IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RHODES PHARMACEUTICALS L.P.	:	
	:	**CIVIL ACTION**
Plaintiff,	:	
	:	
v.	:	
	:	**NO. 16-1308**
INDIVIOR, INC.	:	
	:	
Defendant.	:	

Goldberg, J. **January 8, 2018**

MEMORANDUM OPINION

This case involves a patent dispute between manufacturers of opioid addiction substitution therapy drugs. Plaintiff Rhodes Pharmaceuticals, L.P. ("Rhodes") has sued Defendant Indivior, Inc. ("Indivior") alleging patent infringement in connection with Defendant's sale of Suboxone Sublingual Film. Specifically, Plaintiff brings claims for direct infringement, indirect infringement, contributory infringement, and willful infringement. Defendant moves to dismiss the case for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). For the following reasons, the Motion will be granted in part and denied in part.

I. FACTUAL BACKGROUND[1]

On June 21, 2016, the United States Patent and Trademark Office ("USPTO") issued United States Patent No. 9,370,512 (the "512 Patent")—entitled "Buprenorphine-Wafer for Drug Substitution Therapy"—to Plaintiff Rhodes. (Compl. ¶ 9.) Independent claim 1 of the '512 patent contains the following eight distinct elements:

A method of opioid substitution therapy for treating opioid addiction, the method
comprising contacting the sublingual mucosa of a patient in need thereof with a sublingual film dosage form comprising:
a) approximately 0.1 mg to approximately 16 mg buprenorphine, or an equivalent amount of a pharmaceutically acceptable salt thereof;
b) naloxone or a pharmaceutically acceptable salt thereof; and
c) at least one non-gelatin polymeric film-forming material in which the buprenorphine or the equivalent amount of the pharmaceutically acceptable salt thereof, are dissolved or homogeneously dispersed;
the buprenorphine or the equivalent amount of the pharmaceutically acceptable salt thereof and the naloxone or the pharmaceutically acceptable salt thereof being present in the sublingual film dosage form in a weight ration of from 1:1 to 10:1;
such that within less than 5 minutes after contacting the sublingual mucosa of the patient with the sublingual film dosage form, the buprenorphine or the pharmaceutically acceptable salt thereof and approximately substantially all of the naloxone or the pharmaceutically acceptable salt thereof contact the sublingual mucosa,
And wherein said contacting achieves (i) an average buprenorphine AUC_{0-48} from approximately 10 to approximately 15 (hrs*ng)/ml when the sublingual film dosage form includes 4 mg buprenorphine or an equivalent amount of a pharmaceutically acceptable salt thereof; (ii) an average buprenorphine AUC_{0-48} from approximately 15 to approximately 25 (hrs*ng)/ml when the sublingual film dosage form includes 8 mg buprenorphine or an equivalent amount of a pharmaceutically acceptable salt thereof or (iii) an average buprenorphine AUC_{0-48} from approximately 25 to approximately 40 (hrs*ng)/ml when the sublingual film dosage form includes 16 mg buprenorphine or an equivalent amount of a pharmaceutically acceptable salt thereof.

(Compl., Ex. A.) Independent claim 19 contains at least seven distinct elements:

[1] When determining whether to grant a motion to dismiss, a federal court must construe the complaint liberally, accept all well-pleaded factual allegations in the complaint as true, and draw all reasonable inferences in favor of the plaintiff. Fowler v. UPMC Shadyside, 578 F.3d 203, 211 (3d Cir. 2009). In accordance with this principle, my recitation of the facts assumes the truth of the factual statements in the Complaint.

A method of opioid substitution therapy for treating opioid addiction, the method comprising
Contacting the sublingual mucosa of a patient in need thereof with a sublingual film dosage form comprising:
a) an amount of buprenorphine, or an equivalent amount of a pharmaceutically acceptable salt thereof, sufficient to provide an average buprenorphine C_{max} of less than 40 (hrs*ng)/ml;
b) naloxone or a pharmaceutically acceptable salt thereof; and
c) at least one non-gelatin polymeric film-forming material in which the burprenorphine or the equivalent amount of the pharmaceutically acceptable salt thereof and the naloxone or the pharmaceutically acceptable salt thereof, are dissolved or homogeneously dispersed; the buprenorphine or the equivalent amount of the pharmaceutically acceptable salt thereof and the naloxone or the pharmaceutically acceptable salt thereof being present in the sublingual film dosage form in a weight ration of from 1:1 to 10:1;
Such that within less than 5 minutes after contacting the sublingual mucosa of the patient with the sublingual film dosage form, the buprenorphine or the pharmaceutically acceptable salt thereof and approximately substantially all of the naloxone or the pharmaceutically acceptable salt thereof contact the sublingual mucosa.

(Id.)

Defendant Indivior is the holder of a New Drug Application ("NDA") No. 22-410 for SUBOXONE® (buprenorphine and naloxone) Sublingual Film ("Suboxone Sublingual Film"). The FDA approved NDA No. 22-410, on August 30, 2010, for the treatment of opioid dependence. Since its approval, Defendant has sold and continues to sell Suboxone Sublingual Film in the United States. In connection with those sales, Defendant provides information and instructions to healthcare professionals and/or patients regarding its Suboxone Sublingual Film, including Prescribing Information and Medication Guides ("Prescribing Information"). (Id. ¶¶ 10–13.) The Prescribing Information provides, in pertinent part:

- "SUBOXONE sublingual film is indicated for treatment of opioid dependence and should be used as part of a complete treatment plan to including counseling and psychosocial support." (Id. ¶ 14.)

- "Sublingual Administration: Place one film under the tongue, close to the base on the left or right side, and allow to completely dissolve." (Id. ¶ 15.)

- Suboxone Sublingual Film "contains polyethylene oxide, hydroxypropl methylcellulose, maltitol, acesulfame potassium, lime flavor, citric acid, sodium citrate, FD&C yellow #6, and white ink." (Id. ¶ 16.)

- Suboxone Sublingual Film comes in four dosage strengths: "Sublingual film: 2 mg buprenorphine with 0.5 mg naloxone, 4 mg buprenorphine with 1 mg naloxone, 8 mg buprenorphine with 2 mg naloxone and 12 mg buprenorphine with 3 mg naloxone." (Id. ¶ 17.)

On December 23, 2016, Plaintiff initiated this litigation alleging that the use or administration of any of the four aforementioned dosage strengths of Defendant's Suboxone Sublingual Film by healthcare professionals and/or patients for treating opioid addiction has and continues to directly infringe on one or more claims of the '512 patent under 35 U.S.C. § 271(a), including, at minimum, independent claims 1 and 19.

On May 9, 2017, Defendant filed a Motion to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). Plaintiff responded on May 23, 2017 and Defendant filed a Reply Brief on May 30, 2017.

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); see also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). The United States Supreme Court has recognized that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quotations omitted). "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" and "only a complaint that states a plausible claim for relief survives a motion to dismiss." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. A complaint does not show an entitlement to relief when the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct. Id.

The United States Court of Appeals for the Third Circuit has detailed a three-step process to determine whether a complaint meets the pleadings standard. Bistrian v. Levi, 696 F.3d 352 (3d Cir. 2014). First, the court outlines the elements a plaintiff must plead to state a claim for relief. Id. at 365. Next, the court must "peel away those allegations that are no more than conclusions and thus not entitled to the assumption of truth." Id. Finally, the court "look[s] for well-pled factual allegations, assume[s] their veracity, and then 'determine[s] whether they plausibly give rise to an entitlement to relief.'" Id. (quoting Iqbal, 556 U.S. at 679). The last step is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. (quoting Iqbal, 556 U.S. at 679).

Although claims of direct infringement were previously governed by Federal Rule of Civil Procedure 84 and the Appendix of Forms, those rules were abrogated effective December 1, 2015. Raindance Techs., Inc. v. 10x Genomics, Inc., No. 15-150, 2016 WL 927143, at *2 (D. Del. Mar. 4, 2016). It is now well established that both direct and indirect infringement claims are subject to the Twombly/Iqbal standard. IP Commc'n Solutions, LLC v. Viber Media (USA) Inc., No. 16-134, 2017 WL 1312942, at *2 (D. Del. Apr. 5, 2017); RAH Color Techs LLC v. Ricoh USA Inc., 194 F. Supp. 3d 346, 350–51 (E.D. Pa. 2016).

III. DISCUSSION

Defendant's Motion to Dismiss argues that Plaintiff's Complaint is too vague and conclusory to pass muster under the Iqbal/Twombly pleading standard. Defendant specifically contends that the Complaint fails to adequately plead claims of direct infringement, indirect infringement, contributory infringement, or willful infringement of the '512 patent. Plaintiff responds that the Complaint sufficiently sets forth both elements of its claims and factual allegations in support, as required by Federal Rule of Civil Procedure 8.

A. Direct Infringement Under 35 U.S.C. § 271(a)

Defendant first challenges Plaintiff's direct infringement claim, brought pursuant to 35 U.S.C. § 271(a).

The direct infringement of a patent occurs when a party, without authority, "makes, uses, offers to sell, or sells any patented invention, within the United States. . . ." 35 U.S.C. § 271(a). A patentee may prove direct infringement under § 271(a) either by (1) demonstrating specific instances of direct infringement; or (2) showing that an accused device necessarily infringes on the patent. ACCO Brands, Inc. v. ABA Locks Mfrs. Co., 501 F.3d 1307, 1313 (Fed. Cir. 2007).

In order to adequately plead a cause of action for direct infringement of a method claim,[2] the complaint must allege that the accused infringer "perform[ed] all the steps of the claimed method, either personally or through another acting under his direction or control." Courtesy Prods, LLC v. Hamilton Beach Brands, Inc., 73 F. Supp. 3d 435, 439 (D. Del. 2014). In other words "direct infringement requires a single party to perform every step of a claimed method." Forest Labs. Holdings Ltd. v. Mylan, Inc., 206 F. Supp. 3d 957, 973 (D. Del. 2016).

Defendant contends that the Complaint fails to include an allegation that it practices any of the method claims in the '512 patent or that the use of Suboxone Sublingual Film meets each and every limitation of any claim of the '512 patent. Plaintiff concedes, in its response to the Motion to Dismiss, that it does not and cannot allege direct infringement under § 271(a) because the methods were not practiced by Defendant.[3] Given this concession, I will grant this portion of the Motion to Dismiss.

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[2] Unlike a product claim, a method claim applies "to a process, which consists of a series of acts or steps." In re Kollar, 286 F.3d 1326, 1332 (Fed. Cir. 2002).

[3] Plaintiff states that it did not bring a claim for direct infringement against Defendant. Specifically, Plaintiff states that it "does not allege that Indivior directly infringes the '512

B. Inducement of Infringement Under 35 U.S.C. § 271(b)

Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Id. "Inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities." DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part). To prevail on a claim of induced infringement, the patentee "must show [(1)] direct infringement, and [(2)] that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." Toshiba Corp. v. Imation Corp., 681 F.3d 1358, 1363 (Fed. Cir. 2012) (quoting i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 851 (Fed. Cir. 2010)).

Defendant avers that the Complaint fails to adequately plead either of the required elements for inducement of infringement. Upon consideration of each argument, I find that the inducement claim survives Rule 12(b)(6) scrutiny.

1. Direct Infringement by Healthcare Professionals and Patients

Defendant first challenges the adequacy of Plaintiff's allegations of direct infringement by others, asserting that Plaintiff fails either to allege that all claim elements have been infringed or to identify a specific direct infringer.

As set forth above, "[l]iability for indirect infringement may arise "if, but only if, [there is] . . . direct infringement." Limelight Networks, Inc. v. Akamai Techs., Inc., 134 S. Ct. 2111, 2117 (2014) (citation omitted). To prove direct infringement, the infringing entity must perform each and every step or element of the claimed method or product." Exergen Corp. v. Wal–Mart

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patent." (Pl.'s Opp'n Mot. to Dismiss, p. 1, n.1.) However, the Complaint expressly seeks a judgment that "Defendant has infringed one or more claims of the '512 Patent." (Compl., Prayer for Relief ¶ A.) For purposes of clarity, I will dismiss any potential claim of direct infringement by Indivior.

Stores, Inc., 575 F.3d 1312, 1320 (Fed. Cir. 2009) (quoting BMC Res., Inc. v. Paymentech, L.P., 498 F.3d 1373, 1378 (Fed. Cir. 2007)). On a motion to dismiss, a complaint for patent infringement need not match up specific instructions to claim elements in a method claim. DermaFocus LLC v. Ulthera, Inc., 201 F. Supp. 3d 465, 471 n.11 (D. Del. 2016).[4] Rather, a plaintiff need only give a defendant reasonable notice of a plausible claim for direct infringement. Id. at 470; see also AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1060 (Fed. Cir. 2010) (noting that inducement need not be premised on explicit instructions to perform the infringing method, where the proposed label "would inevitably lead some consumers to practice the claimed invention.").

Here, Plaintiff has sufficiently alleged direct infringement by healthcare professionals/ patients. The Complaint identifies the elements of the two independent claims at issue. (Compl. ¶¶ 20, 21.) It then states that "Defendant has induced and continues to induce infringement by affirmatively aiding, abetting, urging, or encouraging direct infringement by healthcare professionals and/or patients, by inter alia, instructing them to use Defendant's Suboxone Sublingual Film in a manner that directly infringes one or more claims of the '512 patent." (Id. ¶ 25.) The Complaint further specifies that Defendant's instructions were carried out by:

> providing Prescribing Information and other instructions that instruct healthcare professionals and/or patients to perform the claimed methods, including methods of opioid substitution therapy or treating opioid addiction comprising contacting the sublingual mucosa of a patient in need thereof with a sublingual film dosage form comprising at least one non-gelatin polymeric film-forming material in which certain amounts of buprenorphine and naloxone or their pharmaceutically acceptable salts, are dissolved or

[4] Defendant takes issue with Plaintiff's citation to Dermafocus, arguing that the facts in that case are distinguishable on multiple levels. These distinctions, however, do not detract from the legal point that in pleading a method claim, Twombly/Iqbal standards do not require that a complaint match up claim elements with specific instructions.

> homogeneously dispersed wherein within less than 5 minutes after contacting the sublingual mucosa the buprenorphine and approximately substantially all of the naloxone contact the sublingual mucosa, wherein said contacting achieves the pharmacokinetic of at least claims 1 and 19.

(Compl. ¶ 25.). The Complaint also identifies which claim elements are infringed by which specific instructions.[5] These allegations are sufficient because, as noted above, the Complaint need not match up specific claim elements to specific instructions in order to survive a motion to dismiss.

The fact that Plaintiff has not identified specific healthcare providers or patients that have carried out the allegedly infringing method is also of no moment. A plaintiff need not specifically identify the customers who are induced to infringe, as this is a "proper question for discovery." Minkus Elec. Display Sys., Inc. v. Adaptive Micro Sys. LLC, No. 10–666, 2011 WL 941197, at *3 (D. Del. Mar. 16, 2011). A plaintiff must only "plead[] facts sufficient to allow an inference that at least one direct infringer exists." Bill of Lading Transmission & Processing Sys. Patent Litig., 681 F.3d 1323, 1336 (Fed. Cir. 2012). Such an inference is permissible from an allegation that a product is used by customers who then infringe the patent by practicing the method disclosed in the patent. E.I. Du Pont de Nemours and Co. v. Heraeus Holding GmbH, No. 11-773, 2012 WL 4511258, at *4 (D. Del. Sept. 28, 2012).

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[5] Defendant argues that Plaintiff's direct infringement "claim chart" in its opposition to the Motion to Dismiss constitutes "new factual allegations" which did not appear in the Complaint. I find this characterization incorrect. Plaintiff's chart simply takes the claim elements and the Prescribing Information, all of which are either detailed in the Complaint or included in the exhibits attached to the Complaint, and matches them up in order to demonstrate the alleged infringement. See Hartig Drug Co. Inc. v. Senju Pharm Co. Ltd., 836 F.3d 261, 268 (3d Cir. 2016) (holding that, in consideration of a motion to dismiss, a court may rely on an exhibit attached to the complaint and all reasonable inferences that may be drawn from it). In other words, this chart is not new information, but rather the same information from the Complaint organized in a different way so as to respond appropriately to the Motion to Dismiss.

Here, the Complaint alleges that the Prescribing Information instructs healthcare professionals and/or patients to perform the claimed methods of opioid substitution therapy for treating opioid addiction, and that "[t]he use or administration of any of the four dosage strengths of Defendant's Suboxone Sublingual Film by healthcare professionals and/or patients for opioid substitution therapy for treating opioid addiction has directly infringed and continues to directly infringe one or more claims of the '512 patent." (Compl. ¶¶ 19, 25.) These allegations are sufficient to survive a Rule 12(b)(6) motion.

2. Defendant's Intent to Induce Direct Infringement

Defendant also contends that the induced infringement claim fails because Plaintiff has not adequately pled intent.

"[L]iability for induced infringement can only attach if the defendant knew of the patent and knew as well that 'the induced acts constitute patent infringement." Commill USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920, 1926–27 (2015) (citing Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 763 (2011)). The knowledge requirement must be met by a showing of either actual knowledge or willful blindness. Global–Tech, 563 U.S. at 766. At the pleading stage, "the question before the Court on defendants' motions to dismiss is whether [the plaintiff] has plead sufficient facts . . . for the Court to infer that the defendants had knowledge of [the plaintiff's] patents and that their products infringed on those patents." MONEC Holding AG v. Motorola Mobility, Inc., 897 F. Supp. 2d 225, 229 (D. Del. 2012) (quotations omitted) (emphasis in original); see also In re Bill of Lading, 681 F.3d at 1339 ("To survive . . . a motion to dismiss, therefore, [the plaintiff's] amended complaint[ ] must contain facts plausibly showing that [the defendant] specifically intended [its] customers to infringe the [patents-in-suit] and knew that the customer's acts constituted infringement.").

When the alleged inducement relies on a drug label's instructions, "[t]he question is not just whether [those] instructions describ[e] the infringing mode, . . . but whether the instructions teach an infringing use such that we are willing to infer from those instructions an affirmative intent to infringe the patent." Takeda Pharms. U.S.A., Inc. v. West-Ward Pharms. Corp., 785 F.3d 625, 631 (Fed. Cir. 2015) (internal quotations omitted) (emphasis in original). "The label must encourage, recommend, or promote infringement." Id.; see also Eli Lilly and Co. v. Teva Parenteral Medicines, Inc., 845 F.3d 1357, 1368 (Fed. Cir. 2017) (noting that it is irrelevant that some users may ignore the proposed label). However, "there is no requirement that Defendants['] [prescribing labels] need to have mimicked the precise wording of [the patent claim]." GlaxoSmithKline LLC v. Glenmark Generics Inc., USA, Nos. 14-877, 14-878, 2015 WL 3793757, at *8 (D. Del. Apr. 22, 2015). "Instead the question is whether the allegations, when considered in their entirety and in context, plausibly suggest an intent and actions to encourage administration of [the drug at issue] in a manner that would meet the claim limitations." Id. (emphasis in original).

Here, Plaintiff alleges that although Indivior began using the alleging infringing Prescribing Instructions before the '512 patent issued, Indivior continued to instruct physicians and patients to use Suboxone Sublingual Film in an infringing manner after it became aware of the '512 patent and its claimed methods. The Complaint asserts that "since at least the date that the '512 patent issued, Defendant has had knowledge that the induced acts would constitute infringement of the '512 patent and has specifically intended to cause such infringement." (Compl. ¶ 26.) The Complaint further states that Defendant has "intentionally provided Prescribing Information and other instructions to healthcare professionals and/or patients that instruct . . . [them] to perform the claimed methods . . . with knowledge that use by healthcare

professionals and/or patients in accordance with the Prescribing Information and other instructions directly infringes the '512 patent." (Id.)

Defendant responds that prior to the issuance of the '512 patent, it used the same Prescribing Information for Suboxone, but obviously could not have intended to induce infringement at that time because there was no patent to be infringed. Defendant argues that for a plausible claim of inducement of infringement, Plaintiff would have to allege that—after the issuance of the '512 patent six years later—Defendant took some affirmative acts to teach an infringing method, or that its intentions in continuing to use the Prescribing Information somehow changed. Defendant contends that the Complaint makes no allegation of any intervening affirmative act, and that Plaintiff cannot feasibly allege a change in Defendant's intentions because "[w]hatever Indivior's 'intention' may have been in providing a label for Suboxone Sublingual Film, that intention was fixed as of the time the label first issued in 2010 following FDA approval." (Def.'s Mem. Supp. Mot. to Dismiss p. 17.)

While Defendant's theory could potentially have merit following discovery, it is a fact-based defense that cannot be decided on a Rule 12(b)(6) motion to dismiss. The Federal Circuit has held that, as a general rule, "inducement of infringement under § 271(b) does not lie when the acts of inducement occurred before there existed a patent to be infringed." Nat'l Presto Indus. v. West Bend Co., 76 F.3d 1185, 1196 (Fed. Cir. 1996). Rather, "[t]he purpose must be wrongful at the time of the action with which the abettor is charged." Id. "The question is whether a party had the intent to and did encourage the wrongful act of patent infringement in the relevant time frame—after a patent has issued." GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., No. 14-878, 2016 WL 3946770, at *11 (D. Del. July 20, 2016) (citing Nat'l Presto, 76 F.3d at 1194) (emphasis in original). To that end, so long as a party has alleged acts of

inducement that occurred after the issuance of the patent-in-suit, a claim of induced infringement can survive a motion to dismiss. Id.

The issue of intent has repeatedly arisen in the context where the allegedly infringing defendant had no knowledge of the patent prior to the initiation of litigation, but was afforded notice of the patent-at-issue through service of the complaint. Courts have found that "[t]here is no requirement that a plaintiff's induced infringement claim be limited to presuit knowledge and facts." Telecomm Innovations, LLC v. Ricoh Co., Ltd., 966 F. Supp. 2d 390, 393 (D. Del. 2013) (citing Walker Digital, LLC v. Facebook, Inc., 852 F. Supp. 2d 559, 565 (D. Del. 2012) (finding "there is no legal impediment to having an indirect infringement cause of action limited to post-litigation conduct")). Rather, the complaint must allege that the defendant has made a decision to continue the alleged inducement post-service of the complaint. Id. Allegations that a defendant continued to induce infringement after learning about the existence of the patent have been deemed sufficient to plead a claim for inducement of infringement. See, e.g., MyMedicalRecords, Inc. v. Jardogs, LLC, 1 F. Supp. 3d 1020, 1025 (C.D. Cal. 2014) (declining to find that a defendant has "carte blanche to continue to indirectly infringe a patent—now with full knowledge of the patents-in-suit—so long as it was ignorant of the patents prior to being served itself with the complaint."); L.A. Biomed. Rsch. Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co., No. 13-8567, 2014 WL 11241786, at *3 (C.D. Cal. May 12, 2014) (declining to dismiss claim of induced infringement where the complaint contained allegations of "continued culpable conduct after the issuance of the patent" through defendants' failure to change the label on their drug after the issuance of the patent-in-suit).

Similar to the foregoing cases, the Complaint here alleges that following the issuance of the patent, Defendant—acting with knowledge of the patent—continued to provide the

Prescribing Information with the intent of encouraging healthcare professionals and/or patients to perform the claimed methods. (Compl. ¶¶ 23, 25.) While somewhat cursory in nature, these allegations are facially plausible and provide Defendant notice of the induced infringement claim. At this early juncture of the litigation, I find that the Complaint sufficiently pleads that Defendant intentionally induced infringement by purposefully encouraging health care providers and patients to practice the method claims of the patent-in-suit.[6]

C. Contributory Infringement Under 35 U.S.C. § 271(c)

Defendant next seeks dismissal of Plaintiff's contributory infringement claim. To establish contributory infringement, the patent owner must demonstrate the following: (1) an offer to sell, sale, or import; (2) a component or material for use in a patented process constituting a material part of the invention; (3) knowledge by the defendant that the component is especially made or especially adapted for use in an infringement of such patents; and (4) the component is not a staple or article suitable for substantial noninfringing use. See Fujitsu Ltd. v. Netgear Inc., 620 F.3d 1321, 1326 (Fed. Cir. 2010) (citing 35 U.S.C. § 271(c)). A defendant "must know 'that the combination for which his component was especially designed was both patented and infringing.'" Global–Tech, 563 U.S. at 763 (citing Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 488 (1964)). "This form of infringement is premised on the idea that a defendant who displays sufficient culpability should be held liable as an infringer, even though he may not have made, used, or sold a patented invention." Arthrocare Corp. v. Smith & Nephew, Inc., 310 F. Supp. 2d 638, 656 (D. Del. 2004) (citing Hewlett–Packard Co. v.

[6] In its responsive brief, Plaintiff argues that Indivior amended its Prescribing Information in December 2016, but declined to remove instructions to perform the claimed method of sublingual administration, thereby evidencing Indivior's intent to continue the induced infringement. This allegation, however, is not in the Complaint and is supported by an exhibit which was not attached to the original pleading. Accordingly, I may not consider it on a motion to dismiss.

Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990)), vacated on other grounds, 406 F.3d 1365 (Fed. Cir. 2005).

First, Defendant contends that the Complaint fails to allege, under the second required element, that Indivior sells "a component . . . of an infringing combination" because it does not identify any particular alleging infringing combination, who knew it was infringing, who made it, where it was sold, or who else contributed to it. This argument, however, disregards the fact that § 271(c) presents two paths to liability: (1) sale or import of a component of a patented machine, manufacture, combination or composition; or (2) sale or import of a composition, or a material or apparatus for use in practicing a patented process. 35 U.S.C. § 271(c). While Defendant is correct that Plaintiff does not set forth allegations under the first path, Plaintiff properly asserts, under the second path, that "Defendant's Suboxone Sublingual Film is a material or apparatus for use in practicing the methods of the '512 patent, because, inter alia , it is a sublingual film dosage form comprising at least one non-gelatin polymeric film-forming material in which certain amounts of buprenorphine and naloxone or their pharmaceutically acceptable salts, are dissolved or homogeneously dispersed, as described by the claims of the '512 patent." (Compl. ¶ 29.)

Defendant's second argument asserts that the Complaint fails to plausibly allege, under the fourth required element, that Suboxone Sublingual Film has no substantial non-infringing use. To establish a claim of contributory infringement, the patentee must plead facts that allow an inference that the components sold or offered by the alleged infringer have no substantial non-infringing uses, "that is, uses that are 'not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.'" Aeritas, LLC v. Alaska Air Grp., Inc., 893 F. Supp. 2d 680, 684 (D. Del. 2012) (quoting In re Bill of Lading, 681 F.3d at 1337 (further citations omitted)). A simple

allegation that the product at issue is not suitable for substantial non-infringing use is generally sufficient to satisfy the pleading requirements of Twombly and Iqbal. Id.; see also Cipla Ltd. v. Sunovion Pharms. Inc., 174 F. Supp. 3d 869, 873 (D. Del. 2016) (allegation that defendant's "levalbuterol tartrate . . . can only be used for Xopenex HFA," sufficient to allege no substantial non-infringing uses).

Here, the Complaint specifically asserts that the allegedly infringed method set forth in the '512 patent requires contact with the "sublingual mucosa"—i.e. administration by placing the medicine under the tongue—as a method of administration of the drug, and the Prescribing Information for Suboxone Film infringes this method by requiring that Suboxone Film be administered by contact with the sublingual mucosa of a patient. (Id. ¶¶ 20–21, 25, 30 & Ex. A., col. 11:40–41.) The Complaint then states that "[o]n information and belief, since at least the date that the '512 patent issued, Defendant has known that there is no substantial non-infringing use for Defendant's Suboxone Sublingual Film." (Id. ¶ 32.) In stark contrast to the allegations of the Complaint, however, the Prescribing Information, which is attached as an exhibit to the Complaint, expressly provides for an alternate form of administration through buccal administration—i.e. topical administration of a medicine by placing the drug between the gums and cheek—as opposed to contact with the sublingual mucosa. (Id., Ex. B, at 2–5.) Defendant contends that if physicians and patients are free to choose between buccal or sublingual administration, as the Prescribing Information clearly states, then there is no facially plausible support for Plaintiff's allegation of "no substantial non-infringing use."

While there appears to be a discrepancy between Plaintiff's Complaint and the exhibit attached thereto, the pleading stage of this case is not the time to conclusively determine that buccal administration is a substantial non-infringing use of Suboxone film. This is particularly

so where I must "assume the veracity" of the facts pled. Although the Prescribing Instructions provide that Suboxone film may be administered bucally or sublingually during the maintenance stage of treatment, they expressly state that, during the induction form of treatment, "it is recommended that the sublingual site of administration be used" because "the exposure to naloxone is somewhat higher after buccal than after sublingual administration." (Compl., Ex. B, at p.1.) Without further evidence and explanation, I cannot conclude, as a matter of law, that the mere availability of buccal administration in the Prescribing Instructions constitutes a "substantial, non-infringing use." Accordingly, I will deny Defendant's motion to dismiss on this ground.

D. Willful Infringement

Finally, Defendant seeks dismissal of Plaintiff's willful infringement claim, arguing that the Complaint fails to put forth any factual allegations that Indivior willfully infringed the patent-in-suit.

Pursuant to § 284 of the Patent Act, once infringement has been established, the court "may increase the damages up to three times the amount found or assessed." 35 U.S.C. § 284. Enhanced damages are "designed as a 'punitive' or 'vindictive' sanction for egregious infringement behavior," commonly described as "willful, wanton, malicious, bad faith, deliberate, consciously wrongful, flagrant, or . . . characteristic of a pirate." Halo Elecs,, Inc. v. Pulse Elecs., Inc., 136 S. Ct. 1923, 1932 (2016). "[C]ulpability is generally measured against the actor's knowledge of the actor at the time of the challenged conduct." Id. at 1933 (citations omitted). "A patent infringer's subjective willfulness, whether intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless." Id. at 1926. Under this standard, generalized allegations of willfulness are sufficient

to withstand a motion to dismiss. Bio-Rad Labs Inc. v. Thermo Fisher Scientific Inc., __ F.3d __, 2017 WL 437733, at *1 (D. Del. Feb. 1, 2017); DermaFocus LLC v. Ulthera, Inc., 201 F. Supp. 3d 465, 472 (D. Del. 2016).

The Complaint's willful allegation claim, while a bit sparse, sets forth sufficient facts to survive a Rule 12(b)(6) motion to dismiss. Plaintiff specifically alleges that "since at least the date that the '512 patent issued, Defendant has had knowledge that the induced acts would constitute infringement of the '512 patent and has specifically intended to cause such infringement." (Compl. ¶ 26.) It goes on to assert that "since at least the date the '512 patent issued, Defendant has known that its Suboxone Sublingual Film is especially made or especially adapted for use in the infringement of one or more claims of the '512 patent." (Id. ¶ 31.) Finally, the Complaint states that "Defendant's conduct, including—inter alia—continuing to knowingly cause widespread direct infringement of the '512 patent, and failure to provide a good faith response or analysis of its non-infringement or invalidity positions in response to licensing communications, justifies a finding of willful infringement." (Id. ¶ 33.) Taking these allegations as true, I can plausibly infer that Defendant's continued use of the Prescribing Instructions at issue after learning of the claims of the '512 patent was done with objective recklessness of the infringement risk. Accordingly, I decline to dismiss this claim.

IV. CONCLUSION

Defendant's Motion to Dismiss is granted only as to the direct infringement claim against Indivior. In all other respects, the Motion will be denied. An appropriate Order follows.