

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

ALLERGAN HOLDINGS UNLIMITED  
COMPANY, ABBVIE INC., ABBVIE US  
LLC, and EDEN BIODESIGN, LLC,

Plaintiffs,

v.

MSN LABORATORIES PRIVATE  
LIMITED, MSN PHARMACEUTICALS  
INC., and SUN PHARMACEUTICAL  
INDUSTRIES LIMITED,

Defendants.

Civil Action No. 23-794-RGA  
(CONSOLIDATED)

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Before me is Plaintiffs' motion to dismiss the third counterclaim and to strike the seventh and eighth affirmative defenses from Defendant Sun Pharmaceutical Industries Limited's Amended Answer. (D.I. 27). I have considered the parties' briefing. (D.I. 28, 30, 34).

## **I. BACKGROUND**

Plaintiff AbbVie Inc. holds New Drug Application No. 206940 for VIBERZI® eluxadoline tablets. (D.I. 1 ¶ 15). VIBERZI® is approved for the treatment of irritable bowel syndrome with diarrhea in adults. (*Id.*).

Plaintiffs (alternatively, "Allergan") assert U.S. Patent No. 11,484,527 (the "'527 patent"). It belongs to a patent family covering various inventions related to eluxadoline. The '527 patent claims priority to U.S. Patent Application No. 13/829,984 which was filed on Mar. 14, 2013 and issued as U.S. Patent No. 9,675,587 (the "'587 patent") on June 13, 2017. From a continuation of the same patent application, Plaintiffs obtained U.S. Patent No. 10,188,632 (the "'632 Patent") on January 29, 2019.

On May 27, 2019, Defendant Sun filed ANDA No. 213447 seeking to commercialize generic versions of the VIBERZI® brand eluxadoline tablets in the United States before expiration of the '587 and '632 patents. (D.I. 26 ¶ 86, at 23). On September 13, 2019, Allergan filed suit against Sun asserting infringement of the '587 and '632 patents. (D.I. 26 ¶ 95, at 24; *see Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, No. 19-1727-RGA (the "19-1727 Litigation"), D.I. 1 (D. Del. Sept. 13, 2019)). Over the course of the 19-1727 Litigation, Allergan filed continuation applications and prosecuted patents belonging to the patent family at issue. (D.I. 26 ¶¶ 80–144, at 23–30). Allergan would assert these patents against Sun as they issued, resulting

eventually in eight patents being asserted during the 19-1727 Litigation.<sup>1</sup> (*Id.*; see generally *Allergan*, No. 19-1727-RGA).

The application leading to the '527 patent was filed on December 8, 2021. The '527 patent issued on November 1, 2022 and covers methods of treatment by administering eluxadoline.

On July 21, 2023, Allergan filed a complaint against Sun alleging infringement of the '527 patent by Sun's ANDA No. 213447. *Allergan Holdings Unlimited Co. v. Sun Pharm. Indus. Ltd.*, C.A. No. 23-795-RGA, D.I. 1 (D. Del. July 21, 2023). The infringement action against Sun has since been consolidated into the present action along with Allergan's infringement action against two MSN Defendants.<sup>2</sup> (D.I. 14).

On January 19, 2024, Sun filed its Amended Answer asserting, among other counterclaims and defenses, a counterclaim of prosecution laches (Count III counterclaim), an affirmative defense of unenforceability based on prosecution laches and/or unclean hands (Seventh Affirmative Defense), and an affirmative defense of patent misuse (Eighth Affirmative Defense). (D.I. 26). Allergan moves to dismiss or strike these three counterclaims and defenses.

## **II. LEGAL STANDARD**

### **A. Motion to Dismiss**

Rule 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 the claim for failing to meet this standard. A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in the complaint

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<sup>1</sup> After a trial, I ruled in Sun's favor in the 19-1727 litigation. The appeal in that case is pending.

<sup>2</sup> The MSN Defendants are not impacted by the present motion.

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)).

Rule 9 adds a heightened pleading standard for allegations of fraud. It states, “In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” FED. R. CIV. P. 9(b). “Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” *Id.* “To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.” *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007). While courts have relaxed the requirements where the factual information is peculiarly within the defendant’s knowledge or control, boilerplate and conclusory allegations will not suffice. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997). “Plaintiffs must accompany their legal theory with factual allegations that make their

theoretically viable claim plausible.” *Id.* “A counterclaim or affirmative defense that alleges fraudulent conduct must be pled with particularity under Rule 9(b).” *Allergan USA, Inc. v. Sun Pharm. Indus. Ltd.*, 636 F. Supp. 3d 483, 488 (D. Del. 2022).

### **B. Motion to Strike**

Federal Rule of Civil Procedure 12(f) provides that a court “may strike from a pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” “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, Inc. v. Versata Enters., Inc.*, 630 F. Supp. 2d 395, 408 (D. Del. 2009). “Motions to strike are generally disfavored and ordinarily are denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties,” *id.* at 402 (internal quotation marks omitted), “or if the allegations confuse the issues,” *Karpov v. Karpov*, 307 F.R.D. 345, 349 (D. Del. 2015). “A motion to strike will not be granted where the sufficiency of the defense depends on disputed issues of facts or where it is used to determine disputed and substantial questions of law.” *Cadence Pharm., Inc. v. Paddock Lab ’ys, Inc.*, 2012 WL 4565013, at \*1 (D. Del. Oct. 1, 2012). Affirmative defenses are subject to the general pleading requirements Federal Rule of Civil Procedure 8. Rule 8(b)(1)(A) requires that a party “state in short and plain terms its defenses to each claim asserted against it.” FED. R. CIV. P. 8(b)(1)(A). As with any pleading, an affirmative defense must give the plaintiff “fair notice” of the nature of the defense and the grounds upon which it rests, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 553 (2007), and state a plausible defense. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009).

## **III. DISCUSSION**

### **A. Third Counterclaim (Prosecution Laches)**

Plaintiffs maintain that Sun has not adequately plead the required elements of its prosecution laches counterclaim. (D.I. 28 at 4).

The doctrine of prosecution laches “may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances.” *Cancer Rsch. Tech. Ltd. v. Barr Lab'ys, Inc.*, 625 F.3d 724, 728 (Fed. Cir. 2010) (quoting *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005), amended on reh'g in part sub nom. *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found., LP*, 429 F.3d 1051 (Fed. Cir. 2005)) (internal quotations omitted). In addition to establishing an unreasonable and unexplained delay, a patent challenger asserting prosecution laches must also show prejudice attributable to the delay. *Id.* “[T]o establish prejudice an accused infringer must show evidence of intervening rights, *i.e.*, that either the accused infringer or others invested in, worked on, or used the claimed technology during the period of delay.” *Id.* at 729.

Sun’s Amended Answer alleges, “By waiting and delaying more than eight years to prosecute the claims of the ’527 patent, Allergan sat on its rights for an unreasonable and inexcusable period of time to the prejudice of Sun. Allergan made no effort to explain during patent prosecution why it sat on its rights for more than eight years prior to the prosecuting the method of treatment claims of the ’527 patent.” (D.I. 26 ¶¶ 175–76, at 33–34). Sun alleges it faces prejudice from the delay because it “invested time and resources seeking to commercialize generic versions of Plaintiffs’ Viberzi® brand eluxadoline tablets.” (*Id.* ¶ 197, at 36). Sun also claims prejudice “because Allergan’s delay has unnecessarily resulted in increased costs and duplicative litigation.” (D.I. 30 at 13 (citing D.I. 26 ¶ 199, at 37)).

I agree with Plaintiffs that Sun's allegations do not raise a plausible inference of prejudice. The invention disclosed by the '527 patent is not the eluxadoline tablet, but a method of treatment involving the eluxadoline tablet. Sun's claims that it invested time and resources into commercializing the tablets is therefore not equivalent to allegations that it "invested in, worked on, or used the claimed technology." *Cancer Rsch.*, 625 F.3d at 729.

Increased litigation costs are also insufficient to demonstrate prejudice. I recognize another district court has found prejudice on the basis that a defendant was forced "to remain embroiled in the instant litigation longer than it otherwise would be if [the patentee] had not delayed the filing of its patent applications for the alleged purpose of keeping [the defendant] entangled in litigation, thereby undermining the goals of the Hatch-Waxman Act." *Jazz Pharms., Inc. v. Roxane Lab'ys, Inc.*, 2013 WL 6858765, at \*6 (D.N.J. Dec. 30, 2013). I note, however, that the *Jazz* court appears to focus its concern on the subversion of the Hatch-Waxman act as "the effect of prolonging [the] litigation . . . ha[d] the practical effect of preventing [the defendant] from launching its product." *Id.* at \*5. The same concern is not present here. Sun is precluded from launching its generic product until July 7, 2028, about four years from now. (*See* D.I. 28 at 5). The litigation will be over long before then. There is no plausible basis to assert that litigation over the asserted patent will improperly delay launch or otherwise subvert the goals of the Hatch-Waxman Act.

Sun is not saved by the rebuttable presumption expressed in *Hyatt v. Hirshfeld*, 998 F.3d 1347 (Fed. Cir. 2021)). The Federal Circuit in *Hyatt* held "in the context of a [35 U.S.C.] § 145 action, the PTO must generally prove intervening rights to establish prejudice, but an unreasonable and unexplained prosecution delay of six years or more raises a presumption of prejudice, including intervening rights." *Hyatt*, 998 F.3d at 1370. Another district court has

already addressed the question of whether this presumption should apply when prosecution laches is asserted in an infringement action:

In a § 145 action, the district court is required to make de novo factual findings, without any deference to the PTO or presumptions of administrative correctness. The case cited by the Federal Circuit in *Hyatt* for the presumption of prejudice also arose in the context of an unreasonable delay in filing suit—a charge that does not impugn the patentee's prosecution conduct. In contrast, the PTO can issue prosecution laches rejections, and when prosecution laches is raised as a defense to infringement, the accused infringer challenges the PTO's correctness in not rejecting the patent. An issued patent, whose enforceability is challenged for prosecution laches, remains clothed in the presumptions of validity and enforceability. Accordingly, the Court does not find it appropriate to shift the burden on the issue of prejudice when prosecution laches is raised as a defense to infringement.

*Personalized Media Commc'ns, LLC v. Apple, Inc.*, 552 F. Supp. 3d 664, 685 (E.D. Tex. 2021), *aff'd*, 57 F.4th 1346 (Fed. Cir. 2023). I agree with the *Personalized Media* court's rationale and conclusion that the presumption from *Hyatt* is limited to the context of a § 145 action.

For the reasons stated, Sun has not plausibly alleged prejudice resulting from Allergan's delay in prosecuting the '527 patent. I will dismiss Sun's prosecution laches counterclaim.

## **B. Seventh Affirmative Defense**

As its seventh affirmative defense, Sun contends that Plaintiffs' infringement claims "are barred in whole or in part under principles of equity, including prosecution laches and/or unclean hands." (D.I. 26 at 9). Plaintiffs move to strike both theories as defenses. (D.I. 28 at 7–8).

### **1. Prosecution Laches**

Plaintiffs contend Sun's prosecution laches defense and the corresponding counterclaim are insufficiently plead for the same reasons. (*Id.*). The parties concur on the substantive duplication between the affirmative defense and counterclaim. (*See id.*; D.I. 30 at 15). 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 Sun faces any prejudice as a



result of Allergan's delay in prosecuting the '527 patent. *See 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.”), *report and recommendation adopted*, 2012 WL 749378 (D. Del. Mar. 1, 2012). Sun's Amended Answer fails to properly plead an affirmative defense based on prosecution laches.

## 2. Unclean Hands

Plaintiffs maintain that Sun's unclean hands affirmative defense is either duplicative of its invalidity defense of inadequate written description or alleges fraudulent conduct while failing to satisfy the Rule 9(b) pleading standard. (D.I. 34 at 8).

“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 pleadings standard for unclean hands depends on the specific conduct alleged.” *Allergan USA, Inc. v. Sun Pharm. Indus. Ltd.*, 2022 WL 11819975, at \*3 (D. Del. Oct. 20, 2022). “[A]n unclean hands defense based on fraud or misrepresentation must satisfy the pleading requirements of Rule 9(b).” *AbbVie Inc. v. Boehringer Ingelheim Int'l GmbH*, 2018 WL 2604825, at \*1 (D. Del. June 4, 2018).

Sun argues that it has properly alleged that “Allergan has acted unconscionably and/or with bad faith.” (D.I. 30 at 17). Sun alleges, “Allergan is fully aware that the '527 patent and the similar patents being prosecuted are invalid and should never have been issued by the U.S.

Patent and Trademark Office” but still sought “to enforce these patents—to harass Sun as part of an egregious case of misuse of the statutory patent system.” (D.I. 26 at 10–11)). Sun states, “Despite representing to the Patent Office that ‘the only way to truly understand how food will affect the pharmacokinetic and pharmacodynamics of a drug is to conduct a food effect study,’ the inventors never conducted a food effect study on eluxadoline.” (D.I. 30 at 16 (quoting D.I. 26 at 10–11); *see also* D.I. 26 at 11 (“Plaintiffs drafted claims of the ’527 patent that require administration of eluxadoline twice daily with food in an improper attempt to cover Sun’s ANDA Product, despite the inventors not having conducted a food effect study.”)).

Looking beyond Sun’s labelling of its unclean hands defense as being based on unconscionable or bad faith acts, Sun’s defense inherently relies on allegations that Allergan made misrepresentations to the Patent Office in securing the ’527 patent. Allergan’s unclean hands defense theory, in substance, is based on inequitable conduct before the PTO. *See* 37 C.F.R. § 1.56 (2023) (“Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.”); *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (“To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO.”).

As Sun’s affirmative defense sounds in fraud, it must satisfy the heightened Rule 9(b) pleading standard. *Barry v. Stryker Corp.*, 2023 WL 2733652, at \*9 (D. Del. Mar. 20, 2023), *report and recommendation adopted*, 2023 WL 3224498 (D. Del. May 3, 2023) (“[T]here is no dispute that an unclean hands defense based on allegations of inequitable conduct sounds in

fraud.”). Sun’s pleadings fail to “provide the essential factual background that would accompany ‘the first paragraph of any newspaper story’—that is, the ‘who, what, when, where and how’ of the events at issue.” *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (quoting *In re Burlington*, 114 F.3d at 1422). Sun’s Amended Answer fails to properly plead a defense based on unclean hands.

For the reasons stated, I will strike Sun’s seventh affirmative defense.

### **C. Eighth Affirmative Defense (Patent Misuse)**

Plaintiffs maintain that Sun’s patent misuse affirmative defense is inadequately pleaded. (D.I. 28 at 11).

The parties focus their dispute on whether allegations that Plaintiffs filed suit to enforce a patent they knew to be invalid are sufficient for a patent misuse defense to survive at this stage. (*Id.* at 12–13; D.I. 30 at 19–20; D.I. 34 at 8–10). I need not reach this question. Sun’s patent misuse defense theory relies on the same factual allegations as its unclean hands defense. (*See* D.I. 26 at 12; D.I. 30 at 19–20). Notably, Sun alleges, “in prosecuting the ’527 patent, Plaintiffs impermissibly broadened the scope of the patent grant to cover claims that they knew to be invalid” by “draft[ing] claims of the ’527 patent that require administration of eluxadoline twice daily with food in an improper attempt to cover Sun’s ANDA Product, despite the inventors not having conducted a food study.” (D.I. 26 at 12). As Sun’s patent misuse defense sounds in fraud and it failed to comply with the Rule 9(b) pleading requirements, I will strike Sun’s eighth affirmative defense.

## **IV. CONCLUSION**

An appropriate order will issue.