

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

ALLERGAN USA, INC., ALLERGAN
HOLDINGS UNLIMITED COMPANY, and
EDEN BIODESIGN, LLC,

Plaintiffs,

v.

SUN PHARMACEUTICAL INDUSTRIES
LIMITED,

Defendant.

C.A. No. 19-1727-RGA

MEMORANDUM OPINION

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ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me is Plaintiffs' motion for judgment on the pleadings with respect to Defendant's counterclaim for unclean hands and affirmative defenses of unclean hands, prosecution history estoppel and/or judicial history estoppel, and patent misuse. (D.I. 423). The motion has been fully briefed. (D.I. 423, 428). For the reasons set forth below, Plaintiffs' motion is granted in part and denied in part.

I. BACKGROUND

On September 13, 2019, Plaintiffs Allergan USA, Inc., Allergan Holdings Unlimited Company, and Eden Biodesign, LLC (collectively, "Allergan" or "Plaintiffs") filed their Complaint alleging infringement of U.S. Patent Nos. 9,675,587 (the "'587 Patent") and 10,188,632 (the "'632 Patent") against Defendant Sun Pharmaceutical Industries Limited. The alleged infringement is based on Sun filing Abbreviated New Drug Application ("ANDA") No. 213447 with the FDA. Over the course of the litigation in this case, Allergan filed continuation applications and prosecuted patents belonging to the patent family at issue. Allergan later obtained U.S. Patent Nos. 11,007,179 (the "'179 Patent"), 11,090,291 (the "'291 Patent"), and 11,160,792 (the "'792 Patent"), and asserted them against Sun in July 2021, August 2021, and November 2021, respectively. The actions asserting these patents were consolidated with this action.

Allergan obtained U.S. Patent Nos. 11,229,627 (the "'627 Patent") and 11,311,516 (the "'516 Patent") in January 2022 and April 2022, respectively. Allergan filed an Amended Complaint asserting the '627 Patent and the '516 Patent against Sun. (D.I. 343). Sun filed its Answer on May 16, 2022 (D.I. 346) and an Amended Answer on May 27, 2022. (D.I. 349). In its Amended Answer, Sun raises, among other things, a counterclaim and affirmative defense that the '516 Patent is unenforceable because of Allergan's unclean hands. (*Id.* at 8-10, 15-18). Sun also

pled three other affirmative defenses. Sun alleges that the asserted claims of the '627 Patent and '516 Patent are barred by prosecution history estoppel and/or judicial estoppel, that Allergan's claims are barred by the equitable doctrines of waiver, estoppel, and/or laches, and that Allergan's claims are barred by the doctrine of patent misuse. (D.I. 349 at 10).

Allergan filed a motion to dismiss Sun's counterclaim of unclean hands and to strike Sun's related defenses. (D.I. 354). I denied Allergan's motion to dismiss Sun's counterclaim of unclean hands. (D.I. 420). I also denied Allergan's motion to strike Sun's defense of unclean hands, Sun's defense of prosecution history estoppel and/or judicial estoppel, and Sun's defense that Allergan's claims are barred by the doctrine of patent misuse. (*Id.*).¹

On October 25, 2022, Allergan filed the present motion for judgment on the pleadings with respect to Sun's counterclaim and defense of unclean hands, defense of prosecution history estoppel and/or judicial estoppel, and defense that Allergan's claims are barred by the doctrine of patent misuse. (D.I. 423).

II. LEGAL STANDARD

A. RULE 12(c)

A Rule 12(c) motion for judgment on the pleadings is reviewed under the same standard as a Rule 12(b)(6) motion to dismiss when the Rule 12(c) motion alleges that the plaintiff failed to state a claim upon which relief can be granted. *See Turbe v. Gov't of the Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991); *Revell v. Port Auth.*, 598 F.3d 128, 134 (3d Cir. 2010). The court must accept the factual allegations in the complaint and take them in the light most favorable to the non-moving party. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Christopher v. Harbury*,

¹ Sun withdrew its defense of waiver, estoppel, and/or laches and so I granted Allergan's motion to strike this defense. (D.I. 420).

536 U.S. 403, 406 (2002). “When there are well-ple[d] factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.” *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). The court must “draw on its judicial experience and common sense” to make the determination. *See id.* In ruling on a motion for judgment on the pleadings, the court is generally limited to the pleadings. *Mele v. Fed. Reserve Bank of N.Y.*, 359 F.3d 251, 257 (3d Cir. 2004). The court may, however, consider documents incorporated into the pleadings and those that are in the public record. *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

With respect to affirmative defenses, a Rule 12(c) motion is treated “as one to strike Defendant's affirmative defenses pursuant to Rule 12(f).” *Intellectual Ventures I LLC v. Symantec Corp.*, 2014 WL 4773954, at *1 (D. Del. Sept. 24, 2014). “[P]ursuant to Rule 12(f), the Court may strike from a pleading any insufficient defense.” *Wyeth Holdings Corp. v. Sandoz, Inc.*, 2012 WL 600715, at *4 (D. Del. Feb. 3, 2012) (internal quotation marks omitted). “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 under law.’” *Sun Microsystems, Inc. v. Versata Enters., Inc.*, 630 F. Supp. 2d 395, 402 (D. Del. 2009) (quoting *Proctor & Gamble Co. v. Nabisco Brands, Inc.*, 697 F. Supp. 1360, 1362 (D. Del. 1988)). “However, a court is not required to accept affirmative defenses that are mere ‘bare bones conclusory allegations,’ and may strike such inadequately pleaded defenses.” *Sun Microsystems*, 630 F. Supp. 2d at 408 (quoting *Cintron Beverage Group, LLC v. DePersia*, 2008 WL 1776430, at *2 (E.D. Pa. Apr. 15, 2008)). “A motion to strike a defense should not be granted ‘unless the insufficiency of the defense is clearly apparent.’” *Sun Microsystems*, 630 F. Supp. 2d at 402 (quoting *Cipollone v.*

Liggett Group, Inc., 789 F.2d 181, 188 (3d Cir. 1986), *rev'd on other grounds*, 505 U.S. 504 (1992)).

B. UNCLEAN HANDS

“Unclean hands is an equitable defense requiring the showing of five elements: (1) the party seeking affirmative relief (2) is guilty of conduct involving fraud, deceit, unconscionability, or bad faith (3) directly related to matter in issue (4) that injures other party (5) and affects balance of equities between litigants.” *Sonos, Inc., v. D&M Holdings Inc.*, 2016 WL 4249493, at *5 (D. Del. Aug. 10, 2016) (quoting *Sun Microsystems*, 630 F. Supp. 2d at 410). The conduct “must have an immediate and necessary relationship to the equity which [the plaintiff] seeks to obtain in the matter in litigation.” *Sun Microsystems*, 630 F. Supp. 2d at 410 (quoting *Blanchette v. Providence & Worcester Co.*, 428 F. Supp. 347, 357 (D. Del. 1977)).

III. DISCUSSION

Sun’s Amended Answer alleges, “On information and belief, Plaintiffs misused Sun’s confidential information relating to its eluxadoline ANDA product formulation to obtain claims that Plaintiffs did not invent and then asserted those claims against Sun.” (D.I. 349 at 16). Sun alleges that prior to the date suit was filed in 2019, Allergan consistently prosecuted patent applications that recited “colloidal silica” or “colloidal silicon dioxide” as a required limitation in “each and every claim.” (*Id.* at 8-9, 16-17). Sun further alleges that after Allergan “had accessed Sun’s confidential information regarding its ANDA Product formulation,” Allergan eliminated the limitation requiring “colloidal silicon dioxide” from claims in the patent application that led to the ’179 Patent. (*Id.* at 9, 17). Sun alleges that Dr. Tim Costello, one of the inventors named on the ’516 Patent, has stated “that he never invented any eluxadoline composition that did not include colloidal silica.” (*Id.* at 17). Based on these allegations, Sun alleges that Allergan “drafted claims

of the '516 patent (and other claims in this patent family) that do not explicitly require colloidal silica in an improper attempt to cover Sun's ANDA Product Formulation, which Plaintiffs did not invent." (*Id.*).

I previously addressed the issue of whether Sun's Amended Answer stated a claim for unclean hands under the Rule 12(b)(6) standard when I denied Allergan's motion to dismiss Sun's counterclaim and to strike Sun's related affirmative defenses. (D.I. 420). I found that Sun's Amended Answer stated a plausible claim for unclean hands by alleging "that Allergan misused Sun's confidential information, which Allergan obtained from Sun, to prosecute the '516 Patent in a manner to cover Sun's ANDA formulation, and then assert that patent against Sun." (*Id.* at 8). My finding was based on Sun alleging a change in patent prosecution strategy that coincided with Allergan gaining access to Sun's confidential information. (*Id.* at 8-9). I also noted the similarities between the facts pled here and those in *Natera, Inc. v. Genosity, Inc.*, 2022 WL 767602 (D. Del. March 14, 2022). (D.I. 420 at 9 n.4).²

After briefing for Allergan's motion to dismiss closed, the parties agreed to a stipulation that Sun "will not introduce evidence at trial to support an argument that Plaintiffs violated the Protective Order, D.I. 100, or fraudulently used confidential information belonging to Defendants in connection with the [] matter." (D.I. 405 at 1).³

² In its Answering briefing for that motion, Sun argued for a different theory of unclean hands. In its Answering Brief, Sun stated, "Sun is not alleging a violation of the Stipulated Protective Order or any *fraudulent* use of Sun's confidential information." (D.I. 358 at 16). Sun, instead, argued, "Allergan gleaned Sun's confidential noninfringement position from the 2020 *Markman* proceedings and then ran to the Patent Office to seek new claims to formulations it did not invent." (*Id.*). I did not read these facts or this theory into Sun's Amended Answer because a complaint cannot be amended by the briefings. See *M2M Sols. LLC v. Telit Commc'ns PLC*, 2015 WL 4640400, at *3 (D. Del. Aug. 5, 2015).

³ This argument is also reflected in the Joint Pretrial Order. In the Joint Pretrial Order, Sun bases its claim of unclean hands on the theory that Allergan's patent prosecution attorneys drew

Based on this stipulation, Allergan now moves for judgment on the pleadings asserting, “there is no material issue of fact to support Sun’s counterclaim of unclean hands or its related Fourth Defense of unclean hands concerning the ’516 Patent based on alleged misuse of Sun’s confidential information by [Allergan].” (D.I. 423 at 3). Allergan also moves for judgment on the pleadings with respect to Sun’s defenses of prosecution history estoppel and/or judicial estoppel and patent misuse because these defenses are premised on the same allegations as Sun’s unclean hands defense. (*Id.*).

A. COUNTERCLAIM OF UNCLEAN HANDS

The crux of this motion is whether there is a material issue of fact as to whether Allergan “is guilty of conduct involving fraud, deceit, unconscionability, or bad faith,” *Sonos*, 2016 WL 4249493, at *5, based on the pleadings. The parties do not dispute that the other four elements constituting unclean hands are satisfied. (*See* D.I. 423 at 3; D.I. 428 at 13-14).

Allergan argues Sun’s allegation that Allergan misused Sun’s confidential information to obtain claims in the ’516 Patent is the conduct involving unconscionability or bad faith. (D.I. 423 at 3). Allergan contends that because Sun has stipulated that it will not introduce evidence to show that Allergan violated the Protective Order or fraudulently used confidential information, there is no material issue of fact that Allergan is guilty of the conduct underlying Sun’s unclean hands claim. (*Id.*).

Sun argues that the unconscionable conduct stems from Allergan “us[ing] what they learned through this litigation about Sun’s formulation ‘to obtain claims that [Allergan] did not invent and then asserted those claims against Sun.’” (D.I. 428 at 14). Sun contends that by

inferences about Sun’s formulation from the claim construction process and used these inferences to obtain patents to cover Sun’s ANDA formulation. (D.I. 414, Ex. 3 at 23).

“[r]elying on a public litigation proceeding to infer details about a confidential ANDA formulation for the purpose of prosecuting patents that improve an infringement position—*with no specification, inventor, or documentary support of inventorship*—constitutes misuse of Sun’s product-development information.” *Id.* (emphasis in original). Sun cites to *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, 2013 WL 6858765 (D.N.J. Dec. 30, 2013), for support. In *Jazz*, the district court found that the defendant had made out a *prima facie* defense for unclean hands by alleging that the plaintiff used “confidential information that it acquired during the course of the instant litigation . . . for the purpose of filing and prosecuting continuation patents, not based on what the inventors thought they invented, but for the purpose of prolonging the instant litigation in order to effectively prevent Roxane from launching its generic product.” 2013 WL 6858765, at *6.⁴

I find that the unconscionable conduct alleged in Sun’s Amended Answer is Allergan misusing Sun’s confidential information to draft claims of the ’516 Patent to cover Sun’s ANDA formula. Sun’s Amended Answer specifically claims that Allergan “misused Sun’s confidential information relating to its eluxadoline ANDA product formulation to obtain claims that Plaintiffs did not invent and then asserted those claims against Sun.” (D.I. 349 at 16). The timing of the alleged change in Allergan’s patent prosecution strategy only references the timing of Allergan accessing Sun’s confidential information, not the 2020 *Markman* hearing or some other stage in this litigation. (*Id.* at 16-17 (“On March 16, 2021, during the course of the instant litigation and after Plaintiffs had accessed Sun’s confidential information regarding its ANDA Product formulation, Plaintiffs amended the claims that led to the ’179 patent.”); *id.* at 17 (“The claims of

⁴ Sun also argues that public policy favors permitting its counterclaim of unclean hands to stand. (D.I. 428 at 16-18).

the '516 patent were all prosecuted after Plaintiffs had accessed Sun's confidential information describing Sun's confidential formulation for its eluxadoline ANDA Product.")).

It is true that Sun's Amended Answer only alleges Allergan did not begin prosecuting claims that do not require colloidal silica until after Allergan had "access" to Sun's confidential information. (D.I. 428 at 10). Sun may be able to prove that fact without proving a violation of the Protective Order. Sun's Amended Answer, however, does not allege that Allergan learned of Sun's ANDA formulation from any other sources of information. (D.I. 439 at 15-18). Sun does not allege, nor does it provide any facts to support the inference, in its Amended Answer that Allergan inferred details about the Sun ANDA formulation through the public aspects of this litigation. Sun's theory of unconscionable conduct, as argued in its Answering Brief, is not supported by the content of the Amended Answer.⁵ The Amended Answer makes clear that Sun is alleging that Allergan used its "access" to Sun's confidential information to draft the claims of the '516 Patent to cover Sun's ANDA formulation.

⁵ Sun asserts that it was Allergan who introduced the theory that Allergan "made inferences about Sun's confidential formulation from *publicly* available information." (D.I. 428 at 10-11 ("Instead, Plaintiffs apparently assert they simply made inferences about Sun's confidential formulation from *publicly* available information, and 'parties can pursue patent claims based on public information, even when those claims cover competitors' products.'" (citing D.I. 363 at 1-2))). The brief that Sun cites to, however, is only responding Sun's previous argument that "it appears Allergan gleaned Sun's confidential noninfringement position from the 2020 *Markman* proceedings." (See D.I. 363 at 1-2; D.I. 358 at 16). Allergan refutes Sun's assertion in the Joint Pretrial Order stating, "It is not the case that Plaintiffs, after a *public* *Markman* hearing that was held on December 21, 2020, sought claims that did not require colloidal silica for the first time." (D.I. 414, Ex. 2 at 54).

Therefore, I find the alleged unconscionable conduct underlying Sun's unclean hands claim is that Allergan misused Sun's confidential information to obtain claims in the '516 Patent that cover Sun's ANDA formulation.⁶

I also find that Allergan is entitled to judgment on the pleadings because there is no material issue of fact that Allergan misused Sun's confidential information. The Protective Order covers confidential information, which includes ANDAs, and prevents persons receiving confidential information from using it in connection with any practice before the USPTO. (D.I. 100 at 2-8). Using confidential information about Sun's ANDA formulation to prosecute patents would constitute a violation of the Protective Order. *Id.* Sun, however, has stipulated that it "will not introduce evidence at trial to support an argument that Plaintiffs violated the Protective Order, D.I. 100, or fraudulently used confidential information belonging to Defendants in connection with [this] matter." (D.I. 405). Sun has also confirmed in its Answering Brief that it "lacks direct evidence" to prove that Allergan has violated the Protective Order. (D.I. 428 at 9). While I must accept the factual allegations in the complaint and take them in the light most favorable to the non-moving party, *see Erickson v. Pardus*, 551 U.S. 89, 94 (2007), Sun's stipulation eliminates any allegation or inference that Allergan misused Sun's confidential information. Thus, there is no material issue of fact as to whether Allergan misused Sun's confidential information to draft claims of the '516 Patent to cover Sun's ANDA formulation.⁷

⁶ My reading of the Amended Answer now is also consistent with my reading when I ruled on Allergan's motion to dismiss. (D.I. 420 at 8-9, 9 n.4).

⁷ I previously found that the timing of Allergan's access to Sun's confidential information and Allergan's change in patent prosecution strategy led to a plausible inference that Allergan misused Sun's confidential information in drafting the claims of the '516 Patent. (D.I. 420). I did not consider the stipulation by Sun that it would not present evidence that Allergan violated the Protective Order or fraudulently used confidential information (D.I. 405) when I previously ruled

Even if Sun were to prove the facts alleged in its Answering Brief, Sun still would not have shown Allergan acted with unclean hands.

First, observing a public proceeding, such as a *Markman* hearing, and making intelligent guesses based on the information disclosed at those proceedings is not a misuse of confidential information. Sun cites to *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, 2013 WL 6858765 (D.N.J. Dec. 30, 2013), for the proposition that “a claim of unclean hands can be supported by allegations that the patentee gleaned information about a confidential ANDA formulation from litigation proceedings.” (D.I. 428 at 15; *see* D.I. 428, Ex. D at 16-17).

Jazz, however, is distinguishable. The court in *Jazz* based its determination on its characterization of Roxane’s proposed Amended Answer as alleging the plaintiff “used confidential information that it acquired during the course of litigation.” *Jazz*, 2013 WL 6858765, at *6. There is no similar allegation here. Perhaps recognizing that difference, Defendant provides some of the underlying briefing in *Jazz*. The defendant in *Jazz* in its briefing stated its theory of unclean hands was based on the plaintiff “gleaning [the defendant’s] noninfringement defenses from [the defendant’s] notice letters or from litigation.” (D.I. 428, Ex. D at 1).⁸ I am not sure what exactly that is supposed to mean. But I do not understand it to be what is argued here. The court in *Jazz* did not address whether a party inferring details or making intelligent guesses based on public information (whether obtained at a *Markman* hearing or otherwise) constitutes misuse of

on this issue. The inference that Allergan misused Sun’s confidential information is no longer plausible when accounting for Sun’s stipulation.

⁸ The court in *Jazz* also found a defense of unclean hands was pled because the assertion of the patents was “for no other purpose but to prolong litigation . . . and thereby effectively prevent Roxane from introducing a competing product into the market.” *Jazz*, 2013 WL 6858765, at *6. Sun’s Amended Answer does not allege that Allergan is asserting these patents in an attempt to prolong litigation.

confidential information. I would think, by definition, there is nothing by itself wrong with using public information to shape patent strategy including the drafting of claims.

Second, if Sun were to prove the facts alleged in its unclean hands counterclaim, it would, at best, prove that the '516 Patent is invalid due to inadequate written description, not that Allergan acted with unclean hands. Sun alleges that one or more claims of the '516 Patent are invalid under U.S.C. §§ 101, 102, 103, and/or 112. Asserting a patent that is proven through litigation to be invalid, however, by itself, is not unconscionable. Rather, it is one of the ordinary outcomes of patent litigation.

Third, Sun alleges Dr. Costello, one of the named inventors of the '516 Patent, stated that he never invented an eluxadoline composition that did not include colloidal silica. (D.I. 439 at 17). Sun argues Dr. Costello's statements show that the inventors never invented the formulations claimed by the '516 Patent (D.I. 428 at 6-8), and that Allergan "knew or should have known that claims of the '516 Patent that lack colloidal silica are invalid under at least 35 U.S.C. § 112." (D.I. 349 at 17-18). Sun alleges that Allergan acted with unclean hands by asserting the '516 Patent when it knew it was invalid. (D.I. 349 at 17-18).

Taking Dr. Costello's statement as true, however, does not prove Sun's allegation that the inventors lacked possession of the claimed invention, nor that Allergan knew that the inventors lacked possession. Determining whether an inventor possessed an invention "requires an objective inquiry into the four corners of the specification," *see Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010), not the beliefs of the inventor. Therefore, allegations of Dr. Costello's testimony are insufficient to show that Allergan acted with unclean hands.

Taking all of Sun's asserted facts as true, and considering them collectively, Sun would still fail to prove that Allergan is guilty of unconscionable conduct. Therefore, there is no material

issue of fact as to whether Allergan is guilty of unconscionable conduct. Allergan is entitled to judgment on the pleadings with respect to Sun's counterclaim of unclean hands.

B. SUN'S AFFIRMATIVE DEFENSES

1. Unclean Hands

Allergan argues that it is entitled to judgment on the pleadings with respect to Sun's Fourth Defense of unclean hands for the same reasons as Sun's counterclaim of unclean hands. (D.I. 423 at 3).

Sun argues that Allergan has not met its burden to strike the affirmative defense under Rule 12(f), which is less demanding than Rule 12(b)(6) standard. (D.I. 428 at 15-16).

I find that Allergan is entitled to judgment on the pleadings because there is no material issue of fact that Allergan misused Sun's confidential information. While the Rule 12(f) standard for striking an affirmative defense is lower than the Rule 12(b)(6) standard, Sun's Amended Answer fails to adequately allege that Allergan committed any unconscionable conduct underlying its defense of unclean hands. *See also Wyeth Holdings Corp. v. Sandoz, Inc.*, 2012 WL 600715, at *4 (D. Del. Feb. 3, 2012) (“[Rule 12(f)] has been used in this jurisdiction to strike affirmative defenses where a party has failed to state a corresponding claim upon which relief can be granted.” (citing *Power Integrations, Inc. v. Fairchild Semiconductor Int'l Inc.*, 2009 WL 4928024, at *8–10 (D. Del. Dec. 18, 2009))), *report and recommendation adopted*, 2012 WL 749378 (D. Del. Mar. 1, 2012).

2. Defenses of Prosecution History Estoppel and/or Judicial Estoppel and Patent Misuse

Allergan argues that it is entitled to judgment on the pleadings with respect to Sun's Fifth Defense of prosecution history estoppel and/or judicial estoppel and Seventh Defense of patent misuse because they “re-allege[] and incorporate[] by reference the allegations in’ Sun's Fourth

Defense of unclean hands.” (D.I. 423 at 3 (citing D.I. 349 at 10)). Allergan argues because there is no material issue of fact to support the unclean hands defense, there is no material issue of fact to support these defenses. (D.I. 423 at 3).

Sun argues that Allergan has not met its burden to strike the affirmative defense under Rule 12(f), which is less demanding than the Rule 12(b)(6) standard. (D.I. 428 at 15-16).

I find Allergan is not entitled to judgment on the pleadings for Sun’s defense of prosecution history estoppel and/or judicial estoppel and patent misuse. My determination that there is no material issue of fact with respect to Sun’s unclean hands defense stems from Sun being unable to provide any evidence of Allergan’s unconscionable conduct. Allergan has not shown how the insufficiency of these two defenses is “clearly apparent.” *Sun Microsystems*, 630 F. Supp. 2d at 402.

IV. CONCLUSION

For the reasons stated above, Plaintiff’s motion is GRANTED in part and DENIED in part. An appropriate order (D.I. 435) has previously issued.