

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

TEVA NEUROSCIENCE, INC., et al.,

Plaintiffs,

v.

WATSON LABORATORIES, INC., et al.,

Defendants.

Civil Action No.: 10-5078 (JLL)

**OPINION**

**LINARES**, District Judge.

This matter comes before the Court by way of Plaintiffs' motion to dismiss the Mylan Defendants'<sup>1</sup> Third and Sixth Counterclaims pursuant to Federal Rule of Civil Procedure 12(b)(6) and to strike the Mylan Defendants' Fifth Affirmative Defense pursuant to Federal Rule of Civil Procedure 12(f) [Docket entry no. 64]. The Court has considered the submissions made in support of and in opposition to the instant motion.<sup>2</sup> No oral argument was heard. Fed. R. Civ. P. 78. This motion is returnable today, February 22, 2011. Based on the reasons that follow, Plaintiffs' motion is granted. The Mylan Defendants are hereby granted thirty (30) days in which to file an amended pleading which cures the deficiencies discussed herein.

**LEGAL STANDARD**

Rule 12(f) of the Federal Rules of Civil Procedure provides: "The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). A motion to strike an affirmative defense pursuant to 12(f) is governed by the same standards as a motion to dismiss pursuant to 12(b)(6). See In re Gabapentin Patent Litig., 648

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<sup>1</sup> The "Mylan Defendants" are comprised of Mylan Pharmaceuticals, Inc., Mylan Inc. and Mylan LLC.

<sup>2</sup> This Court's jurisdiction over this matter is premised on 28 U.S.C. § 1331.

F.Supp.2d 641, 647-48 (D.N.J. 2009) (“Because a motion [to strike] challenges the legal sufficiency of the pleading, it is governed by the same standards as a motion to dismiss[.] ... An affirmative defense is insufficient as a matter of law if it cannot succeed under any circumstances.”). “Courts recognize that a motion to strike can save time and litigation expense by eliminating the need for discovery with regard to legally insufficient defenses.” F.D.I.C. v. White, 828 F. Supp. 304, 307 (D.N.J. 1993); see also United States v. Geppert Bros., Inc., 638 F. Supp. 996, 998 (E.D. Pa. 1986). Nevertheless, the Third Circuit has cautioned that courts “should not grant a motion to strike a defense unless the insufficiency of the defense is ‘clearly apparent.’ ” Cipollone v. Liggett Group, Inc., 789 F.2d 181, 188 (3d Cir. 1986).

For a complaint 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) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). In determining the sufficiency of a complaint, the Court must accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in favor of the non-moving party. See Phillips v. County of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008). Additionally, in evaluating a plaintiff’s claims, generally “a court looks only to the facts alleged in the complaint and its attachments without reference to other parts of the record.” Jordan v. Fox, Rothschild, O’Brien & Frankel, 20 F.3d 1250, 1261 (3d Cir. 1994).

## **DISCUSSION**

On October 1, 2010, Plaintiffs, Teva Neuroscience, Inc., et al. (collectively referred to as “Teva”), filed the Complaint in this matter against various defendants, including the Mylan Defendants, for infringement of United States Patent No. 5,453,446 (“ the ’446 patent”) based on Mylan’s submission of an Abbreviated New Drug Application (“ANDA”) seeking approval by the United States Food and Drug Administration (“FDA”) to sell a generic versions of Azilect®, Teva’s oral treatment for idiopathic Parkinson’s disease, prior to the expiration of the ’446 patent. The Mylan Defendants filed an Answer and Counterclaims to Teva’s Complaint on November 30, 2010.

Plaintiffs have now filed a motion to dismiss the Mylan Defendants’ third and sixth counterclaims and to strike their fifth affirmative defense, all of which involve allegations of

inequitable conduct. In particular, the fifth affirmative defense alleged by the Mylan Defendants claims that the '466 patent at issue in this matter is unenforceable. The third and sixth counterclaims go on to allege the following:

The '466 patent is unenforceable due to inequitable conduct because of intentionally misleading the Examiner during the prosecution of the '466 patent with the statement at '466 patent, col. 3, ll. 11-26 and the arguments made during the prosecution of parent U.S. patent application serial no. 07/632,184 in the amendment dated August 12, 1992, at p. 8, ll. 15-27 and p. 12, ll. 6-26. The applicants intentionally and repeatedly explained that since the structures of deprenyl and the R-enantiomer of rasagiline are structurally similar and (-) deprenyl is more pharmaceutically active than (+) deprenyl, one would have expected that only the (-) enantiomer of rasagiline would be the active MAO-type B inhibitor. Therefore, the applicants submitted that their invention using R-rasagiline was surprising and unexpected. This is clearly misleading as both (-) deprenyl and (+) PAI are R enantiomers. The activity of the R-enantiomer was not surprising or unexpected in light of this fact that was not disclosed to the Examiner.

(Docket Entry No. 31). Thus, the Mylan Defendants allege that the '466 patent is unenforceable due to inequitable conduct by the Plaintiffs in the form of a material false representation or omission before the United States Patent and Trademark Office ("PTO"). Plaintiffs now argue that all counterclaims and/or affirmative defenses based on such inequitable conduct should be dismissed and/or stricken because the allegations upon which they are based fail to meet the pleading standard of Federal Rule of Civil Procedure 9(b), as interpreted by the Federal Circuit in Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1328 (Fed. Cir. 2009).

Generally speaking, "a patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution." Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1313 (Fed. Cir. 2006). In this regard, the party asserting inequitable conduct must ultimately "prove a threshold level of materiality and intent by clear and convincing evidence." Id. Although such a showing is clearly not required at the pleading stage, the Federal Circuit has held that inequitable conduct is analogous to fraud, which, under Federal Rule of Civil

Procedure 9(b), must be pled with particularity. See Exergen, 575 F.3d at 1326. The Exergen court summarized the applicable pleading standard for inequitable conduct as follows:

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. 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.

Exergen, 575 F.3d at 1328 -1329.

In moving to dismiss the Mylan Defendants’ third and sixth counterclaims, Plaintiffs argue that said Defendants have failed to sufficiently plead the “who,” “why,” and “how” requirements of Exergen. In particular, Plaintiffs claim that the Mylan Defendants fail to: (a) identify any specific individual who knowingly made false statements or withheld information known to the individual to be material, (b) explain why and how the allegedly misleading and withheld information was material to the issued claims in the ‘466 patent, and (c) specifically allege that any individual acted with the requisite knowledge of falsity and intent to deceive the PTO.

The Court has carefully considered the submissions made in support of and in opposition to Plaintiffs’ motion and concludes that the Mylan Defendants’ allegations regarding material false representations before the PTO do not adequately allege inequitable conduct under Exergen. In particular, for the reasons that follow, the Court finds that the Mylan Defendants have not sufficiently identified the individuals involved or why the information withheld or misrepresented was material, nor have said Defendants alleged sufficient facts to support Plaintiffs’ deceptive intent.

First, Exergen requires a party bringing an inequitable conduct claim to identify “the specific individual associated with the filing or prosecution of the application . . . who both knew of the material information and deliberately withheld or misrepresented it.” Exergen, 575 F.3d at 1329. The counterclaims at issue, referring generally to “the applicants,” contain no such information.

Although Plaintiffs have attempted to clarify, by way of opposition brief, that “the applicants” referred to in their pleading are the named inventors whose names are listed on the faces of the patents-at-issue, their pleading must be amended to include such relevant information. See generally Com. of Pa. ex rel. Zimmerman v. PepsiCo, Inc., 836 F.2d 173, 181 (3d Cir.1988) (“[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.”).

Next, the Mylan Defendants allege that the applicants misrepresented to the PTO that their invention using R-rasagiline was surprising and unexpected. Defendants further allege that “[t]his is clearly misleading as both (-) deprenyl and (+) PAI are R enantiomers. The activity of the R-enantiomer was not surprising or unexpected in light of this fact that was not disclosed to the Examiner.” In response to Plaintiffs’ motion, the Mylan Defendants maintain that such allegations sufficiently fulfill Exergen’s “why” requirement. This Court disagrees. Allegations linking the misrepresented or withheld information to the claims of the patent “are 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.” Exergen, 575 F.3d at 1329-30. It is clear in this case that Defendants’ pleading fails to identify how the withheld (or misrepresented) information was relevant to any particular claim(s) of the ‘466 patent or how an examiner would have used this information in assessing the patentability of its claims. See Exergen, 575 F.3d at 1329-30 (“Second, the pleading fails to 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 the “where” of the material omissions.”).

Lastly, the Mylan Defendants have failed to allege sufficient facts to support Plaintiffs’ deceptive intent. “Although ‘knowledge’ and ‘intent’ may be averred generally, our precedent . . . requires that the pleading 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. Aside from the conclusory allegation that the applicants “intentionally” submitted that their invention using R-rasagiline was surprising and unexpected – which, according to Defendants was “misleading” – the Mylan Defendants have failed to allege any other facts to support a reasonable inference that the applicants knew such statement to be false or that they intended to deceive the PTO. See, e.g., Exergen, 575 F.3d at 1330 (“No facts are alleged from which one can reasonably infer that, at the

time of the allegedly false statement, the individual who made this statement to the PTO was aware of an allegedly contradictory statement on Exergen's website."); Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Sys., LLC, 350 F.3d 1327, 1344 (Fed. Cir. 2003) (“[W]e decline to infer facts to support a claim that must be pled with particularity.”).

In light of the foregoing, the Court finds that the Mylan Defendants' third and sixth counterclaims fail to state a claim for unenforceability based on inequitable conduct. Plaintiffs' motion to dismiss the foregoing counterclaims is granted. By virtue of such insufficient pleading, Plaintiffs argue that the Mylan Defendants' fifth affirmative defense (which is pled even more broadly and appears to incorporate the inequitable conduct allegations) also fails to meet the heightened pleading standard. To the extent the Mylan Defendants' fifth affirmative defense is, in fact, based on inequitable conduct, the Court agrees and will grant Plaintiffs' motion to strike such defense from their pleading pursuant to Federal Rule of Civil Procedure 12(f).

#### **CONCLUSION**

In light of the foregoing, Plaintiffs' motion to dismiss the Mylan Defendants' third and sixth counterclaims and to strike their fifth affirmative defense is granted. However, the shortcomings of the Mylan Defendants' pleading do not foreclose the possibility that they may be able to state a cognizable claim of inequitable conduct by filing an amended pleading. Thus, the Court will afford the Mylan Defendants thirty (30) days from the date of entry of this Opinion and corresponding Order in which to file an amended pleading which cures the deficiencies addressed above.

An appropriate Order accompanies this Opinion.

Date: February 22, 2011

Jose L. Linares  
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JOSE L. LINARES,  
UNITED STATES DISTRICT JUDGE