IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFF THE MEDICINES COMPANY'S OBJECTIONS TO THE SPECIAL MASTER'S AMENDED REPORT & RECOMMENDATION REGARDING APP'S MOTION FOR LEAVE TO FILE FIRST AMENDED ANSWERS AND COUNTERCLAIMS (DM 2)

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INTRODUCTION

Pursuant to Rule 53(f)(2), Plaintiff The Medicines Company ("MedCo") objects to the Special Master's Amended Report and Recommendation ("the R&R") granting APP's Motion for Leave to File First Amended Answers and Counterclaims (DM 2)[1] and respectfully requests *de novo* review of the R&R.[2] (D.I. 444).

First, with respect to APP's allegations of inequitable conduct, the R&R is based on legal error in view of the controlling standards set forth by the Federal Circuit 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) and *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009). The R&R ignores the impact of *Therasense* on the pleading standards for inequitable conduct set forth in *Exergen*. In *Therasense*, the Federal Circuit instructed that intent and materiality are ***separate*** requirements. 2011 WL 2028255, at *10. Contrary to *Therasense*, APP's inequitable conduct allegations in its proposed amended pleadings ***rely*** on the materiality of the allegedly withheld information to support its allegations of intent. (*See* D.I. 181, Ex. A at ¶¶ 116, 125, 133, Ex. B at ¶¶ 115, 124, 132). APP's allegations fail as a matter of law.

Further, under *Exergen*, 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. *Exergen*, 575 F.3d at 1331. In the absence of such allegations, such as in APP's proposed pleading, 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 under *Exergen*. *Id.* APP's allegations of inequitable conduct are deficient of the requisite particularity. In addition, under *Exergen*, it is necessary for an inequitable conduct pleading to identify the specific claim ***limitations*** relevant to allegedly withheld material information. *Exergen*, 575 F.3d at 1329-30. Despite the fact that APP's proposed amended pleading ***fails*** to identify ***any*** of the requisite claim limitations, the R&R ***assumes*** that APP's allegations are directed to "all" claim limitations. (D.I. 444 at 35-36). However, the complete silence in APP's proposed pleadings as to claim limitations is fatal to APP's motion for leave under *Exergen*.

Second, with respect to APP's allegations of unclean hands [redacted] the R&R is based on legal error. By ***statute***, there is ***no cause of action*** for APP's proposed unclean hands claim. A private party ***cannot*** bring an action to enforce provisions of the Federal Food, Drug & Cosmetic Act ("the FFDCA"). The passage of 21 U.S.C. § 355(j)(5)(C)(ii) in 2003 ("the 2003 Amendment") does ***not*** provide the court with independent jurisdiction to entertain APP's defense of unclean hands [redacted]

The R&R committed legal error in declining to follow Federal Circuit case law and Senior Judge Debevoise of New Jersey's ruling in *Schwarz Pharma, Inc. v. Teva Pharms. USA, Inc.*, No. 01-4995, 2005 WL 4158850 (D.N.J. Feb. 4, 2005). (D.I. 444 at 46). The Federal Circuit construed the 2003 Amendment and stated that it "provides a ***limited*** counterclaim to a generic manufacturer in a Paragraph IV infringement action." *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1364 (Fed. Cir. 2010) *reh'g and reh'g en banc denied*, 615 F.3d 1374 (Fed. Cir. 2010) (emphasis added). The Federal Circuit further instructed that "the counterclaim provision ***only authorizes*** suits to correct or delete an erroneous patent number or

[1] MedCo denies APP's allegations of inequitable conduct and unclean hands, but solely for the purposes of this exception limits its objections to those set forth herein.

[2] The R&R should be reviewed *de novo* in view of its legal conclusions. Fed. R. Civ. P. 53(f)(4).

expiration date." *Id.* at 1366 (emphasis added). Likewise, in *Schwarz*, Senior Judge Debevoise held that "[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. The R&R improperly ignored precedent, and therefore was legally erroneous. APP's allegation of unclean hands [redacted] is not recognized under the law and is therefore futile.

For these reasons, APP's allegations directed to inequitable conduct and unclean hands are both futile and its motion for leave should be denied in its entirety.

ARGUMENT

I. Standard of Review

A report and recommendation by a special master that involves conclusions of law should be reviewed *de novo*. *U.S. v. Penny Lane Partners, L.P.*, No. 06-CV-1894, 2010 WL 5796465, at *5 (D.N.J. Oct. 26, 2010) (citing Fed. R. Civ. P. 53(f)(3)-(4)). Here, the R&R involves legal conclusions concerning the futility of APP's proposed amended pleading. (D.I. 444 at 32). Thus, the R&R should be reviewed *de novo*. *Id.*

II. The R&R Committed Legal Error By Determining That APP's Inequitable Conduct Allegations Are Proper

APP's proposed amended pleadings are fatally flawed as they fail to meet the heightened pleading standards mandated by the Federal Circuit in light of *Therasense*. APP fails to plead allegations of intent that are independent of materiality, and fails to identify the claim limitations that are relevant to the allegedly withheld material.

A. The R&R Erred by Ignoring the Impact of *Therasense* On Inequitable Conduct Pleading Standards Under *Exergen*

As the R&R recognizes, *Therasense* "tighten[ed] the standards for finding both intent and materiality" for claims of inequitable conduct. (D.I. 444 at 29). However, the R&R commits legal error in concluding that the Federal Circuit's holding in *Therasense* has **no impact** on the pleading standards for inequitable conduct as set forth in *Exergen*. (D.I. 444 at 29-31). The R&R also incorrectly **assumes** that "MedCo appears to agree that *Therasense* did not change the standard for pleading inequitable conduct." (D.I. 444 at 31 n.14). Contrary to the R&R, the pleading standards for inequitable conduct as set forth in *Exergen* **must** be viewed in light of the **new** standards mandated by the Federal Circuit in *Therasense*.

In *Exergen*, the Federal Circuit clarified that "in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." 575 F.3d at 1327. In *Therasense*, the Federal Circuit instructed that "[i]ntent [to deceive] and materiality are **separate** requirements." 2011 WL 2028255, at *10 (emphasis added). "[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).

APP's proposed amended pleadings have no legal basis in view of *Exergen* taken with *Therasense*. Each of APP's allegations of purported intent to deceive do not meet the Federal Circuit's standard in *Therasense*. Namely, APP's allegations of intent to deceive rely upon allegations based on (i) "highly material" information; (ii) that the accused "must have known";

and (iii) "no plausible explanation" exists. (D.I. 181, Ex. A at ¶¶ 116, 125, 133, Ex. B at ¶¶ 115, 124, 132). APP's allegations of intent therefore are based on the alleged materiality of the withheld information. Such allegations are improper under *Therasense*'s requirement that intent and materiality are **separate** requirements. 2011 WL 2028255, at *10. The R&R erred in finding APP's allegations to be proper.

APP's proposed pleadings fail to meet the requisite standards for inequitable conduct as a matter of law. Accordingly, APP's motion for leave should be denied.

B. The R&R Erred By Ignoring the Absence of Particularity Concerning an Intent to Deceive and Claim Limitations

APP fails to plead with particularity an intent to deceive under *Exergen*. Mere knowledge of information is insufficient. "[O]ne 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. Allegations sufficient to support a "deliberate decision to withhold" material information is "a necessary predicate for inferring deceptive intent." *Id.* at 1331. In the absence of such allegations, it is improper to draw an inference of deceptive intent "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.'" *Id.* (citation omitted) (finding that the "fact that an applicant disclosed a reference during prosecution of one application, but did not disclose it during prosecution of a related application, is insufficient to meet the threshold level of deceptive intent required to support an allegation of inequitable conduct").

Most telling, the R&R commits legal error by relying upon APP's allegations that [redacted] "knew or should have known" of the materiality of information to support an inference of intent to deceive. (D.I. 444 at 37-42). Under *Exergen*, ***mere knowledge*** of materiality is an ***insufficient*** basis to support an allegation of an intent to deceive. There must ***also*** be allegations to support a deliberate decision to withhold information. *Exergen*, 575 at 1331.

APP also fails to properly plead with particularity the "what" of the alleged inequitable conduct. Further, because APP fails to meet the "what" requirement of *Exergen*, the "why" and "how" of the alleged inequitable conduct are also not met. In *Exergen*, The Federal Circuit instructed that a pleading must identify, *inter alia*, the specific claim ***limitations*** that are relevant to the allegedly withheld information. *Id.* at 1329. The identification of claim limitations is "necessary to explain both 'why' the withheld information is material and not cumulative, and 'how' an examiner would have used this information in assessing the patentability of the claims." *Id.* at 1329-30.

Nowhere in APP's proposed pleading does APP identify claim limitations. Unable to identify any claim limitations, the R&R merely ***assumes*** that APP's allegations are directed to "all" claim limitations. (D.I. 444 at 35-36). The R&R assumes that because APP asserts that none of the patent claims would have issued, then "none of the limitations of those claims" would have issued. (D.I. 444 at 36) (emphasis in original). In a non-sequitur, the R&R then concludes that APP has sufficiently plead the "what" because the alleged inequitable conduct relates to "all" the claim limitations.[3] (D.I. 444 at 36). The R&R's "assumption" is unsupported by the Federal Circuit's mandate in *Exergen*, requiring that specific claim ***limitations*** be

[3] Asserting that none of the claim limitations would have issued is irrelevant to which claim limitations are relevant to the allegedly withheld material information.

identified in a pleading of inequitable conduct. Moreover, the R&R's conclusion that the "what" is satisfied is misplaced. (D.I. 444 at 36). Under *Exergen*, the purpose of identifying specific claim limitations is to identify the "why" and "how." 575 F.3d at 1329-30. APP's utter failure to identify claim ***limitations*** fails to sufficiently plead the requisite "why" or "how."

In view of APP's failure to meet the *Exergen* pleading requirements for, *inter alia*, alleging with particularity intent to deceive and the claim limitations relevant to its inequitable conduct claims, APP's motion for leave concerning inequitable conduct is futile as a matter of law and should be denied.

III. The R&R Committed Legal Error By Ignoring The Statutory Restriction Precluding APP's Unclean Hands Claims

APP's proposed amendment to add an unclean hands counterclaim is futile because it is "legally insufficient on its face." *See Koken v. GPC Int'l, Inc.*, 443 F. Supp. 2d 634 (D. Del. 2006) (quoting *Harrison Beverage Co. v. Dribeck Importers, Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990)). Unclean hands based on [redacted] is merely a private action seeking to enforce provisions of the FFDCA. This remains unchanged even after the passage of the 2003 Amendment. The 2003 Amendment does **not** provide the court with independent jurisdiction to entertain such a defense. Therefore, the R&R committed legal error in granting APP's motion to amend.

A private party cannot enforce alleged violations of the FFDCA under the guise of a private cause of action. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (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"); *see also Nycomed US Inc. v. Glenmark Generics, Ltd.*, No. 08-5023, 2010 WL 1257803, at *6 (E.D.N.Y. Mar. 26, 2010) (reviewing 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 Act shall be by and in the name of the United States."). The R&R's attempt to distinguish *Nycomed* fails. (*See* D.I. 444 at 45-46). *Nycomed* cannot be distinguished on the facts because the relevant proposition is legal in nature: a private party **cannot** enforce violations of the FFDCA. *Nycomed*, 2010 WL 1257803, at *6.

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*. . . ." *Novo Nordisk*, 615 F.3d 1374 (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 Federal Circuit instructed that "the counterclaim provision **only authorizes** suits to correct or delete an erroneous patent number or expiration date," and did not even extend to use code

narratives.[4] *Id.* at 1366 (emphasis added). Thus, 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.*

The R&R also improperly declined to follow *Schwarz*. (D.I. 444 at 46). 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. Thus, in declining to follow *Schwarz*, the R&R committed legal error.

APP's proposed claims amount to a private action for the enforcement of the FFDCA. APP's allegation that the patents-in-suit are unenforceable because [redacted] Pursuant to 21 U.S.C. § 337(a) and Federal Circuit case law, APP's unclean hands proposed counterclaim is not legally cognizable, and thus futile.

Additionally, the R&R erred in determining that this Court's powers of equity can reach APP's unclean hands counterclaim. (D.I. 444 at 47). 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 Act 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. The 2003 Amendment not once refers to unclean hands. Indeed, it 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)." Further, "[i]t is a well known canon of statutory construction that courts should construe statutory language to avoid interpretations that would render any phrase superfluous." *U.S. v. Cooper*, 396 F.3d 308, 312 (3d Cir. 2005). The R&R's interpretation of Subclause II renders the title and word "counterclaim" in Subclause I superfluous, which is contrary to basic canons of statutory construction. Therefore, APP's proposed amendment is futile and fails to state a legally cognizable claim.

APP's proposed amended pleadings are fatally flawed as allegations of unclean hands [redacted] are not cognizable under the law.

CONCLUSION

For the foregoing reasons, MedCo respectfully requests that the Court deny APP's motion for leave to file its first amended answer and counterclaims in its entirety.

[4] A "use code narrative" refers to the description required by the FDA for each method of using an NDA drug covered by a patent. *See Novo Nordisk*, 601 F.3d at 1361. We note that the Supreme Court has just agreed to review this case pursuant to a petition for certiorari. *Caraco Pharm. Labs. Ltd. v. Novo Nordisk A S*, No. 10-844, 2011 U.S. LEXIS 4901 (U.S. Jun. 27, 2011).

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