

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

LEO PHARMA A/S, LEO )  
LABORATORIES LIMITED, and LEO )  
PHARMA, INC., )

Plaintiffs, )

v. )

Civil Action No. 16-333-JFB-SRF

ACTAVIS LABORATORIES UT, INC., )

Defendant. )

**REPORT AND RECOMMENDATION**

**I. INTRODUCTION**

Presently before the court in this patent infringement action brought under the Hatch-Waxman Act is the motion to dismiss the inequitable conduct counterclaim of defendant Actavis Laboratories UT, Inc. (“Actavis”), filed by plaintiffs LEO Pharma A/S, LEO Laboratories Limited (“LEO Labs”), and LEO Pharma, Inc. (“LEO Pharma”) (collectively, “LEO”) pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. (D.I. 104) For the following reasons, I recommend that the court grant LEO’s motion to dismiss without prejudice.

**II. BACKGROUND**

On May 6, 2016, LEO filed a complaint for patent infringement under the Hatch-Waxman Act against Actavis. (D.I. 1) The action relates to Abbreviated New Drug Application (“ANDA”) Nos. 208807 and 209086 (together, “the Actavis ANDAs”), which were filed by Actavis with the U.S. Food and Drug Administration (“FDA”) seeking approval to market generic versions of LEO’s Picato® pharmaceutical products. (D.I. 73 at ¶ 1) The Picato® products are gels containing ingenol mebutate as the active pharmaceutical ingredient (“API”) at

dosage strengths of 0.015% and 0.05%. (*Id.*) LEO Pharma is the holder of New Drug Application (“NDA”) No. 202833 for ingenol mebutate gel at concentrations of 0.015% and 0.05%, which was approved by the FDA on January 23, 2012. (*Id.* at ¶ 13) LEO’s Picato® products are approved for the topical treatment of actinic keratosis. (*Id.* at ¶ 16)

The second amended complaint alleges infringement of ten patents: U.S. Patent Nos. 7,410,656 (“the ‘656 patent”), 8,278,292 (“the ‘292 patent”), 8,372,827 (“the ‘827 patent”), 8,372,828 (“the ‘828 patent”), 8,377,919 (“the ‘919 patent”), 8,536,163 (“the ‘163 patent”), 8,716,271 (“the ‘271 patent”), 8,735,375 (“the ‘375 patent”), 9,416,084 (“the ‘084 patent”), and 9,676,698 (“the ‘698 patent”) (collectively, the “patents-in-suit”). (*Id.* at ¶ 8) The ‘084 patent and the ‘698 patent, identified as the “Process Patents,” cover methods of producing ingenol mebutate. (*Id.* at ¶ 20) The Process Patents are both entitled, “Method of Producing Ingenol-3-Angelate,” they share a common specification and common inventors,<sup>1</sup> and both claim priority to Provisional Application No. 61/366,018, which was filed in 2010. (D.I. 106, Exs. 6-7) The ‘698 patent is a continuation of the ‘084 patent. (*Id.*, Ex. 7)

Actavis filed its answer and counterclaims to the second amended complaint on July 10, 2017, which included a counterclaim and an affirmative defense that the Process Patents are unenforceable for inequitable conduct. (D.I. 85 at 55, ¶¶ 159-196<sup>2</sup>) Actavis’ allegations of inequitable conduct are based on LEO’s purportedly deliberate failure to disclose as prior art U.S. Patent No. 7,378,445 (“the ‘445 patent”) to the U.S. Patent and Trademark Office (“USPTO”) during prosecution of the Process Patents. (*Id.* at 84-85) The ‘445 patent, entitled

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<sup>1</sup> The named inventors of the Process Patents are Thomas Hogberg, Gunnar Grue-Sorensen, Xifu Liang, Anne Marie Hrneman, and Anders Karskov Petersen. (D.I. 106, Exs. 6-7)

<sup>2</sup> All references to paragraph numbers in D.I. 85 are to the numbered paragraphs in the Counterclaims portion of Actavis’ pleading.

“Treatment of Prostate Cancer,” does not share a common inventor<sup>3</sup> with the Process Patents. (D.I. 106, Ex. 8) In 2011, the assignee of the ‘445 patent assigned its entire patent portfolio, including the ‘445 patent and U.S. Patent No. 7,449,492 (“the ‘492 patent”) to LEO Labs. (D.I. 73 at ¶ 21; D.I. 85, Ex. 3; D.I. 85 at ¶¶ 188-89) During prosecution of the Process Patents, Actavis disclosed the ‘492 patent to the USPTO, but did not disclose the ‘445 patent as prior art. (D.I. 85 at ¶ 187) Presently pending before the court is LEO’s motion to dismiss Actavis’ counterclaim for inequitable conduct, which is based on LEO’s alleged failure to disclose the ‘445 patent during prosecution of the Process Patents. (D.I. 104)

### III. LEGAL STANDARDS

#### A. Rule 12(b)(6)

Rule 12(b)(6) permits a party to move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, the court must accept as true all factual allegations in the complaint and view them in the light most favorable to the plaintiff. *Umland v. Planco Fin. Servs.*, 542 F.3d 59, 64 (3d Cir. 2008).

To state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a complaint must contain a “short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). Although detailed factual allegations are not required, the complaint must set forth sufficient factual matter, accepted as true, to “state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A claim is facially plausible when the factual allegations allow the court to draw the reasonable inference that the defendant is liable for the misconduct

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<sup>3</sup> The named inventor of the ‘445 patent is James Harrison Aylward.

alleged. *Iqbal*, 556 U.S. at 663; *Twombly*, 550 U.S. at 555-56.

When determining whether dismissal is appropriate, the court must take three steps.<sup>4</sup> See *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). First, the court must identify the elements of the claim. *Iqbal*, 556 U.S. at 675. Second, the court must identify and reject conclusory allegations. *Id.* at 678. Third, the court should assume the veracity of the well-pleaded factual allegations identified under the first prong of the analysis, and determine whether they are sufficiently alleged to state a claim for relief. *Id.*; see also *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). The third prong presents a context-specific inquiry that “draw[s] on [the court’s] experience and common sense.” *Id.* at 663-64; see also *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). As the Supreme Court instructed in *Iqbal*, “where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not ‘show[n]’ - ‘that the pleader is entitled to relief.’” *Iqbal*, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

**B. Rule 12(f)**

Rule 12(b)(6) does not offer a mechanism for dismissing affirmative defenses because it refers only to “claim[s].” See *Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 WL 600715, at \*4 (D. Del. Feb. 3, 2012). However, Rule 12(f) 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). “When ruling on a motion to strike, the [c]ourt must construe all facts in favor of the nonmoving party and deny the motion if the defense is sufficient

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<sup>4</sup> Although *Iqbal* describes the analysis as a “two-pronged approach,” the Supreme Court observed that it is often necessary to “begin by taking note of the elements a plaintiff must plead to state a claim.” 556 U.S. at 675, 679. For this reason, the Third Circuit has adopted a three-pronged approach. See *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 n.7 (3d Cir. 2010); *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011).

under the law. Further, a court should not grant a motion to strike a defense unless the insufficiency of the defense is clearly apparent.” *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 356 (D. Del. 2009) (citations and internal quotation marks omitted). “As a general matter, motions to strike under Rule 12(f) are disfavored.” *Fesnak & Assocs., LLP v. U.S. Bank Nat’l Ass’n*, 722 F. Supp. 2d 496, 502 (D. Del. 2010).

#### IV. DISCUSSION

LEO asks the court to dismiss and strike Actavis’ inequitable conduct allegations because they do not meet the minimum requirements for pleading inequitable conduct under Fed. R. Civ. P. 9(b) and Federal Circuit precedent. (D.I. 105 at 7-14) “An individual associated with the filing and prosecution of a patent application commits inequitable conduct when he or she (1) makes an affirmative misrepresentation of a material fact, fails to disclose material information, or submits false material information to the PTO; (2) with the specific intent to deceive the PTO.” *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 379 (D. Del. 2012) (internal quotation marks omitted).

A claim of patent unenforceability premised on inequitable conduct is a claim sounding in fraud. Under Rule 9(b), fraud is a clear exception to the otherwise broad notice-pleading standards. A party alleging unenforceability, therefore, must plead with particularity those facts which support the claim that the patent holder acted fraudulently before the PTO. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009).

“To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011). The standard for proving inequitable conduct is a more rigorous one than the standard for pleading inequitable conduct. Accordingly,

the proper standard of review is that articulated in *Exergen*, which held that “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; *see also Evonik Degussa GmbH v. Materia Inc.*, C.A. No. 09-636, 2012 WL 4503771, at \*6 (D. Del. Oct. 1, 2012) (discussing *Exergen* as the applicable heightened pleading standard for inequitable conduct).

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 1328-29.

Just as a claim for inequitable conduct must meet the heightened pleading requirements of Rule 9(b), a defendant is also “required to plead this affirmative defense with particularity under Rule 9(b).” *See Bayer CropScience AG v. Dow AgroSciences LLC*, C.A. No. 10-1045, 2011 WL 6934557, at \*3 (D. Del. Dec. 30, 2011). As a result, Actavis’ counterclaim and affirmative defense of inequitable conduct rise or fall together. *See XpertUniverse*, 868 F. Supp. 2d at 379-83 (assessing the sufficiency of counterclaims and affirmative defenses of inequitable conduct together); *Southco, Inc. v. Penn Eng’g & Mfg. Corp.*, 768 F. Supp. 2d 715, 721-24 (D. Del. 2011) (same). Actavis concedes that its Sixth Affirmative Defense rises or falls with its inequitable conduct counterclaim, and does not separately address the affirmative defense in its arguments. (D.I. 121 at 3 n.2)

LEO’s motion to dismiss and strike the inequitable conduct allegations is based on the assertion that Actavis failed to adequately plead inequitable conduct as articulated by the Federal Circuit and required by Fed. R. Civ. P. 9(b). Specifically, LEO maintains that Actavis has not sufficiently pleaded facts to show: (1) misrepresentations of facts that contradict other positions

offered by the applicant to the USPTO; (2) but-for materiality; or (3) intent to deceive. The court considers each separately, as required by the Federal Circuit. *See Therasense*, 649 F.3d at 1290 (“A district court should not use a ‘sliding scale,’ where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa.”).

## **A. Misrepresentations of Fact**

### **1. The “who”**

Actavis’ inequitable conduct allegations fail to sufficiently identify the “who” of the misrepresentation because the counterclaim does not name a specific person who made the alleged material omission. *See Exergen*, 575 F.3d at 1329. Instead, Actavis broadly identifies (1) the inventors named on the face of the Process Patents, (2) attorneys or agents preparing or prosecuting the Process Patents, and / or (3) LEO Labs employees substantively involved in the preparation or prosecution of the Process Patents. (D.I. 85 at ¶¶ 160-61; 178; 192-95) These generalized allegations leave open the possibility that the counterclaim “implicate[s] all or none of the individuals who had dealings with the PTO” during prosecution of the Process Patents. *Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 307 (D. Del. 2013).

In *Exergen*, the Federal Circuit held that general references to a corporate entity, its agents, or attorneys in lieu of naming a specific individual associated with the filing or prosecution of the patent application is not adequate to satisfy the “who” of the material omissions and misrepresentation. 575 F.3d at 1329. Consequently, Actavis’ identification of LEO Labs employees and prosecuting attorneys or agents are inadequate to establish a claim for inequitable conduct. Likewise, broad references to named inventors are inadequate in the absence of identifying a specific individual who knew about the withheld information and its materiality. *See Senju*, 921 F. Supp. 2d at 307 (concluding that a “broadly cast net around the

inventors and those acting on their behalf also does not allow the court to reasonably infer that a specific individual both knew of the invalidating information and had a specific intent to deceive the PTO.”); *see also XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 379-83 (D. Del. 2012) (finding that allegations of inequitable conduct against “Abraham Zelkin or one or more of the other individuals listed as an inventor” fell short of the pleading standard).

Actavis’ assertions that “LEO Labs has been aware of the ‘445 Patent at least since the April 15, 2011 assignment agreement, if not before,” and that “LEO Labs did not submit the ‘445 Patent . . . to the [USPTO] during prosecution of either of the Process Patents-in-Suit,” are also inadequate under the standard set forth in *Exergen*. (D.I. 85 at ¶¶ 177, 183) The law is well-established that only individuals associated with the filing and prosecution of a patent application have a duty of candor and good faith in dealing with the USPTO. *Exergen*, 575 F.3d at 1329 (citing 37 C.F.R. § 1.56(c) and Manual of Patent Examining Procedures (“MPEP”) § 2001.01 (8th ed., rev. 2, May 2004)).

## **2. The “what”**

The counterclaim adequately pleads the “what” of the material omission, which requires identification of the claims, and the limitations in those claims, relevant to the ‘445 patent. *See Exergen*, 575 F.3d at 1329. Although paragraph 175 of Actavis’ counterclaim for inequitable conduct generally pleads that “[a]ll claims of the Process Patents-in-Suit are invalid” based on the ‘445 patent, paragraphs 169 through 171 draw a direct comparison between Example 17 of the ‘445 patent and independent claim 1 of each of the Process Patents, as cited in paragraphs 210 and 224 in the second amended complaint. (D.I. 85 at ¶¶ 169-71, 175) All claims of the ‘084 patent depend from claim 1 of that patent, and claims 2 through 7 of the ‘698 patent depend



from claim 1 of that patent, thereby defining the scope of the claims affected by the purported omission of the '445 patent during prosecution of the Process Patents.

The facts presently before the court are distinguishable from the circumstances in *Exergen* on this point. In *Exergen*, the pleading alleged that the omitted prior art references were material to the patentability of the patents-in-suit because they generally disclosed techniques of scanning or swiping a radiation detector across a target. *See Exergen*, 575 F.3d at 1325. The pleading did not otherwise identify specific claim language or claim numbers. In contrast, paragraphs 170 and 171 of Actavis' counterclaim quote specific claim limitations from the Process Patents. (D.I. 85 at ¶¶ 170-71) Paragraph 170 of the inequitable conduct counterclaim recites a portion of claim 1 of the '698 patent describing a process of "esterifying ingenol protected with a dihydroxyl protecting group at the 5 and 20 positions with angelic acid or a derivative thereof selected from the group consisting of" angelic anhydride, among others, and "removing the dihydroxyl protective [sic] group" to produce the product comprising ingenol-3-angelate. (D.I. 85 at ¶ 170; D.I. 106, Ex. 7 at col. 46:21-50) Paragraph 171 of the inequitable conduct counterclaim quotes similar language from independent claim 1 of the '084 patent. (D.I. 85 at ¶ 171; D.I. 106, Ex. 6 at col. 44:50-45:22)

### **3. The "how" and "why"**

The inequitable conduct counterclaim sufficiently pleads how an examiner would have used the information in assessing the patentability of the claims. *See Exergen*, 575 F.3d at 1329-30. Actavis' counterclaim pleads that the '445 patent is material because it purportedly renders the Process Patents invalid as anticipated or obvious under 35 U.S.C. §§ 102(b) or 103, respectively. (D.I. 85 at ¶¶ 174-76) As previously stated at § IV.A.2, *supra*, paragraphs 169 to

171 of the inequitable conduct counterclaim establish how the '445 patent allegedly reads on the claims of the Process Patents. (*Id.* at ¶¶ 169-171)

Moreover, the disputed counterclaim alleges that the relevant limitations disclosed in the '445 patent are otherwise absent from the prosecution history. Specifically, the counterclaim alleges that a cited prior art reference, U.S. Patent No. 7,449,492 (“the ‘492 patent”) “discloses the use of ingenol-3-angelate for treating cancer” like the '445 patent, but “does not disclose the methods for synthesizing ingenol-3-angelate claimed by the Process Patents-in-Suit.” (D.I. 85 at ¶¶ 190-91)

### **B. But-For Materiality**

The court next considers separately whether the pleading adequately satisfies the but-for materiality standard. “[A]s a general matter, the materiality required to establish inequitable conduct is but-for materiality,” meaning that a misrepresentation is immaterial if it is “not the but-for cause of the patent’s issuance.” *Therasense*, 649 F.3d at 1291 (citing *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 373-74 (1928)). Courts are unwilling “to extinguish the statutory presumption of validity where the patentee made a misrepresentation to the PTO that did not affect the issuance of the patent.” *Id.* At the pleading stage, the court does not decide the merits of the claim, and focuses only on whether materiality was properly alleged with sufficient particularity. *Evonik Degussa GmbH v. Materia Inc.*, C.A. No. 09-636, 2012 WL 4503771, at \*6 (D. Del. Oct. 1, 2012). Therefore, allegations that “are not self-evidently false . . . must be taken as true at the motion to dismiss stage of litigation.” *Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013).

Actavis sufficiently pleads the but-for materiality of the alleged misrepresentations in its inequitable conduct counterclaim by pleading that, had the USPTO considered the '445 patent,

the Process Patents would have been rejected as anticipated or obvious. (D.I. 85 at ¶¶ 174-76)

LEO has failed to establish that the cumulative nature of the '445 patent in view of other disclosed references is self-evident on the present record. Example 17 of the '445 patent is founded on steps disclosed in the Sorg and Opferkuch references. ('445 patent, col. 31:16-33)

The Process Patents disclose on their face the Sorg and Opferkuch references, confirming that the USPTO considered these references prior to issuing the Process Patents. (D.I. 106, Exs. 6-7)

However, at this stage of the proceedings, the court cannot properly determine whether the Sorg and Opferkuch references are wholly cumulative of the '445 patent because this would require the court to render an interpretation of the facts contained in the references. Actavis notes that there are unresolved factual disputes regarding whether ingenol-3-angelate is an ingenol-3-acylate, and whether the combination of Sorg and Opferkuch would yield ingenol-3-angelate. (D.I. 121 at 19 n.6) Factual disputes such as these are the proper subject of expert testimony.

Consequently, the record presently before the court does not self-evidently establish that the '445 patent is cumulative of other references considered by the USPTO.

### **C. Intent to Deceive**

As discussed at § IV.A.1, *supra*, the inequitable conduct counterclaim fails to identify a specific individual who owed a duty of disclosure in prosecuting the Process Patents and knew of the specific information in the '445 patent that is alleged to be material to the claims of the Process Patents. Applying binding Federal Circuit precedent to the facts of the present case, Actavis' failure to identify a specific individual with knowledge of the '445 patent is fatal to Actavis' efforts to plead the requisite scienter. *See Exergen*, 575 F.3d at 1330 (declining to find knowledge of the withheld material information where the pleading contained no allegations that a specific individual knew of specific material information contained in the reference). As a

result, I recommend that the court grant LEO's motion to dismiss Actavis' inequitable conduct counterclaim and affirmative defense.

## V. CONCLUSION

For the foregoing reasons, I recommend that the court grant LEO's motion to dismiss Actavis' inequitable conduct counterclaim and strike its affirmative defense for inequitable conduct. (D.I. 104) I recommend that Actavis be given permission to file an amended pleading curing the deficiencies in its inequitable conduct counterclaim and affirmative defense in accordance with the foregoing decision within twenty (20) days of the District Judge's ruling on this Report and Recommendation, if leave to amend is adopted.<sup>5</sup>


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)(2). The objections and responses to the objections are limited to ten (10) pages each. 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 Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

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<sup>5</sup> During oral argument on the pending motion, the parties raised discovery issues regarding the inequitable conduct claim. Specifically, Actavis alleged that LEO had stonewalled its efforts to subpoena the depositions of the prosecuting attorneys of the Process Patents. (10/23/17 Tr. at 28:23-30:12) In response, LEO alleged that the depositions would not be fruitful because of the prosecuting attorneys' anticipated assertion of the attorney-client privilege. (*Id.* at 33:4-20) This Report and Recommendation is limited to the sufficiency of the pleading, and should not be construed to extend to discovery issues not properly before the court at this time.

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, <http://www.ded.uscourts.gov>.

Dated: February 26, 2018



Sherry R. Fallon  
United States Magistrate Judge