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

| | |
|---|---|
| THE MEDICINES COMPANY,<br><br>Plaintiff,<br><br>v.<br><br>TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD.<br><br>Defendants. | C.A. No. 09-750 (ER)<br>(Consolidated)<br><br>[redacted] |

**PLAINTIFF THE MEDICINES COMPANY'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS, STRIKE OR ALTERNATIVELY BIFURCATE DEFENDANTS APP PHARMACEUTICALS, LLC AND APP PHARMACEUTICALS, INC.'S ALLEGATIONS OF INEQUITABLE CONDUCT AND UNCLEAN HANDS**

*Of Counsel*

Edgar H. Haug
Porter F. Fleming
Angus Chen
Mark P. Walters
Gina M. Bassi
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

Frederick L. Cottrell, III (#2555)
cottrell@rlf.com
Laura D. Hatcher (#5098)
hatcher@rlf.com
Richards, Layton & Finger P.A.
One Rodney Square
920 N. King Street
Wilmington, DE 19801
(302) 651-7700

*Attorneys for Plaintiff*
*The Medicines Company*

Dated: August 8, 2011

## TABLE OF CONTENTS

TABLE OF AUTHORITIES ..... iii

SUMMARY OF ARGUMENT ..... 1

STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS ..... 3

STATEMENT OF FACTS ..... 4

ARGUMENT ..... 4

I. Legal Standards ..... 4

II. The Court Should Dismiss and Strike APP's Inequitable Conduct Allegations for Failure to State a Proper Claim Under *Exergen* ..... 5

A. APP's Inequitable Conduct Allegations Fail to Plead the Requisite Intent to Deceive That is Separate and Independent From Materiality ..... 6

B. APP's Inequitable Conduct Allegations Fail to Properly Plead Materiality ..... 10

1. APP's Inequitable Conduct Allegations Fail to Identify the Requisite "What" or "Where"—the Claim Limitations to Which the Alleged Omissions are Material ..... 10

2. None of APP's Three Theories of Inequitable Conduct Plead the Requisite "Why" or "How" the Allegedly Withheld Information is Material ..... 12

a. Theory #1: Allegedly Withheld Methods of Making Angiomax® ..... 12

b. Theory #2: Allegedly Withheld Experimental Data for Angiomax® ..... 13

c. Theory #3: Allegedly Withheld Prior Art and Inventorship Information ..... 14

III. The Court Should Dismiss and Strike APP's Unclean Hands Allegations for Failure to State a Legally Cognizable Claim ..... 15

IV. In the Alternative, the Court Should Bifurcate APP's Inequitable Conduct and Unclean Hands Allegations to Streamline the Case and Minimize Delay ..... 19

CONCLUSION ..... 20

## TABLE OF AUTHORITIES

**Cases**

*Aptix Corp. v. Quickturn Design Sys., Inc.*,
269 F.3d 1369 (Fed. Cir. 2001) ..... 2, 15

*Ashcroft v. Iqbal*,
129 S. Ct. 1937 (2009) ..... 4

*Broadcom Corp. v. Emulex Corp.*,
No. 710, Civ. 09-01058 (C.D. Cal. Aug. 1, 2011) ..... 18

*Buckman Co. v. Plaintiffs' Legal Comm.*,
531 U.S. 341 (2001) ..... 15

*Burlington Indus., Inc. v. Dayco Corp.*,
849 F.2d 1418 (Fed. Cir. 1988) ..... 6

*Ciena Corp. v. Corvis Corp.*,
210 F.R.D. 519 (D. Del. 2002) ..... 19

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

*FMC Corp. v. Manitowoc Co., Inc.*,
835 F.2d 1411 (Fed. Cir. 1987) ..... 10

*France Telecom S.A. v. Novell, Inc.*,
No. 02-437, 2002 WL 31355255 (D. Del. Oct. 17, 2002) ..... 18

*Fred Hutchinson Cancer Research Ctr. v. BioPet Vet Lab, Inc.*,
No. 10-616, 2011 U.S. Dist. LEXIS 68800 (E.D. Va. June 27, 2011) ..... 2, 8, 9

*In re Gabapentin Patent Litig.*,
649 F. Supp. 2d 340 (D.N.J. 2009) ..... 2, 15

*Jersey Asparagus Farms, Inc. v. Rutgers Univ.*,
No. 10-2849, 2011 U.S. Dist. LEXIS 58053 (D.N.J. May 31, 2011) ..... *passim*

*Keystone Driller Co. v. Gen. Excavator Co.*,
290 U.S. 240 (1933) ..... 18

*New Valley Corp. v. Corporate Prop. Assocs. 2 & 3*,
181 F.3d 517 (3d Cir. 1999) ..... 18

*Novo Nordisk A/S v. Caraco Pharm. Labs. Ltd.*,
601 F.3d 1359 (Fed. Cir. 2010) ..... 16, 17

*Nycomed US Inc. v. Glenmark Generics. Ltd.*,
No. 08-5023, 2010 WL 1257803 (E.D.N.Y. Mar. 26, 2010) ..... 15, 16

*S.O.I.TEC Silicon On Insulator Techs., S.A. v. MEMC Elec. Materials, Inc.*,
745 F. Supp. 2d 489 (D. Del. 2010) ..... 19

*Schwarz Pharma, Inc. v. Teva Pharms. USA, Inc.*,
No. 01-4995, 2005 WL 4158850 (D.N.J. Feb. 4, 2005) ..... 16, 17

*Sun Microsystems, Inc. v. Versata Enters.*,
630 F. Supp. 2d 395 (D. Del. 2009) ..... 4

*Therasense, Inc. v. Becton, Dickinson & Co.*,
Nos. 2008-1511, 2008-1512, 2008-1513, 2008-1514, 2008-1595,
2011 WL 2028255 (Fed. Cir. May 25, 2011) ..... *passim*

*United States v. Cooper*,
396 F.3d 308 (3d Cir. 2005) ..... 18

**Statutes**

21 U.S.C. § 337(a) ..... 16, 17

21 U.S.C. § 355(j)(5)(C)(i) ..... 18

21 U.S.C. § 355(j)(5)(C)(ii) ..... 17

**Rules**

Fed. R. Civ. P. 12(b)(6) ..... 4

Fed. R. Civ. P. 12(f) ..... 4

Fed. R. Civ. P. 42(b) ..... 19

Fed. R. Civ. P. 9(b) ..... 5

**Miscellaneous**

BLACK'S LAW DICTIONARY 265 (8th ed. 2007) ..... 11

## SUMMARY OF ARGUMENT

The Court should dismiss and strike APP Pharmaceuticals, LLC's and APP Pharmaceuticals, Inc.'s (jointly, "APP") inequitable conduct and unclean hands allegations in its First Amended Answers and Counterclaims (D.I. 500; D.I. 501)[1] for failure to state a claim for relief under Federal Rule of Civil Procedure 12(b)(6) and failure to state a sufficient defense under Federal Rule of Civil Procedure 12(f). APP's amended pleadings:[2]

- Fail to plead intent to deceive that is separate and independent from materiality;
- Fail to identify the claim limitations to which (i.e. what and where) the alleged material information is relevant;
- Fail to identify why and how the alleged withheld information is material; and
- Fail to state a legally cognizable claim for unclean hands in a patent suit.

For the avoidance of any doubt, the instant motion raises new law and deficiencies in APP's amended pleadings that were not previously before the Court in The Medicines Company's ("MedCo's") opposition to APP's motion for leave to amend (D.I. 181). (*Compare e.g. infra* Sec. II.B.2 *with* D.I. 444 at 37; *see also e.g. infra* Sec. II.A and Sec. V). In particular, since the briefing on APP's motion for leave, MedCo has identified a second case—a District of New Jersey case—that supports its position on inequitable conduct pleading standards, and also raises additional deficiencies in APP's pleadings, namely failure to plead "why" or "how" the allegedly withheld information is material. *See Jersey Asparagus Farms, Inc. v. Rutgers Univ.*, No. 10-2849, 2011 U.S. Dist. LEXIS 58053 (D.N.J. May 31, 2011) (Wolfson, J.).

---

[1] APP's amended pleadings for the two patents-in-suit contain virtually the same allegations for inequitable conduct (Seventh Additional Defenses and Counterclaim Count Four) and unclean hands (Eighth Additional Defense and Counterclaim Count Five). D.I. 500 is APP's answer to MedCo's complaint regarding U.S. Patent No. 7,582,727 ("the '727 patent"), while D.I. 501 is APP's answer to MedCo's complaint regarding U.S. Patent No. 7,598,343 ("the '343 patent").

[2] MedCo reserves the right to dispute the factual bases for the allegations in APP's pleadings.

APP's inequitable conduct allegations as set forth in its Seventh Additional Defense and Counterclaim Count Four of the amended pleadings fail to properly plead intent to deceive that is separate and independent from materiality, based on the pleading standards of *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009) in light of the Federal Circuit's *en banc* holding in *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511, 2008-1512, 2008-1513, 2008-1514, 2008-1595, 2011 WL 2028255 (Fed. Cir. May 25, 2011). *See also Jersey Asparagus Farms*, 2011 U.S. Dist. LEXIS 58053; *Fred Hutchinson Cancer Research Ctr. v. BioPet Vet Lab, Inc.*, No. 10-616, 2011 U.S. Dist. LEXIS 68800, at *13-14 (E.D. Va. June 27, 2011).

In addition, APP's inequitable conduct allegations fail to properly plead materiality. The allegations fail to specifically identify the claims and claim limitations to which the alleged omissions are material—the what and where of materiality. Further, the allegations fail to specifically identify why the alleged withheld information is material, and how the Examiner would have used the information. As recognized by the Special Master, these arguments were not referenced in connection with APP's motion for leave to amend. (*See* D.I. 444 at 37 (stating that MedCo did not challenge the pleading of "why" and "how" in opposing APP's motion)).

The Court should also dismiss APP's Eighth Additional Defense and Counterclaim Count Five, which pertain to APP's unclean hands allegations. APP's allegations concerning unclean hands fail to state a legally cognizable claim. Unclean hands based on conduct before FDA is not a recognized basis for a claim in a patent case. *See e.g., In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 348 (D.N.J. 2009) (citing *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1378 (Fed. Cir. 2001)).

Because APP's inequitable conduct and unclean hands allegations fail as a matter of law, they should be dismissed and stricken in their entirety. Alternatively, should the Court deem

APP's allegations permissible, those claims and defenses should be bifurcated to streamline the case and minimize delay of the resolution of the remaining issues in the case.

## STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS

MedCo sued APP for infringement of the '727 and '343 patents under C.A. Nos. 09-752 (ER) and 10-476 (ER), which were consolidated under C.A. No. 09-750 (ER). (D.I. 27; 10-476, D.I. 17). APP filed ANDA No. 90-189 ("APP's ANDA") and seeks approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic Angiomax® before the '727 and '343 patents expire. (09-752, D.I. 24 ¶¶ 14, 22; 10-476, D.I. 1 ¶¶ 14, 22).

On October 8, 2009, MedCo sued APP for patent infringement of the '727 patent. (09-752, D.I. 1). MedCo amended its complaint pursuant to the parties' stipulation on February 5, 2010. (09-752, D.I. 23-24). APP answered the amended '727 patent complaint on February 12, 2010. (09-752, D.I. 25). On June 1, 2010, MedCo sued APP for patent infringement of the '343 patent. (10-476, D.I. 1). APP answered the '343 patent complaint on June 28, 2010. (10-476, D.I. 7). On July 19, 2011, the Court granted APP leave to amend its original Answers and Counterclaims filed in C.A. Nos. 09-752 and 10-476 to add counterclaims and affirmative defenses of both inequitable conduct and unclean hands. (D.I. 494). APP served its amended Answers and Counterclaims on July 25, 2011. (D.I. 500; D.I. 501).

APP's amended pleadings differ from APP's original Answers and Counterclaims in that they include additional defenses and counterclaims of unenforceability due to (i) inequitable conduct based on three theories and (ii) unclean hands based on conduct before FDA. (*See* D.I. 500 & 501, Seventh & Eighth Additional Defenses and Countercl. Counts 4 & 5). Fact discovery in the consolidated case closed on July 29, 2011. (D.I. 426).

## STATEMENT OF FACTS

MedCo markets Angiomax®, a product approved for, among other things, use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty. Prior to the inventions in the '727 and '343 patents, Angiomax® was subject to inconsistent levels of an impurity known as $Asp^9$-bivalirudin. High levels of this impurity resulted in batch failures and rejections, which were costly and unpredictable. The inventors of the '727 and '343 patents overcame this problem by developing a manufacturing process that created consistent pharmaceutical batches, thereby avoiding failures and the associated costs.

## ARGUMENT

### I. Legal Standards

Under Rule 12(b)(6), a court should dismiss a pleading when the factual allegations fail to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). In evaluating a motion to dismiss, a court must accept all factual allegations as true and view them in the light most favorable to the moving party. *Sun Microsystems, Inc. v. Versata Enters.*, 630 F. Supp. 2d 395, 401 (D. Del. 2009) (citation omitted). For a pleading to survive dismissal, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citation omitted).

Under Rule 12(f), a court should "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "Motions to strike serve 'to clean up the pleadings, streamline litigation, and avoid unnecessary forays into immaterial matters.'" *Sun Microsystems*, 630 F. Supp. 2d at 402 (citation and internal quotation marks omitted). "When ruling on a motion to strike, the court must construe all facts in favor of the nonmoving party and deny the motion if the defense is sufficient under law." *Id.*

## II. The Court Should Dismiss and Strike APP's Inequitable Conduct Allegations for Failure to State a Proper Claim Under *Exergen*

APP's inequitable conduct allegations fail to state a proper claim for relief. The allegations in the Seventh Additional Defense and Counterclaim Count Four of APP's First Amended Answers and Counterclaims fail to meet the Federal Circuit's heightened pleadings standards. In particular, APP's pleadings fail to allege with particularity: (i) a specific intent to deceive that is separate and independent from materiality; (ii) what claim limitations are relevant to what allegedly material information; or (iii) why the allegedly withheld information is material and how the Examiner would have used it to assess the patentability of the claims.

"Inequitable conduct, while a broader concept than fraud, must be pled with particularity under Rule 9(b)." *Exergen*, 575 F.3d at 1326 (citation and internal quotation marks omitted). Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Further, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id.* However, the pleadings must "allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind." *Exergen*, 575 F.3d at 1327 (emphasis added). Specific factual allegations are required to show that the accused knew of the specific information that is alleged to be material and then decided to deliberately withhold it. *Id.* at 1331. In the absence of such allegations it is not permissible to draw any inference of deceptive intent. *Id.* The mere knowledge of information and failure to disclose such information is insufficient to infer a deliberate withholding or an intent to deceive. *Id.*

"Whether inequitable conduct has been pleaded with particularity under Rule 9(b) is a question governed by Federal Circuit law." *Exergen*, 575 F. 3d at 1318. "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." *Id.* at 1327 n.3 (citations omitted) (emphasis added). "In sum, to 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." *Id.* at 1328 (emphasis added). Failure to identify all of these particulars is fatal. *Id.* at 1329-31.

Inequitable conduct allegations can result in "unforeseen and unintended consequences," such as "expand[ed] discovery into corporate practices." *Therasense*, 2011 WL 2028255, at *7. In particular, "inequitable conduct charges cast a dark cloud over the patent's validity and paint the patentee as a bad actor... [T]he doctrine focuses on the moral turpitude of the patentee with ruinous consequences for the reputation" of the patent applicants. *Id.* (emphasis added). "The habit of ***charging*** inequitable conduct in almost every major patent case has become an absolute plague" on the patent system. *Id.* at *8 (quoting *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (emphasis added)).

The factual allegations of inequitable conduct in APP's amended pleadings are deficient as a matter of law. They fail to state a claim of inequitable conduct as required by the Federal Circuit. APP's charges of inequitable conduct should be dismissed and stricken.

### A. APP's Inequitable Conduct Allegations Fail to Plead the Requisite Intent to Deceive That is Separate and Independent From Materiality

APP's allegations of intent to deceive are insufficient in view of the Federal Circuit's pleading standards for inequitable conduct and should be dismissed. In addressing the "absolute plague" of "charging" (i.e. pleading) inequitable conduct the Federal Circuit recently "tighten[ed] the standards for finding both intent and materiality." *Therasense*, 2011 WL

2028255, at *8-9. The Court expressly held that "[i]ntent [to deceive] and materiality are separate requirements." *Id.* at *10. In so holding, the Court abandoned a "sliding scale" approach, "where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa." *Id.* "[A] district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality." *Id.* (emphasis added). Further, "that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive." *Id.* (emphasis added).

The Federal Circuit's mandate in *Therasense* impacts the requirements for pleading intent to deceive for inequitable conduct under the heightened standards of *Exergen.* Following *Therasense*, specific intent to deceive under *Exergen* must be pled separately and independently from materiality. Since the parties' briefing on APP's motion for leave to amend (D.I. 181), MedCo has become aware of two recent district court decisions—including one in the Third Circuit—that have expressly relied upon *Therasense* for this proposition at the pleading stage.

In *Jersey Asparagus Farms*—which has not been considered by this Court previously—the District Court for the District of New Jersey granted the patentee's motion to dismiss the second amended complaint for "fail[ing] to sufficiently allege scienter." *Jersey Asparagus Farms*, 2011 U.S. Dist. LEXIS 58053, at *47. The pleading at issue concerned allegations of fraud on the U.S. Patent & Trademark Office. *Id.* at *27-28. The patentee successfully challenged the infringer's failure to properly plead intent. *Id.*

Notably, the court in *Jersey Asparagus Farms* also commented that while "*Therasense* does not address the initial pleading stage," the focus of *Therasense* nevertheless is "to sharpen the inquiry in order to weed out frivolous inequitable conduct-based claims." *Id.* at *46

(emphasis added). In evaluating whether intent was properly pled, the court looked to the Federal Circuit's instruction in *Therasense*:

> [T]he language of Therasense is ***emblematic*** of the increasingly ***strict*** approach the Federal Circuit is taking toward fraud-on-the-PTO ***allegations***.

*Id.* at *43-44 (emphasis added). The court concluded that the allegations failed to sufficiently allege scienter: "Plaintiff must carefully craft its allegations to satisfy the Federal Circuit's dictates regarding both scienter and materiality." *Id.* at *47-48 (emphasis added). The conclusion that intent was insufficiently pled expressly considered "the recent narrowing of the inequitable conduct doctrine by *Therasense*." *Id.* at *47.

Similarly, in the *Fred Hutchinson* case, the court granted a motion to dismiss inequitable conduct allegations in an amended complaint for failure to state a claim for relief. *Fred Hutchinson*, 2011 U.S. Dist. LEXIS 68800, at *13-14. The court concluded, *inter alia*, that the allegations of intent were insufficient in view of the requirements under *Therasense*, as they "failed to provide factual allegations that would prove by clear and convincing evidence" that the applicants "knew of the reference, knew that it was material, *and* made a deliberate decision to withhold it." *Id.* at *13 (quoting *Therasense*, 2011 WL 2028255, at *9-10) (emphasis in original). The pleading alleged that because (i) the product market was worth millions of dollars per year, (ii) the inventors had knowledge of undisclosed prior art, and (iii) evidence supported the inventors' knowledge of the materiality of the prior art coupled with their nondisclosure of it, "upon information and belief" the inventors' oaths were submitted with specific intent to deceive. *Id.* at *13-14. The court concluded that such a pleading of intent was insufficient:

> However, these allegations merely invite speculation about specific intent rather than alleging any facts pertaining to knowledge of the reference and its materiality along with a deliberate decision to withhold it.

*Id.* at *14 (emphasis added). As such, the pleading "lacks the specificity required under Rule 9(b) as to the specific intent element of inequitable conduct." *Id.*

Like *Jersey Asparagus Farms* and *Fred Hutchinson*, APP's allegations of intent fail to state a claim because they fail to satisfy the Federal Circuit's pleading requirements. APP's allegations at best merely invite speculation rather than allege facts of an intent to deceive.

APP's allegations of intent to deceive are dependent—not separate—from its allegations of materiality. This is fatal to APP's pleadings. All three of APP's theories of inequitable conduct consist of a single conclusory paragraph containing intertwined statements of materiality and intent that (i) the allegedly withheld information was "highly material"; (ii) the inventors "must have known" about the materiality; and (iii) "no plausible explanation" exists for why the information was not disclosed to the Examiner. (D.I. 500 ¶¶ 116, 125, 133; D.I. 501 ¶¶ 115, 124, 132). APP has failed to allege an intent to deceive that is separate and independent from materiality. *See Jersey Asparagus Farms*, 2011 U.S. Dist. LEXIS 58053, at *47-48; *Fred Hutchinson*, 2011 U.S. Dist. LEXIS 68800, at *14.

Moreover, APP's amended pleadings fail to allege any facts of a "deliberate decision" by either inventor to withhold the allegedly material information, which is "a necessary predicate for inferring deceptive intent." *Exergen*, 575 F.3d at 1331 (emphasis added) (citation omitted)); *see also Fred Hutchinson*, 2011 U.S. Dist. LEXIS 68800, at *14 (stating that the defendant "has not alleged any facts indicating that the co-inventors knew of a material reference and made a *deliberate decision* to withhold it" (emphasis in original)). APP's assertion that "no plausible explanation" exists for the alleged non-disclosure fails to support an inference of intent. *Exergen*, 575 F.3d at 1331; *Therasense*, 2011 WL 2028255, at *10. Absent specific factual allegations showing knowledge of the purportedly material information and a deliberate decision

to withhold such information, there can be no such inference, "lest inequitable conduct devolve into a 'magic incantation to be asserted against every patentee' and its 'allegation established upon a mere showing that art or information having some degree of materiality was not disclosed.'" *Exergen*, 575 F.3d at 1331 (quoting *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987)).

In addition, with respect to APP's allegations concerning its third theory of inequitable conduct (failure to disclose prior art), APP fails to allege any facts concerning what the inventors knew or believed concerning the information disclosed by the alleged "prior art" identified by APP. Without alleging anything beyond that [redacted] an allegation of intent to deceive is insufficient because "one cannot assume that an individual, who generally knew that a reference existed, also knew of the specific material *information* contained in that reference." *Exergen*, 575 F.3d at 1330 (emphasis in original). [redacted] (D.I. 500 ¶ 131; D.I. 501 ¶ 130). APP's factual allegations of intent, therefore, rely upon the materiality of the omitted information and do not provide an independent factual basis for the alleged intent to deceive. Such allegations are inappropriate. *See Therasense*, 2011 WL 2028255, at *10. Accordingly, APP's allegations of intent to deceive are insufficient as a matter of law and should be dismissed and stricken.

### B. APP's Inequitable Conduct Allegations Fail to Properly Plead Materiality

#### 1. APP's Inequitable Conduct Allegations Fail to Identify the Requisite "What" or "Where"—the Claim Limitations to Which the Alleged Omissions are Material

APP's allegations concerning materiality are also insufficient in view of the Federal Circuit's pleading standards for inequitable conduct and should be dismissed. To satisfy the materiality element of inequitable conduct, a pleading must "identify which claims, and ***which***

***limitations*** in those claims, the withheld references are relevant to, and where in those references the material information is found—i.e., the 'what' and 'where' of the material omissions." *Exergen*, 575 F.3d at 1329 (emphasis added).[3]

Here, APP's amended pleadings fail to address any claim limitation, let alone with particularity. The pleadings merely generally allege that the "patent claims" would not have issued but for the inventors' material misrepresentations or omissions. (D.I. 500 ¶¶ 45, 114, 123; D.I. 501 ¶¶ 44, 113, 122). Such allegations clearly do not comport with the pleading requirements of *Exergen*. 575 F.3d at 1329. To argue generally that claims would not have issued is irrelevant and does not address the required analysis of what claim limitations are relevant to the allegedly material information.

Specifically, none of APP's three theories of inequitable conduct identify which claim limitations to which the allegedly withheld material information is relevant. With respect to the first theory regarding methods of making Angiomax®, APP's allegations fail to describe which limitation(s) in the claims in the patents-in-suit are relevant to these processes. (D.I. 500 ¶¶ 110-116; D.I. 501 ¶¶ 109-115). In particular, the '727 patent contains composition claims—not process claims. (D.I. 500 ¶¶ 88-89). APP's allegations also fail to describe which limitation(s) in the claims are relevant to the specific data in its second theory regarding experimental results. (D.I. 500 ¶¶ 117-125; D.I. 501 ¶¶ 116-124). And, finally, APP's allegations fail to describe which limitation(s) in the claims of the patents-in-suit are relevant to the allegedly withheld prior art in its third theory. Accordingly, APP's Amended Answers and Counterclaims fail to plead with particularity the requisite "what" and "where" of APP's inequitable conduct allegations.

[3] A claim limitation is a term or phrase in a claim that "define[s] the invention by distinguishing it from prior art." BLACK'S LAW DICTIONARY 265 (8th ed. 2007).

APP's allegations of materiality are deficient as a matter of law. Accordingly, APP's inequitable conduct defenses should be stricken and its corresponding counterclaims dismissed.

### 2. None of APP's Three Theories of Inequitable Conduct Plead the Requisite "Why" or "How" the Allegedly Withheld Information is Material

Even accepting APP's inequitable conduct allegations as true, they nevertheless fail to satisfy the pleading requirements for materiality. Under *Exergen*, the identification of "the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record" is necessary "to explain both 'why' the withheld information is material ... and 'how' an examiner would have used this information in assessing the patentability of the claims." *Exergen*, 575 F.3d at 1329-30 (emphasis added). As explained *infra*, none of APP's three theories of inequitable conduct meet this standard because the facts alleged do not identify the requisite "why" or "how." These deficiencies were not previously before the Court in the parties' briefing on APP's motion for leave to amend its pleadings.

#### a. Theory #1: Allegedly Withheld Methods of Making Angiomax®

APP's first theory of inequitable conduct asserts that the inventors purportedly misrepresented and omitted information concerning methods used to make Angiomax®. (D.I. 500 ¶ 110; D.I. 501 ¶ 109). According to APP, [redacted] (D.I. 500 ¶ 112; D.I. 501 ¶ 111). On this basis, APP alleges that these documents show [redacted]

[redacted] (D.I. 500 ¶ 113; D.I. 501 ¶ 112).

Notably absent from APP's allegations is an explanation of why this information was material or how the Examiner would have used the allegedly withheld documents to reject the claims of the patents-in-suit. Indeed, other allegations in APP's pleadings contradict APP's assertion that the "old" and "new" processes for making Angiomax® are similar.

For example, APP's own allegations show [redacted] (D.I. 500 ¶ 62; D.I. 501 ¶ 61). The patents-in-suit, however, describe the new process as a method which, *inter alia*, involves a controlled rate of addition of the base using a peristaltic pump. (D.I. 500 ¶ 100; D.I. 501 ¶ 99). Further, the arguments made to the Examiner regarding the differences between the processes focused on the control of the base-addition step. (D.I. 500 ¶ 103; D.I. 501 ¶ 102 (APP's allegations contrasting the old process addition of base "either all at once, or rapidly in multiple portions" with the new process addition of base "at a controlled rate")).

In light of APP's other allegations demonstrating that the processes are different, APP's pleadings fail to explain how the Examiner would have used the information concerning the [redacted] to assess patentability of the claims. On their face, APP's allegations fail to comply with the "why" or "how" requirements of *Exergen*. 575 F.3d at 1329-30.

**b. Theory #2: Allegedly Withheld Experimental Data for Angiomax®**

APP's second theory of inequitable conduct asserts that the inventors purportedly

misrepresented and failed to disclose experimental results of Angiomax® batches. (D.I. 500 ¶ 117; D.I. 501 ¶ 116). APP alleges, *inter alia*, that the inventors misrepresented the data from the "old" and "new" process Angiomax® batches. (D.I. 500 ¶¶ 118-121; D.I. 501 ¶¶ 117-120).

Again, APP's allegations fail to identify why this information was material or how the Examiner would have used the allegedly withheld data in evaluating the claims of the patents-in-suit. APP's factual allegations are also inconsistent on their face. For example, with respect to the "old" process data, the allegations fail to explain how the underlying data for the old process Angiomax® batches is material in light of the summary table, Table 6, in the patents-in-suit, which expressly discloses that the mean (average) values of the impurities and reconstitution times for the Angiomax® batches made under the old process were less than the limits of the patents' claims. For example, the mean value of the $Asp^9$-bivalirudin impurity in the old process batches was 0.5%, i.e., less than 0.6%. (D.I. 500 ¶ 97; D.I. 501 ¶ 96). The failure to explain how the allegedly withheld information is material in light of the disclosure of the patent fails to satisfy the requisite pleading of "why" or "how" under *Exergen*. 575 F.3d at 1329-30.

**c. Theory #3: Allegedly Withheld Prior Art and Inventorship Information**

APP's third theory of inequitable conduct asserts that the inventors purportedly withheld prior art concerning inventorship, and then made material misrepresentations pertaining to inventorship. (D.I. 500 ¶ 126; D.I. 501 ¶ 125). APP alleges that [redacted] (D.I. 500 ¶ 127; D.I. 501 ¶ 126).

APP fails to plead why the allegedly withheld information is relevant or how it would have been used by the Examiner to reject the claims. Indeed, APP's allegations are contradicted by later pleaded facts. [redacted]

[redacted] (D.I. 500 ¶¶ 63-64, 66; D.I. 501 ¶¶ 62-63, 65). The process was subsequently optimized into the new process. (D.I. 500 ¶ 103; D.I. 501 ¶ 102). Thus, the alleged facts indicate that the manufacturing changes suggested [redacted] were not the "new" process. APP's failure to explain how the allegedly withheld information is material in light of these contradictory facts is fatal to its pleadings. *Exergen*, 575 F.3d at 1329-30.

## III. The Court Should Dismiss and Strike APP's Unclean Hands Allegations for Failure to State a Legally Cognizable Claim

APP's First Amended Answers and Counterclaims fail to state a legally cognizable claim for unclean hands. There is no basis in a patent litigation suit for claims based on conduct before the FDA, as alleged in APP's Eighth Additional Defenses and Counterclaim Counts Five. (D.I. 500; D.I. 501). A private party cannot bring a suit to enforce another party's compliance with the FDA's requirements. The Hatch-Waxman statute provides only a limited carve-out to correct patent information, and does not permit private actions for alleged FDA regulation violations.

Count Five of APP's amended counterclaims fails as a matter of law because "unclean hands ***cannot*** form the basis for a declaration of unenforceability of a patent." *In re Gabapentin Litig.*, 649 F. Supp. 2d at 348 (emphasis added) (citing *Aptix*, 269 F.3d at 1378).[4] Because a party cannot affirmatively assert unclean hands against a patentee, APP's counterclaims for unenforceability based on unclean hands should be dismissed. A private party cannot enforce alleged violations of the Federal Food Drug and Cosmetic Act ("FFDCA"), the FDA's governing statute, under the guise of a private cause of action. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341. 349 n.4 (2001) ("[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions" (emphasis added)); *see also Nycomed U.S. Inc. v. Glenmark Generics. Ltd.*,

[4] The *Aptix* case was not previously considered by the Court.

No. 08-5023, 2010 WL 1257803, at *6 (E.D.N.Y. Mar. 26, 2010) (discussing Federal Circuit case law separating alleged misconduct before the FDA from defenses in private actions). This prohibition is fundamental and based in statute. 21 U.S.C. § 337(a) ("Except as provided in subsection (b) [allowing a state to bring certain actions in its own name], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). *Nycomed* makes clear that a private party ***cannot*** enforce violations of the FFDCA. 2010 WL 1257803, at *6; *cf. Schwarz Pharma, Inc. v. Teva Pharms. USA, Inc.*, No. 01-4995, 2005 WL 4158850, at *3 (D.N.J. Feb. 4, 2005) (Debevoise, J.) (concluding that defendant ANDA holder was unable to assert the equitable defense of patent misuse based upon a wrongful Orange Book listing by plaintiff).

The passage of 21 U.S.C. § 355(j)(5)(C)(ii) in 2003 ("the 2003 Amendment") did not change this broad statutory separation. While the Federal Circuit recently acknowledged that prior to the 2003 Amendment, "private litigants could not challenge FDA submissions at all," the Federal Circuit held that "the 2003 Amendment sought to correct the specific issue raised in *Mylan*, i.e., to deter pioneering manufacturers from listing patents that were not related at all to the patented product or method." *Novo Nordisk A/S v. Caraco Pharm. Labs. Ltd.*, 601 F.3d 1359, 1365 (Fed. Cir. 2010). In *Novo Nordisk*, the Federal Circuit stated:

> The Hatch-Waxman Act provides a ***limited*** counterclaim to a generic manufacturer in a Paragraph IV infringement action. The Act authorizes the generic manufacturer to assert a counterclaim "on the ground that the patent does not claim either (aa) the drug for which the application was approved; or (bb) an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

*Novo Nordisk*, 601 F.3d at 1364 (emphasis added). Construing the 2003 Amendment, the Court instructed that "the counterclaim provision ***only authorizes*** suits to correct or delete an erroneous patent number or expiration date." *Id.* at 1366. In other words, the Hatch-Waxman Act only

authorizes counterclaims to correct listing of patent information in the Orange Book. The 2003 Amendment only covers a limited amount of subject matter, clearly otherwise leaving in place the general statutory prohibition against private enforcement actions. *Id.* Here, APP has already asserted separate counterclaims for delisting (D.I. 500 & 501, Countercl. Count 3.

The ruling in *Schwarz* is consistent with Federal Circuit case law. Senior Judge Debevoise appreciated that the 2003 Amendment did not upset the prohibition against private suits to enforce the FFDCA: "[t]he statute does not create a counterclaim asserting the defense of misuse of the patent in a patent infringement action for alleged improper listing of the patent." *Schwarz*, 2005 WL 4158850, at *7 n.1. In other words, the Hatch-Waxman Act does not create a counterclaim for any equitable defenses or remedies other than correcting Orange Book patent listing information. Likewise, a private party cannot bring a counterclaim to assert the defense of unclean hands based on improper listing as such a claim is not cognizable under the law.

Further, the FFDCA ***expressly*** and impliedly restricts the court's jurisdiction in equity. As described above, 21 U.S.C. § 337(a) provides that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). The unfettered ability to bring suits in equity clearly conflicts with this provision of the FFDCA. What is more, as reinforced by the Federal Circuit in *Novo Nordisk*, the 2003 Amendment is narrow in scope. *Novo Nordisk*, 601 F.3d at 1364.

Basic principles of statutory construction further demonstrate that unclean hands based on improper listing is not a legally cognizable claim. Indeed, the 2003 Amendment does not once refer to unclean hands and specifically states: "Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I)." 21 U.S.C. § 355(j)(5)(C)(ii). The statute refers to a

"claim described in subclause (I)," demonstrating the intention to limit claims to those explicitly "described in subclause (I)," i.e., claims for delisting. 21 U.S.C. § 355(j)(5)(C)(i). "It is a well known canon of statutory construction that courts should construe statutory language to avoid interpretations that would render any phrase superfluous." *United States. v. Cooper*, 396 F.3d 308, 312 (3d Cir. 2005). To interpret Subclause II to permit counterclaims aside from delisting (such as unclean hands) would render the title and word "counterclaim" in Subclause I superfluous, which is contrary to basic canons of statutory construction.

Moreover, APP's unclean hands defenses in its Eighth Additional Defense should be stricken as insufficient as a matter of law. "The defense of unclean hands requires 'an immediate and necessary relation' between the plaintiff's alleged misconduct and the equity sought by that party." *France Telecom S.A. v. Novell, Inc.*, No. 02-437, 2002 WL 31355255, at *3 (D. Del. Oct. 17, 2002) (citing *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933)). The nexus between the misconduct and the claim is "the primary principle guiding application of the unclean hands doctrine." *New Valley Corp. v. Corporate Prop. Assocs. 2 & 3*, 181 F.3d 517, 525 (3d Cir. 1999). Here, APP's unclean hands allegations have nothing to do with MedCo's procurement of the patents-in-suit. There is no nexus between the alleged false listing and whether or not APP's ANDA infringes the patents-in-suit. *See Broadcom Corp. v. Emulex Corp.*, No. 710, Civ. 09-01058 (C.D. Cal. Aug. 1, 2011) (Decl. Ex C).[5]

APP's assertion of unclean hands based on improper patent listing is merely a private action attempting to enforce provisions of the FFDCA. The Court does not have independent jurisdiction to entertain such a defense. Therefore, APP's Eighth Additional Defenses should be stricken and Count Five of its Counterclaims should be dismissed.

[5] This case was not previously considered by the Court.

## IV. In the Alternative, the Court Should Bifurcate APP's Inequitable Conduct and Unclean Hands Allegations to Streamline the Case and Minimize Delay

The Court should bifurcate APP's inequitable conduct and unclean hands allegations from the remaining issues in the case. Rule 42(b) permits federal courts to bifurcate one or more issues or claims in a case for trial "[f]or convenience, to avoid prejudice, or to expedite and economize." Fed. R. Civ. P. 42(b). Under Rule 42(b), a court "has broad discretion in separating issues and claims for trial as part of its wide discretion in trial management." *Ciena Corp. v. Corvis Corp.*, 210 F.R.D. 519, 520 (D. Del. 2002) (Farnan, J.) (citation omitted). Further, in exercising their broad discretion, courts "should consider whether bifurcation will avoid prejudice, conserve judicial resources, and enhance juror comprehension of the issues presented in the case." *Id.* (citation omitted).

It is generally the practice in Delaware to bifurcate inequitable conduct claims from the remaining issues in patent cases. For example, Judge Robinson's practice is "to bifurcate the issue of inequitable conduct for a bench trial following a jury trial on other issues." *S.O.I.TEC Silicon On Insulator Techs., S.A. v. MEMC Elec. Materials, Inc.*, 745 F. Supp. 2d 489, 522 n.35 (D. Del. 2010) (Robinson, J.). Indeed, "bifurcation of complex patent trials has become common." *Ciena Corp.*, 210 F.R.D. at 521 (citation omitted).

Here, bifurcation of APP's inequitable conduct and unclean hands allegations would simplify the issues, minimize delay and avoid any prejudice. The procedural posture of this case in particular warrants bifurcation at this time. As fact discovery is now closed, these newly added claims would require reopening fact discovery, resulting in delay of the resolution of the remaining claims. To be sure, the Special Master confirmed that discovery pertaining to APP's unenforceability allegations necessitates a schedule for that discovery. (Decl.[6] Ex. A at 11:17-

[6] "Decl." refers to the *Declaration of Porter F. Fleming, Esq.*, filed herewith.

12:6). APP's counsel stated that depositions will be needed from MedCo to address these new claims, including possibly the inventors, even though each was already deposed for 18 hours (a total of 36 hours). (Decl. Ex. A at 14:20-23). APP has also indicated that it seeks additional interrogatory responses and document production. (Decl. Ex. B). Bifurcation would streamline the case and minimize interference with claim construction and expert discovery, particularly since none of the other Defendants have asserted these claims.

In addition, the new claims could affect the claim construction process, as APP's new allegations concern information related to claims that are not presently being asserted. (*See, e.g.*, D.I. 500 ¶¶ 117-125; D.I. 501 ¶¶ 116-124 (APP's inequitable conduct allegations concerning experimental results including total impurities and reconstitution times)). MedCo is asserting claims 1-3, 7-10 and 17 of the '727 patent and claims 1-3 and 7-11 of the '343 patent against APP. (*See* D.I. 461 at 5-6). These claims concern $Asp^{9}$-bivalirudin and $DPhe^{12}$-bivalirudin impurities, and do not concern total impurities and reconstitution times, which are the subject of other claims. (*See* D.I. 464 at Exs. A & B). As such, the new allegations could require construction of additional terms of claims not presently being asserted by MedCo and not before the Court for consideration. Supplemental claim construction briefing would be needed for these new claims, and would likely delay the timing of the *Markman* hearing, as claim construction briefing was completed on July 29th. (D.I. 137, 162).

Accordingly, should the Court deny MedCo's motion to dismiss and/or strike, APP's inequitable conduct and unclean hands allegations should be bifurcated from the remaining issues in the case to minimize delay, prejudice and to streamline the case going forward.

## CONCLUSION

For the foregoing reasons, the Court should dismiss APP's Seventh and Eighth Additional Defenses and Counterclaim Counts Four and Five in their entirety.

*/s/ Frederick L. Cottrell, III*

Frederick L. Cottrell, III (#2555)
cottrell@rlf.com
Laura D. Hatcher (#5098)
hatcher@rlf.com
Richards, Layton & Finger P.A.
One Rodney Square
920 N. King Street
Wilmington, DE 19801
(302) 651-7700

*Attorneys for Plaintiff*
*The Medicines Company*

*Of Counsel*

Edgar H. Haug
Porter F. Fleming
Angus Chen
Mark P. Walters
Gina M. Bassi
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

Dated: August 8, 2011

**CERTIFICATE OF SERVICE**

I hereby certify that on August 8, 2011, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filings to the following:

Elena C. Norman, Esq.
enorman@ycst.com
Young Conaway Stargatt & Taylor LLP
The Brandywine Building
1000 West Street, 17th Floor
Wilmington DE 19801

Emily A. Evans, Esq.
eevans@mofo.com
Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, CA 94304-1018

John C. Phillips, Esq.
jcp@pgslaw.com
Phillips, Goldman & Spence, P.A.
1200 North Broom Street
Wilmington, DE 19806

Lynn MacDonald Ulrich, Esq.
lulrich@winston.com
Winston & Strawn LLP
35 West Wacker Drive
Chicago, IL 60601

Richard K. Herrmann, Esq.
rherrmann@morrisjames.com
Morris James LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801

William F. Long, Esq.
bill.long@sutherland.com
Sutherland Asbill & Brennan LLP
999 Peachtree Street, NE
Atlanta, GA 30309-3996

*/s/ Laura D. Hatcher*
Laura D. Hatcher (#5098)