of the falsity of any material misrepresentation and that the *same individual* misrepresented the information with a specific intent to deceive the PTO." *Senju Pharm.*, 2013 WL 444928, at \*8 (emphases added). Although M&G's proposed inequitable conduct defense can be found to be futile on this ground alone, the Court will also analyze M&G's allegations in light of the remaining requirements of inequitable conduct.

# b. Materiality and "But For" Causation

As to materiality and "but for" causation, M&G contends that the correct and complete internal test data was material information, as that data cut against the applicants' synergy argument. (Amended Answer at ¶¶ 104-105) It alleges that after repeated rejections of the synergy argument, the Examiner ultimately accepted it and allowed the patents to issue, based on the disclosed data; M&G thus asserts that "[t]he only reasonable inference to make . . . is that the '159 and '216 Patents would not have been issued but for Applicant's deceptive and fraudulent omissions." (Id. at ¶ 106)

Plaintiffs dispute that M&G has sufficiently pled materiality and "but for" causation. In doing so, they focus on the fact, referenced above, that only one of M&G's allegations calls out specific test data—those regarding Run 11 (as reported in Table 4)—and they take issue with M&G's assertion that the data reported in Table 4 had any real impact on the Examiner's decision as to patentability. (D.I. 103 at 15-16 (citing D.I. 103, ex. 7 at 6))

As to "but for" materiality, the Court's task is not to decide the merits of M&G's inequitable conduct claim, but rather to discern "whether materiality has been properly alleged with sufficient particularity." *Evonik Degussa*, 2012 WL 4503771, at \*6. That is accomplished if M&G "show[s] facts indicating that the PTO was particularly concerned with a representation, or that the truth, if presented to the PTO, would have rendered the invention unpatentable." *Human Genome Scis., Inc. v. Genentech, Inc.,* No. 2:11-cv-6519,-MRP (JEMx), 2011 WL 7461786, at \*4 (C.D. Cal. Dec. 9, 2011). Essentially, materiality and but-for causation equate to the "how" of inequitable conduct pleading; the defendant must "identify the basis on which the examiner would have rejected" the patent. *Aevoe Corp. v. AE Tech. Co., Ltd.*, No. 2:12-cv-00053-GMN-NJK, 2013 WL 876036, at \*8 (D. Nev. Mar. 7, 2013).

As noted above, M&G's allegations with regard to misrepresented or undisclosed test results are broader than just those relating to Table 4, and appear to relate to all test data disclosed relating to INVISTA's unexpected results/synergy argument. Plaintiffs acknowledge that the Examiner's initial rejection related to her failure to sufficiently "appreciate the applicants' unexpected results and synergy [arguments] at first"—arguments that INVISTA attempted to overcome prior to and after the rejection, by pointing to test results in various tables in the '159 Application. (D.I. 103 at 5-6, 15)

At this stage, the Court finds that M&G's allegations would be sufficient to establish "but for" materiality, in that: (1) the allegations relate to (an albeit broadly defined group of) test results set out in the '159 Application, which were submitted to support INVISTA's unexpected results/synergy argument; and (2) there are facts pled suggesting that the merits of this argument were significant to the Examiner's ultimate decision on patentability. Although Plaintiffs dispute how specifically related some of these facts were to the Examiner's ultimate acceptance of the synergy argument (and thus, the Examiner's decision on patentability), that dispute is one not meant to be resolved at the pleading stage. Bayer Cropscience, 2012 WL 1253047, at \*3 (finding defendant's materiality and but-for causation arguments sufficient where plaintiff's challenges failed to "appreciate the Court's standard of review at this stage of the proceedings" because they implicated factual disputes (for example, whether the patentability of the claims depended on the distinction relevant to defendant's inequitable conduct defense)); see also Butamax Advanced Biofuels, 2012 WL 2365905, at \*2-3 & n.3 (finding that defendant sufficiently pled inequitable conduct and disregarding plaintiff's disagreements with certain of defendant's factual representations (e.g., whether the plaintiff "disclosed all relevant information relating to its unexpected results"), as "the [C]ourt is not required to judge the merits of the parties' respective positions at this stage of the proceedings").

#### 2. Scienter

Plaintiffs also take issue with M&G's allegations of scienter, arguing that M&G has not alleged facts that give rise to a reasonable inference that or any other individual had (1) knowledge of the allegedly material undisclosed internal data, and (2) specific intent to deceive the PTO. For the following reasons, the Court agrees with Plaintiffs.

### a. Knowledge of the Allegedly Material Undisclosed Data

M&G's allegations regarding knowledge are scant. M&G alleges that "Applicant" knew of the withheld data because "the data they did disclose was specifically extracted from the withheld internal test data (which they possessed) for the sole purpose of filing the '159 Application." (Amended Answer at ¶ 108) M&G adds that "[b]oth the inventors and the prosecuting attorneys were necessarily conscious of this information." (*Id.*) As to knowledge of materiality, M&G asserts that "Applicant knew of the materiality of the withheld internal test data" because inconsistencies between that data and the disclosed data were "obvious on its face" and because the disclosed data was key to "Applicant['s]" argument regarding a "synergistic effect on the lowering of yellowness" and to overcoming the Examiner's rejections of the synergy argument. (*Id.* at ¶¶ 109-111) From these circumstances—the applicants' repeated synergy argument and emphasis on the disclosed data, coupled with their knowledge of withheld data—the only reasonable inference to be drawn, according to M&G, is that the applicants had knowledge of the materiality of the internal test data at issue. (*Id.* at ¶ 111)

The problem with these allegations circles back to the Court's findings with regard to M&G's insufficient pleading as to the "who" of inequitable conduct. This is probably best exemplified by looking to the case of the person who is called out most specifically in the proposed inequitable conduct defense (and even then, not in regard to any specific factual allegations). M&G fails to plead facts plausibly connecting the required knowledge to specifically, or to any other specific individual. M&G's statement that everyone involved in prosecution of the patents were "necessarily conscious" of the withheld information accomplishes very little. (*Id.* at ¶ 108) This is, in and of itself, the most general of factual

allegations, especially because in the preceding sentence, the basis for this "conscious[ness]" is ascribed to the "Applicant," who is said to have known of the withheld information because data "they" disclosed was extracted from the withheld data. (*Id.*)

Even if it can be reasonably inferred than any or all of the individuals who make up the "Applicant" knew of the allegedly withheld data, that is quite another thing from *knowing* that the material before the Examiner was incomplete and incorrect. M&G's bald claim that the materiality of the withheld data was "obvious on its face" is wanting in this regard, as it begs the question: "Obvious to who (and why)?" With no real facts pled that are specific to any individual, there is a clearly insufficient basis to reasonably infer that any particular person (such as for example) did in fact know of the materiality of this data, and intentionally failed to disclose the data or disclosed incomplete data. *See Senju Pharm.*, 2013 WL 444928, at \*7; *XpertUniverse, Inc.*, 868 F. Supp. 2d at 381; *see also Everlight Elecs.*, 2012 WL 5389696, at \*10 (finding that even if defendant was correct that certain of the data presented by plaintiff during prosecution was false, its inequitable conduct defense failed, because, *inter alia*, defendant "fail[ed] to offer any facts to support the inference that any particular individual knew" that such data was false).

Tellingly, as noted above, even after Plaintiffs highlighted M&G's failure to cite to any fact that would suggest that himself or any other specific individual had actual knowledge of the materiality of the data at issue, (D.I. 103 at 11-13), M&G's reply brief did no

Cf. Wyeth Holdings, 2012 WL 600715, at \*14 (finding that defendant sufficiently pled that specific employee of plaintiff had knowledge of misrepresented material information where that individual had signed a declaration in support of the patent application, had developed the manufacturing process for the drug at issue, and had made certain specific statements to the Examiner about the data at issue).

better at connecting knowledge of materiality to a *specific* person or persons. (*See* D.I. 114 at 3-4) M&G's allegations lack specific facts from which the Court may plausibly infer that \_\_\_\_\_, or any other particular individual, had the requisite knowledge required for a sufficient inequitable conduct pleading.

# b. Specific Intent to Deceive the PTO

To meet the threshold level of deceptive intent required to sufficiently plead inequitable conduct, the pleading must "contain specific factual allegations" showing that a specific individual with knowledge of the material information "decided to deliberately withhold it from the relevant examiner." *Exergen*, 575 F.3d at 1331. M&G hinges its specific intent argument on Applicant's repeated omissions of the allegedly material internal test data and or

(Amended Answer at ¶¶ 113-116) The Court finds, however, that M&G's allegations fail to provide a reasonable inference that (or any other specific individual) had a specific intent to deceive the PTO in connection with the prosecution of the '159 and '216 Patents.

First, as to M&G's reliance upon the alleged repeated omissions of material information to establish specific intent, *Therasense* dictated that materiality and intent must be evaluated separately. *Therasense*, 649 F.3d at 1290; *see also Bayer Cropscience*, 2012 WL 1253047, at \*5. Accordingly, in the pleading context as to a claim of inequitable conduct, "intent cannot be solely inferred from materiality." *Cellectis S.A. v. Precision Biosciences*, 883 F. Supp. 2d 526, 534 (D. Del. 2012) (citing *Therasense*, 649 F.3d at 1290). Therefore, even assuming materiality, M&G must offer some additional factual allegations regarding deceptive intent; that is, the Court "must find some other evidence that indicates that the applicant appreciated the information's

materiality." *Id.* (quoting *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F. 3d 724, 733 (Fed. Cir. 2010)). Again, in light of the fact that M&G's allegations do not specifically correlate any particular knowledge or activity to any particular person, they do not enable the Court to make this necessary inferential connection.

M&G attempts to bolster its allegation in this regard by pleading that "Applicant" had a "further motive to deceive the PTO" because of INVISTA and the patent applicants' "desire to acquire patent rights in the gas barrier market." (Amended Answer at ¶ 114) Detailing this alleged "further motive," M&G references (Id. at ¶ 115) M&G claims that in (Id.) Although M&G did not attach as an exhibit to its proposed Amended Answer, Plaintiffs appended it to their responsive brief. (D.I. 104, ex. 13) The Court agrees with Plaintiffs that

As INVISTA points out, (D.I. 103 at 14 n.7), the Court may rely on the content of the in resolving the motion (although not attached to M&G's proposed pleading), since the document is explicitly relied upon in M&G's proposed inequitable conduct defense. *See In re Burlington Coat Factory*, 114 F.3d at 1426.

. (*Id.* at 14) Significantly, after Plaintiffs raised these issues in their answering brief, M&G's reply brief made no effort to better explain how helps to establish a plausible claim regarding intent to deceive as to any specific individual.<sup>8</sup> (*See* D.I. 114 at 6-7)

In line with its overall failure to plead facts involving *specific individuals*, M&G's allegation associating with a showing of specific intent to deceive does not identify how sheds light on the deceptive intent of any particular person. The Court does not believe that M&G can satisfy its burden under *Exergen* by asserting that "Applicant" or INVISTA as a whole had a "desire to acquire patent rights in the gas barrier market," and then suggest that this general statement should reasonably lead to the inference that or any other individual, knowingly withheld or misrepresented material data because of a specific intent to deceive the PTO into issuing the '159 and '216 Patents. *See Mitsubishi Heavy Indus.*, 2012 WL 831525, at \*4 (finding that defendant failed to sufficiently allege scienter where there were "no allegations against specifically identified individuals but instead conduct attributed to a collection of individuals describes as 'Applicants'"). Without more, cannot do all the work M&G asks of it.

For the above reasons, the Court finds that, in regard to the '159 and '216 Patents, M&G has failed to sufficiently plead both the "who" of inequitable conduct as well as the scienter

Instead, the only mention M&G makes of Plaintiffs' argument about the insufficiency of is to assert that Plaintiffs "admit[ted] that referenced by M&G is 'factual support for M&G's allegations regarding intent to deceive the patent office." (D.I. 114 at 6-7 (citing D.I. 103 at 14)) But Plaintiffs did *not* admit that in their answering brief—in fact, they did the opposite, arguing that can provide no such support. (D.I. 103 at 14-15) M&G thereafter makes no further attempt to explain why Plaintiffs are wrong.

requirement. Accordingly, the Court finds that M&G's proposed Ninth Defense and Counts VII and IX of its Counterclaims are futile, as the factual allegations contained therein are simply not enough, even when taken as true, to state a claim that is plausible on its face.

## B. M&G's Proposed Inequitable Conduct Defense Relating to the '930 Patent

The substance of M&G's inequitable conduct allegations relating to the '930 Patent are more sparse than its allegations relating to the '159 and '216 Patents. M&G alleges that during prosecution of the '930 Application, "Applicant" knowingly, and with an intent to deceive the PTO, misrepresented internal test data by altering values prior to disclosing them to the PTO, and failed to disclose the correct data to the PTO throughout prosecution, even though patentability hinged on such information. (D.I. 92 at 5; Amended Answer at ¶ 119) M&G alleges that the '930 Patent covers a composition of materials that is not novel and exists in the prior art (i.e., the composition of a base polymer, an oxidizable organic polymer, a transition metal catalyst, and a colorant), and that patentability depended upon the applicants' discovery of previously unknown relationships among those materials that did not exist in the prior art. (Amended Answer at ¶ 123) In support of applicants' argument in this regard, M&G alleges that they presented the Examiner with test results that purported to compare the oxygen permeability of compositions containing various colorants to the oxygen permeability of a similar control composition. (Id.) Applicants also provided an analysis of those results, which they claimed showed that certain colorants deactivate the transition metal catalyst to a greater extent than others. (Id.)

Specifically, M&G alleges that the applicants strengthened their argument to overcome rejection in reliance on test data in Example 2, which purported to show a higher oxygen permeation in colorants exhibiting a coordination bond with the transition metal ion. (*Id.* at ¶

125) M&G asserts that the applicants put forth a two-pronged theory of novelty (represented by the comparison of two examples of two colorants) that would fail on a finding that either prong was not true, and if testing conditions were not consistent for every run. (*Id.* at ¶ 126) The applicants, M&G contends, in fact omitted "many relevant variables for the series of examples disclosed which prevent another to repeat their tests." (*Id.* at ¶ 127) Further, M&G alleges that the applicants misrepresented data that they did disclose, all in an effort to bolster their argument for patentability. (*Id.*) M&G points to the following instances of allegedly undisclosed test data:

- While the '930 Patent discloses that all of the bottles used in Example 1 were 0.6 liter bottles, this is false. M&G asserts that many bottles had volumes that were liters and the control bottle had a volume of liters, and that such differences have an effect on the differences in permeabilities (id. at ¶ 131);
- The '930 Patent is inconsistent as to when the oxygen permeability of all bottles was measured (i.e., many were tested at tested at some other time from zero hours up to the time from zero hours up to the tested at some other time from zero hours up to the tested at some othe
- While the '930 Patent discloses that all of the colorants tested were at a concentration level of 0.25 weight percent, this is false—many of the colorants tested had concentration values of weight percent, and these differences do not allow the results of different colorants tested to effectively be compared (id. at ¶ 133).

M&G alleges that the withheld information was material and had it been disclosed, the '930 Patent would not have issued. (*Id.* at ¶¶ 135-137) In support of its argument that "Applicant" acted with specific intent to deceive the PTO, M&G alleges that, in sum, "[t]he highly material nature of Applicant's omission, combined with Applicant's repeated opportunities to cure the omission, and Applicant's motive to deceive [as exemplified by the ] show that the single most reasonable inference for why Applicant failed to disclose the internal test data is because they had the specific intent to deceive the PTO." (*Id.* at

¶ 148)

This proposed inequitable conduct defense suffers from the same fatal flaws as described above in relation to the '159 and '216 Patents. For one, M&G has again failed to sufficiently identify the "who" of such inequitable conduct, never connecting specific conduct relating to prosecution of the '930 Patent to a specific individual or individuals. (*See* Amended Answer at ¶¶ 119-149) Instead, M&G repeatedly refers generally to "Applicant," defined in the same manner as above, and utilizes plural pronouns, never specifically linking (or any other specific individual) to the described misconduct. (*Id.*)

This failure, in turn, dooms M&G's allegations regarding the scienter requirements of inequitable conduct in relation to the '930 Patent, as it is impossible to discern from M&G's allegations the identity of the "specific individual associated with the filing or prosecution of the ['930 Patent] who both knew of the material information and deliberately withheld or misrepresented it." *Exergen*, 575 F.3d at 1329. For example, M&G contends in support of the knowledge requirement that "Applicant knew that the requisite scientific precision necessary to gain patent protection would require consistency and repeatability of variables and results between compared test resins" and that, armed with this knowledge, "Applicant purposefully changed the original values for bottle size, bottle age at testing, and concentration of colorant used to values that were all the same." (Amended Answer at ¶ 142) The Court, again, can only speculate as to who M&G means to implicate in the allegation, one that simply casts a broad net

M&G does the same in its briefing. (See, e.g., D.I. 114 at 8 ("M&G alleged that Invista misrepresented internal test data. . . . M&G specifically pled that Invista made further attempts to bolster its argument . . . . And, M&G specifically pled that Invista intended to deceive the PTO . . . .") (emphases added))

around every individual associated with prosecution of the patent (i.e., the inventor, Zhenguo Liu, and all three prosecuting attorneys). (See id. at ¶ 128) The same can be said about M&G's allegations regarding specific intent, which mirror its specific intent allegations relating to the '159 and '216 Patents (including the same attempt to bolster its argument by pointing to the ). (See id. at ¶¶ 144-148)

M&G's proposed inequitable conduct defense regarding the '930 Patent fares even worse than its allegations regarding the '159 and '216 Patents, in that it also fails to satisfy the materiality and "but-for" causation prong. M&G simply makes conclusory allegations that the withheld internal data is material, that it contradicts disclosed data, and that "[t]he sole reasonable inference to make from the aforementioned circumstances is that the '930 Patent would not have been issued but for Applicant's deceptive and fraudulent omissions of the correct internal data." (Id. at ¶ 137) However, M&G asserts no "facts indicating that the PTO was particularly concerned with a representation, or that the truth, if presented to the PTO, would have rendered the invention unpatentable." Human Genome Scis., 2011 WL 7461786, at \*4 (emphasis added). "Mere claims that the PTO would not have granted the patent had it known of the omission or misrepresentation are insufficient because they are conclusory legal conclusions under Iqbal"; instead, the "accused infringer must identify some fact that would make it plausible that the PTO would not have granted the patent but-for the misrepresentation." Id.; see also Aevoe Corp., 2013 WL 876036, at \*8 (finding that conclusory statements that if the examiner had knowledge of certain data, the patent-in-suit would not have issued, to be insufficiently particular to demonstrate materiality regarding inequitable conduct claim). At the stage of its allegations where M&G attempts to assert that certain undisclosed internal test data would, if

disclosed, have rendered the invention unpatentable, M&G's pleading falls back on attorney argument and conclusory statements. (Amended Answer at ¶¶ 131-133, 135-137) M&G's allegations contain insufficient factual content for the Court to reasonably infer that the allegedly withheld test data was "but for" material to patentability.

Accordingly, M&G has failed to sufficiently plead inequitable conduct for the '930 Patent. The factual allegations contained in M&G's Tenth Defense and Count VIII of its Counterclaims are simply not enough, even when taken as true, to state an inequitable conduct claim that is plausible on its face. Therefore, the Court thus finds that M&G's proposed amendment is futile.

#### IV. CONCLUSION

For the reasons set forth above, I recommend that M&G's motion (D.I. 91) be DENIED.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

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 at http://www.ded.uscourts.gov.

Because this Report & Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly

proposed, redacted version (if necessary) of the Report & Recommendation. Any such redacted version shall be submitted no later than May 3, 2013 for review by the Court. The Court will subsequently issue a publicly-available version of its Report & Recommendation.

Dated: April 30, 2013

Christopher J. Burke

UNITED STATES MAGISTRATE JUDGE

Christoper S. Bile