

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

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

Plaintiffs,

v.

MSN LABORATORIES PRIVATE  
LIMITED and MSN PHARMACEUTICALS  
INC.,

Defendants.

C.A. No. 19-1727-RGA

**MEMORANDUM OPINION**

Jack B. Blumenfeld, Jeremy A. Tigan, MORRIS, NICHOLS, ARSHT & TUNNELL LLP,  
Wilmington, DE; Lisa B. Pensabene, Hassen A. Sayeed, Daniel O'Boyle, Carolyn Wall, James  
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October 20, 2022

  
ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me is Defendant's motion for leave to amend. (D.I. 374). The motion has been fully briefed. (D.I. 374, 388, 395). For the reasons set forth below, Defendant's motion is denied.

**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 MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. ("MSN" or "Defendant"). The infringement is based on MSN filing Abbreviated New Drug Application ("ANDA") No. 213576 with the FDA.

Over the course of litigation, 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 MSN 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. By agreement of the parties (D.I. 339), Allergan filed an Amended Complaint on April 28, 2022, asserting the '627 Patent and the '516 Patent against MSN. MSN filed its Answer on May 16, 2022. (D.I. 346). MSN filed the instant motion on July 22, 2022.

**II. LEGAL STANDARD**

Federal Rule of Civil Procedure 15(a)(2) states that, apart from amendments as a matter of course, "a party may amend its pleading only with the opposing party's written consent or the

court's leave. The court should freely give leave when justice so requires." FED. R. CIV. P. 15(a)(2). The Third Circuit has instructed that "absent undue or substantial prejudice, an amendment should be allowed under Rule 15(a) unless 'denial [can] be grounded in bad faith or dilatory motive, truly undue or unexplained delay, repeated failure to cure deficiency by amendments previously allowed or futility of amendment.'" *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004) (quoting *Lundy v. Adamar of New Jersey, Inc.*, 34 F.3d 1173, 1196 (3d Cir. 1994)) (emphasis omitted). An amendment is futile if it "would fail to state a claim upon which relief could be granted." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). The futility analysis follows the standard that applies to a motion under Rule 12(b)(6). *Id.*

A request to amend filed after the court's deadline to amend must also meet the "good cause" standard of Rule 16(b)(4). *Premier Comp Sols. v. UPMC*, 970 F.3d 316, 319 (3d Cir. 2020). Rule 16(b)(4) provides, "A schedule may be modified only for good cause and with the judge's consent." FED. R. CIV. P. 16(b)(4). "'Good cause' exists when the [s]chedule cannot reasonably be met despite the diligence of the party seeking the extension." *ICU Med., Inc. v. RyMed Techs., Inc.*, 674 F. Supp. 2d 574, 577 (D. Del. 2009). Unlike Rule 15(a), the Rule 16(b) standard focuses on the "diligence of the movant, and not on prejudice to the non-moving party." *Roquette Freres v. SPI Pharma, Inc.*, 2009 WL 1444835, at \*4 (D. Del. May 21, 2009). "A party must meet [Rule 16(b)'s] standard before a district court considers whether the party also meets Rule 15(a)'s more liberal standard." *Premier Comp*, 970 F.3d at 319.

### **III. DISCUSSION**

On April 28, 2022, Allergan filed its Amended Complaint (D.I. 341) adding the infringement claims against MSN pertaining to the '627 Patent and the '516 Patent. MSN filed its Answer on May 16, 2022.

The timeline following MSN's filing is in dispute. According to MSN, it "diligently raised the issue of unclean hands with [Allergan] on May 26, 2022 and met and conferred to reach a compromise." (D.I. 374 at 5). MSN does not provide any exhibit (*e.g.*, an email thread) to support its allegation of communicating this issue to Allergan on May 26, 2022. Allergan states that, to the contrary, it was Allergan that raised the issue on June 24, 2022. (D.I. 388 at 8). The only documentation in the record supports Allergan's position. (*See* D.I. 388-1, Exs. A&B). In its reply, MSN appears to concede the point. (*See* D.I. 395 at 3 (arguing "informal notice based on Sun's complaint"))).

On May 27, 2022, MSN and Sun (another defendant in the consolidated case) served their final invalidity and unenforceability contentions relating to the '627 and '516 patents. (*See* D.I. 350).<sup>1</sup> Allergan states that these contentions were the first time MSN asserted an unclean hands defense for the '627 Patent and '516 Patent. (D.I. 388 at 4). Allergan further states that it was only after Allergan read MSN's and Sun's joint opening invalidity report, served on June 17, 2022, that Allergan reached out to MSN to clarify if MSN was asserting a defense of unclean hands. (*Id.*). Allergan and MSN met and conferred on June 27, 2022. (D.I. 374-3, Ex. C; D.I. 388-1, Ex. B).

On July 22, 2022, MSN sought to amend its May 16, 2022 Answer to add counterclaims and affirmative defenses alleging that the '516 Patent, the '627 Patent, and the '291 Patent are unenforceable under the doctrine of unclean hands.

#### **A. RULE 16(b)(4) DILIGENCE**

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<sup>1</sup> Defendant Sun also filed an Amended Answer (D.I. 349) alleging similar claims and affirmative defenses based on the doctrine of unclean hands, which MSN explicitly refers to in its briefing. (D.I. 374 at 3).

MSN asserts that good cause exists for allowing leave to amend. MSN claims it was diligent in raising the issue of unclean hands with Allergan on May 26, 2022. (D.I. 374 at 5; D.I. 395 at 3). The record does not support the date of this claimed diligence.

Allergan counters that MSN cannot show good cause because MSN was not diligent. Allergan argues that MSN was not diligent because Allergan needed to prompt MSN before MSN acted to amend the pleadings to add the proposed affirmative defense and counterclaims. (D.I. 388 at 8). Allergan also argues that MSN was not diligent because MSN was in possession of the information to form its claims of unclean hands in February 2022, five months prior to filing this motion. (*Id.* at 7-8).

I find that MSN is unable to show good cause because it was not diligent. Even if I were to credit MSN with “informal notice” some time before June 24<sup>th</sup>, MSN was not diligent. MSN alleges that it gathered the facts necessary to raise the proposed amendment “[i]n the course of reviewing the pop-up patents asserted against” MSN. (D.I. 374 at 4). The only sources of evidence that MSN cites to in its motion are the patents at issue (i.e., the ’291 Patent, the ’587 Patent, the ’632 Patent, ’627 Patent, and ’516 Patent), the prosecution histories of patent applications in the patent family (U.S. Patent Application Nos. 13/829,984, 15/588,304, 16/213,083, and 16/459,947), and deposition testimony taken on February 16, 2022 from Dr. Costello, one of the named inventors on the patents. (D.I. 374-1, Ex. A). These are all sources of information that MSN possessed before it filed its Answer on May 16, 2022. MSN has not cited to any facts or sources of information that it needed to bring its claims for unclean hands but which it lacked on May 16, 2022.

The date the answer was due—May 16, 2022—was set by court order. (D.I. 340). MSN concedes that the “facts were in existence before the scheduling deadline,” but cites to *Galderma*

*Labs. Inc. v. Amneal Pharm.*, 2013 WL 5461611 (D. Del. Sept. 30, 2013) for the proposition that good cause can be found provided the movant “was diligent after the facts came to its attention.” (D.I. 374 at 5-6). The facts in *Galderma* are distinguishable from the facts here. In *Galderma*, the movant only learned of the facts through deposition testimony that occurred months after the deadline to amend pleadings. *Id.* at \*1. To put it another way, the court found good cause in *Galderma* because the movant first possessed the information after the deadline to amend the pleadings. In the present case, MSN possessed all the relevant information to bring its counterclaims and defenses of unclean hands at the time Allergan filed its amended complaint.

Furthermore, the movant in *Galderma* brought its motion to amend within one month of learning of the new facts. *Id.* In the present case, MSN is bringing its motion almost five months after it obtained the inventor’s testimony and two months after its Answer was due. The Rule 16(b)(4) standard does not allow “an inability to timely amend a pleading within the scheduling order deadline [to] excuse[] a party from exercising diligence in seeking leave to amend outside of the deadline.” *NRT Tech. Corp. v. Everi Holdings Inc.*, 2022 WL 354291, at \*3 (D. Del. Jan. 11, 2022). MSN’s bare claims of diligence in reviewing the patents are insufficient. This court has found excuses of dealing with a “tortuous” record and common litigation activities do not excuse delay. *See Pfizer Inc. v. Sandoz Inc.*, 2013 WL 5934635, at \*4 (D. Del. Nov. 4, 2013). MSN’s claim that it was diligent is further undercut by Allergan’s exhibits showing that it was Allergan who was proactively seeking clarification as to whether MSN was intending to pursue claims of unclean hands, rather than MSN taking the initiative. (D.I. 388-1, Ex. A.).

I find that MSN cannot show good cause under Rule 16(b)(4) because it was not diligent. It appears that MSN was in possession of all the relevant facts to assert its claims and defenses of unclean hands at the time it filed its Answer. MSN has failed to point to new information it came

to possess after the May 16 deadline, or any other explanation for why it was unable to timely plead unclean hands. Therefore, MSN has not shown good cause under Rule 16(b)(4).

Because I find that MSN has not satisfied Rule 16(b)(4)'s standard, it is not necessary to determine whether MSN meets Rule 15(a)'s requirements. *See Premier Comp Sols. v. UPMC*, 970 F.3d 316, 319 (3d Cir. 2020).

#### **IV. CONCLUSION**

For the reasons stated above, Defendant's motion is DENIED.

An appropriate order will issue.

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Attorneys for Defendant.

October 20, 2022



  
ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me is Plaintiffs' motion to dismiss a counterclaim pursuant to Rule 12(b)(6) and to strike four affirmative defenses pursuant to Rule 12(f). (D.I. 354). The motion has been fully briefed. (D.I. 355, 358, 363). 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). Sun later filed 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 pleads three other affirmative defenses. Sun alleges that the '627 Patent's and '516 Patent's claims 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. (*Id.* at 10).

On June 10, 2022, Allergan filed the pending motion to dismiss the counterclaim of unclean hands under Rule 12(b)(6) for failure to state a claim upon which relief can be granted and to strike the related affirmative defenses under Rule 12(f).

## **II. LEGAL STANDARD**

### **A. MOTION TO DISMISS COUNTERCLAIM UNDER RULE 12(b)(6)**

Federal Rule of Civil Procedure 8 requires a complainant to provide “a short and plain statement of the claim showing that the pleader is entitled to relief.” FED. R. CIV. P. 8(a)(2). Rule 12(b)(6) allows the accused party to bring a motion to dismiss a claim for “failure to state a claim upon which relief can be granted.” FED. R. CIV. P. 12(b)(6). A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in the counterclaim complaint as true and viewing them in the light most favorable to the complainant, a court concludes that those allegations “could not raise a claim of entitlement to relief.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a “formulaic recitation” of the claim elements. *Id.* at 555 (“Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact).”). Moreover, there must be sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The facial plausibility standard is satisfied when the complaint’s factual content “allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (“Where a complaint pleads facts that are merely consistent with a defendant’s liability, it stops

short of the line between possibility and plausibility of entitlement to relief.” (internal quotation marks omitted)).

### **B. MOTION TO STRIKE UNDER RULE 12(f).**

“[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)).

### **III. DISCUSSION**

Sun claims that Allergan misused Sun’s confidential information to prosecute the ’516 Patent and then asserted that patent against Sun. 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.” (D.I. 349 at 8-9, 16-17). Sun 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 Allergan later used Sun's confidential information to draft claims in the '516 Patent to "not explicitly require colloidal silica in an improper attempt to cover Sun's ANDA Product Formulation, which [Allergan] did not invent." (*Id.* at 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.*).

In its Answering Brief (D.I. 358), Sun disavows the theory put forth in its Amended Answer. Sun still asserts a claim of unclean hands, but Sun does not allege that Allergan misused confidential information it obtained from Sun during litigation. "Sun is not alleging a violation of the Stipulated Protective Order or any *fraudulent* use of Sun's confidential information." (*Id.* at 16). Sun, instead, argues, "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.*). Allergan replies that Sun's briefing should be grounds for granting Allergan's motion as it refutes the facts Sun alleges in its Amended Answer. (D.I. 363 at 9). I decline to read the facts or new theories from Sun's brief into Sun's Amended Answer. "As the Third Circuit has stated, '[i]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.'" *M2M Sols. LLC v. Telit Commc'ns PLC*, 2015 WL 4640400, at \*3 (D. Del. Aug. 5, 2015) (quoting *Com. of Pa. ex rel. Zimmerman v. PepsiCo. Inc.*, 836 F.2d 173, 181 (3d Cir. 1988)). This new theory and the facts supporting it are "not entitled to consideration in the pleading stage." *Id.* Therefore, Sun's new theory does not factor in my determination that Sun has stated a claim that the '516 Patent is unenforceable under the doctrine of unclean hands.<sup>1</sup>

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<sup>1</sup> Sun will have the burden of proving the facts it has asserted in its Amended Answer. I do not opine on whether Sun's theory discussed in its Answering Brief states a claim for unclean hands. I also am not sure why Sun would pursue the theory stated in its Answering Brief, since the

## A. UNCLEAN HANDS COUNTERCLAIM

### 1. Pleading Standard

Allergan asserts that Sun's counterclaim for unclean hands sounds in fraud. (D.I. 355 at 6; D.I. 363 at 2-5). Allergan argues Sun's unclean hands counterclaim must be pled with particularity as required by the Federal Rule of Civil Procedure 9(b) standard.

Sun contends that its unclean hands counterclaim is based on unconscionability and bad faith. Sun argues it only needs to meet Federal Rule of Civil Procedure Rule 8's less demanding requirements for pleading its counterclaim because it does not sound in fraud. (D.I. 358 at 16). In its Amended Answer, Sun alleges, "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 8, 16). Sun characterizes these allegations as a type of "litigation misconduct." (*Id.* at 9, 17).

"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)).

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premise is that the claims lack written description. If they do, I will not need to reach the equitable defenses. If they do not, the equitable defenses will fail. Thus, it seems the theory adds nothing.

The pleadings standard for unclean hands depends on the specific conduct alleged. A counterclaim or affirmative defense that alleges fraudulent conduct must be pled with particularity under Rule 9(b). *See, e.g., Sonos*, 2016 WL 4249493 at \*5. Allegations that are founded on other theories, however, need only meet the Rule 8 standard. “*Sonos* is authority for the proposition that an unclean hands defense based on fraud or misrepresentation must satisfy the pleading requirements of Rule 9(b), but not for the broader proposition that every invocation of unclean hands must satisfy Rule 9(b).” *AbbVie Inc. v. Boehringer Ingelheim Int’l GmbH*, 2018 WL 2604825, at \*1 (D. Del. June 4, 2018).

I find that Rule 8 is the correct standard to apply in the present case. Sun has only claimed that Allergan has committed litigation misconduct, not fraud. In its Amended Answer, Sun alleges that Allergan misused Sun’s confidential information, which Allergan obtained from Sun through the course of this litigation.<sup>2</sup> Specifically, Sun alleges that Allergan used Sun’s confidential information to draft the claims of the ’179 Patent and the ’516 Patent in an improper attempt to cover Sun’s ANDA formulation.<sup>3</sup> Courts have applied Rule 8 to analyze similar unclean hands

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<sup>2</sup> Allergan also contends, “Sun is necessarily claiming that Allergan’s [patent] prosecutors pursued claims by either intentionally withholding [] testimony or knowingly misrepresenting to the PTO that Allergan invented [certain] claims.” (D.I. 363 at 4). Allergan argues that the conduct Sun accuses Allergan of is akin to “defrauding the PTO,” which must be pled in accordance with Rule 9(b). (*Id.*). Sun’s amended answer, however, does not allege nor claim that Allergan committed inequitable conduct. Therefore, I find Rule 9(b) is not applicable to analyzing the sufficiency of Sun’s counterclaim of unclean hands.

<sup>3</sup> Allergan cites to *Kingsdowne Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988), for the proposition “that there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor’s product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor’s product the applicant’s attorney has learned about during the prosecution of a patent application.” Sun claims that Allergan drafted its claims to cover an invention that Allergan had not invented, using Sun’s confidential information, so that it would cover Sun’s ANDA formulation. The conduct goes beyond simply drafting claims to cover a known competitor’s product. *See also Natera, Inc. v. Genosity, Inc.*, 2022 WL 767602 (D. Del. March 14, 2022).

pleadings. *See, e.g., Jazz Pharms., Inc. v. Roxane Lab'ys, Inc.*, 2013 WL 6858765, at \*5 (D.N.J. Dec. 30, 2013) (applying Rule 8 to analyze the defendant's unclean hands defense alleging plaintiff used confidential information obtained in the course of litigation to prosecute continuation patent).

Therefore, I find that Rule 8 should apply to determine whether Sun has sufficiently pled its counterclaim for unclean hands.

## **2. Sufficiency of the Pleading**

Allergan asserts that Sun's allegations fail to meet Rule 8's requirements. (D.I. 363 at 7). Allergan argues Sun's counterclaim should be dismissed because Sun's Opposition Brief "conced[es] that none of Sun's confidential information was actually misused" by Allergan, and thus is grounds for dismissal. (D.I. 363 at 3, 9).

Sun argues that it has sufficiently stated a claim for unclean hands. In its Amended Answer, Sun alleges 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. (D.I. 349 at 9-10, 17-18). Sun argues such conduct is unconscionable and should render the '516 Patent unenforceable against Sun. (D.I. 388 at 15).

I find that Sun's Amended Answer states a plausible claim for unclean hands. Sun has alleged facts to show that Allergan changed its strategy for prosecuting patents – by eliminating the inclusion of "colloidal silica" or "colloidal silicon dioxide" as a limitation to certain claims – after it had access to Sun's confidential information pertaining to Sun's ANDA formulation. The present case is similar to *Natera, Inc. v. Genosity, Inc.*, 2022 WL 767602 (D. Del. March 14, 2022). In *Natera*, the court found that Genosity had sufficiently pled an affirmative defense of unclean hands by alleging: (1) Natera never claimed ArcherDX's method in previous prosecution at the PTO, (2) one of Natera's executives left Natera to work at ArcherDX, (3) that executive gained

access to the confidential information relating to ArcherDX's technology, (4) that executive then returned to Natera, and (5) Natera then drafted the claims of its patent in an attempt to cover ArcherDX. *Id.* at \*5. Sun alleges a similar timeline of changing patent prosecution strategy after gaining access to confidential information.<sup>4</sup> Therefore, I find Sun has alleged facts to state a plausible claim that Allergan acted with unclean hands, and that the '516 Patent is therefore unenforceable.<sup>5</sup>

## B. SUN'S AFFIRMATIVE DEFENSES

### 1. Unclean Hands

Allergan argues Sun's affirmative defense of unclean hands should be struck under Rule 12(f) because Sun failed to plausibly plead its corresponding counterclaim. (D.I. 355 at 9).

I find that Sun's affirmative defense of unclean hands is properly pled. The pleading standard for an affirmative defense is less demanding than that of a claim or counterclaim. *See Internet Media Corp. v. Hearst Newspapers, LLC*, 2012 WL 3867165, at \*3 (D. Del. Sept. 6, 2012) (noting that affirmative defenses "need not be plausible to survive" under Rule 8(c)). Sun states a plausible claim that the '516 Patent is unenforceable due to the doctrine of unclean hands.

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<sup>4</sup> Even though in *Natera* unclean hands was pled as an affirmative defense, which just needed to comply with Rule 8(c), and not Rule 8(a)'s *Twombly* and *Iqbal* standard, *Senju Pharm. Co., v. Apotex, Inc.*, 921 F. Supp. 2d 297, 303 (D. Del. 2013), *Natera* is still informative. The court there noted that "a plausible inference can be drawn from these alleged facts that Natera misused [the] confidential information to obtain claims that it did not invent and then asserted these claims against Genosity." *Natera*, 2022 WL 767602, at \*5.

<sup>5</sup> Sun's Amended Answer states Sun "reserve[s] the right to rely upon the doctrine of unclean hands to bar the enforceability of U.S. Patent Nos. 11,007,179, 11,090,291, 11,160,792, and 11,229,627." (D.I. 349 at 16 n.2). In its Amended Answer, however, Sun has pled that just the '516 Patent is unenforceable due to Allergan's unclean hands. Therefore, my determination that Sun has stated a claim that Allergan has unclean hands only extends to the '516 Patent. "Reserving a right" does not plead a counterclaim or an affirmative defense.



Therefore, because Sun alleges the same facts for its affirmative defense, Sun's defense meets the Rule 8(c) standard.

## **2. Prosecution History Estoppel and/or Judicial Estoppel**

Allergan argues that Sun's Fifth Defense of prosecution history estoppel and/or judicial estoppel should be "stricken to the extent that it 're-allege[s] and incorporate[s] by reference' [Sun's] unclean hands defense." (D.I. 355 at 10 n.3).

Allergan only seeks to strike this affirmative defense to the extent it re-alleges facts from the unclean hands defense. Because I will not strike the unclean hands affirmative defense, I will not strike the Fifth Defense, either.

## **3. Waiver, Estoppel, and Laches**

In its Answering brief, Sun agrees to withdraw its Sixth Defense of waiver, estoppel, and laches. (D.I. 358 at 1 n.1). Therefore, I will strike it.

## **4. Patent Misuse**

Allergan argues that Sun's Seventh Defense of patent misuse should be struck if the unclean hands defense is struck because they rest on the same allegations. (D.I. 355 9-10).

Since the premise of Allergan's request is not met, I will not strike the Seventh Defense.

## **IV. CONCLUSION**

For the reasons stated above, Plaintiffs' motion is GRANTED in part and DENIED in part. An appropriate order will issue.

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MSN PHARMACEUTICALS INC.,

Defendants.


C.A. No. 19-1727-RGA

ORDER

For the reasons stated in the accompanying Memorandum Opinion, Defendant's motion for leave to amend its answer (D.I. 374) is DENIED.

IT IS SO ORDERED.

Entered this 20<sup>th</sup> day of October, 2022.

  
United States District Judge