IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

RHODES PHARMACEUTICALS L.P.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 16-1308-SLR
	)	
INDIVIOR INC.,	)	
	)	
Defendant.	)	

RHODES PHARMACEUTICALS L.P.'S ANSWERING BRIEF IN OPPOSITION TO INDIVIOR'S MOTION TO DISMISS UNDER RULE 12(b)(6)

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NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff Rhodes Pharmaceuticals L.P. ("Rhodes") filed a Complaint alleging indirect infringement of U.S. Patent 9,370,512 ("the '512 patent") by Indivior Inc. ("Indivior"), based on Indivior's ongoing, express instructions to healthcare providers and patients to perform the methods claimed in the '512 patent. (D.I. 1). Indivior moved to dismiss with prejudice, asking the Court to preclude Rhodes from recovering ***at all*** for Indivior's wrongful activity, based on what Indivior argues is a factually deficient Complaint. For all the reasons stated below, Indivior's motion is factually wrong, legally untenable, and logically unsound.

SUMMARY OF ARGUMENT

1. The Complaint contains factual assertions that support reasonable inferences of Indivior's knowledge and intent, as well as element-by-element allegations of infringement of the '512 patent's independent claims and other details of direct infringement.[1] Likewise, the allegations regarding willful infringement are more than sufficient to satisfy the notice pleading standard. Indivior asks the Court to impose a new and heightened pleading standard – in direct contravention of controlling law – that would require plaintiffs to prove their cases at the pleading stage, and that would require the Court to make inferences in favor of the moving party. The very cases cited by Indivior in support of its motion completely undermine its position.

2. Indivior's request for dismissal ***with*** prejudice of Rhodes' un-amended complaint is unfounded. None of the patent cases Indivior cites takes this drastic step; each instead follows the liberal amendment policy embodied in Fed. R. Civ. P. 15. Moreover, Indivior's argument rests

[1] Rhodes does not allege that Indivior directly infringes the '512 patent. The Complaint alleges direct infringement by "healthcare professionals and/or patients," because such direct infringement is a necessary predicate to Indivior's indirect infringement. (*See* D.I. 1, ¶19). Indivior's request that the Court dismiss the direct infringement claim against it (D.I. 12 at 8-9) thus may be ignored.

on a logically unsound and legally unsupported idea – that Indivior's intent was frozen in time when it submitted its application to the FDA or obtained FDA approval, despite the fact that Indivior continued to provide instructions that expressly direct users to infringe the claimed methods after the issuance of the '512 patent.

STATEMENT OF FACTS

A. Direct Infringement by Healthcare Professionals and Patients

Indivior argues the Complaint does not allege that "the use of Plaintiff's Suboxone Sublingual Film meets each and every limitation of any claim of the '512 patent." (D.I. 12 at 7). On the contrary, the Complaint includes detailed allegations regarding direct infringement arising from the "use or administration" of Suboxone® Sublingual Film by "healthcare professionals and/or patients for opioid substitution therapy." (D.I. 1, ¶19). In particular, the Complaint includes element-by-element allegations of direct infringement of both independent claims of the '512 patent by healthcare providers and patients acting in accordance with the Prescribing Information and other instructions provided by Indivior:

Claim 1	
Claim Element	**Factual Allegations in Complaint (D.I. 1)**
A method of opioid substitution therapy for treating opioid addiction, the method comprising	¶11, ¶14, ¶20, Exh. B at 3[2]
contacting the sublingual mucosa of a patient in need thereof with a sublingual film dosage form comprising:	¶15, ¶20, Exh. B at 1, Exh. B at 3
a) approximately 0.1 mg to approximately 16 mg buprenorphine, or an equivalent amount of a pharmaceutically acceptable salt thereof;	¶17, ¶20, Exh. B at 3, Exh. B at 18
b) naloxone or a pharmaceutically acceptable salt thereof; and	¶17, ¶20, Exh. B at 3, Exh. B at 18

[2] Exh. B to the Complaint is the Indivior Prescribing Information (excerpts with highlighting and page numbers added attached as Exh. 1). *See DermaFocus LLC v. Ulthera, Inc.*, 201 F. Supp. 3d 465, 468 (D. Del. 2016) ("a court may consider the pleadings, public record, orders, exhibits attached to the complaint, and documents incorporated into the complaint by reference") (citations omitted).

c) at least one non-gelatin polymeric film-forming material in which the buprenorphine or the equivalent amount of the pharmaceutically acceptable salt thereof and the naloxone or the pharmaceutically acceptable salt thereof, are dissolved or homogeneously dispersed;	¶16, ¶20, Exh. B at 18
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 ratio of from 1:1 to 10:1;	¶17, ¶20, Exh. B at 18
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:	¶15, ¶17, ¶20, Exh. B at 1, Exh. B at 3, Exh. B at 18
(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.	¶17, ¶20, Exh. B at 18

Claim 19	
Claim Element	**Factual Allegations in Complaint (D.I. 1)**
A method of opioid substitution therapy for treating opioid addiction, the method comprising	¶11, ¶14, ¶21, Exh. B at 3
contacting the sublingual mucosa of a patient in need thereof with a sublingual film dosage form comprising:	¶15, ¶21, Exh. B at 1, Exh. B at 3
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 about 7 ng/ml and an average buprenorphine AUC_{0-48} of less than 40 (hrs*ng)/ml;	¶17, ¶21, Exh. B at 18
b) naloxone or a pharmaceutically acceptable salt thereof; and	¶17, ¶21, Exh. B at 18
c) at least one non-gelatin polymeric film-forming material in which the buprenorphine or the equivalent amount of the pharmaceutically acceptable salt thereof and the naloxone or the pharmaceutically acceptable salt thereof, are dissolved or homogeneously dispersed;	¶16, ¶21, Exh. B at 18

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 ratio of from 1:1 to 10:1;	¶17, ¶21, Exh. B at 18
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.	¶15, ¶17, ¶21, Exh. B at 1, Exh. B at 3, Exh. B at 18

The Complaint thus makes out a plausible claim for direct infringement by healthcare professionals and patients.

B. Inducement of Infringement by Indivior

The Complaint includes factual allegations supporting each element of Rhodes' inducement claim and thus makes out a plausible claim of inducement against Indivior:

Claim Element	Factual Allegations in Complaint (D.I. 1)
Direct Infringement	See discussion and chart regarding direct infringement above.
Knowledge of the '512 patent	"Defendant has had knowledge of the '512 patent since at least June 21, 2016, including knowledge of the claims of the '512 patent." (¶23) **Indivior does not challenge the adequacy of this allegation** and states that "[f]or purposes of this motion, this Court may take as true the allegation that Indivior had *knowledge* of the patent 'since at least June 21, 2016.'" (D.I. 12 at 17 (emphasis in original)).[3]

[3] All factual allegations in Rhodes' Complaint must be taken as true in this context. *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). Indivior's admission nonetheless eliminates any dispute about the sufficiency of the factual allegations regarding Indivior's pre-suit knowledge of the patent.

Acts causing direct infringement	"[C]ommercial manufacture, sale, offer for sale, and instructions for use of the four dosage strengths of Defendant's Suboxone Sublingual Film and other actions . . . ." (¶22); "[E]xplicitly instruct[ing]" and "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." (¶25) "[P]roviding Prescribing Information and other instructions that instruct healthcare professionals and/or patients to perform the claimed methods, including methods of opioid substitution therapy for 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 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, therein said contacting achieves the pharmacokinetic parameters of at least claims 1 and 19." (¶25; *see also* ¶13) Indivior's acts "have induced and/or caused, and continue to induce and/or cause, direct infringement by healthcare professionals and/or patients." (¶27)
Knowledge of infringement and intent to cause infringement	"[S]ince 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 intended to cause such infringement." (¶26) Indivior's knowledge and intent are shown by, *inter alia*: "intentionally provid[ing] Prescribing Information and other instructions to healthcare professionals and/or patients that instruct the healthcare professionals and/or patients to perform the claimed methods of at least independent claims 1 and 19 of the '512 patent, with knowledge of the '512 patent and with knowledge that use by healthcare professionals and/or patients in accordance with the Prescribing Information and other instructions directly infringes the '512 patent." (¶26) The Prescribing Information provided by Indivior includes specific instructions that, when followed, result in infringement of at least claims 1 and 19 of the '512 patent (*see* discussion of direct infringement, *supra*; *see also* ¶¶13, 14, 15, 16, 17).
Claim of inducement	"Defendant has induced and continues to induce infringement of the '512 patent." (¶24)

C. Contributory Infringement by Indivior

The Complaint alleges facts sufficient to make out a plausible claim of contributory infringement against Indivior:

Claim Element	Factual Allegations in Complaint (D.I. 1)
Direct Infringement	See discussion and chart above regarding direct infringement.
Knowledge of the '512 patent	Admitted by Indivior. See discussion and chart above regarding inducement.
271(c) Element 1: "Whoever offers to sell or sells within the United States . . . a material or apparatus for use in practicing a patented process, . . ."	Indivior'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." (¶29). See also discussion and chart above regarding direct infringement for comparison of claimed dosage form and Suboxone Sublingual Film dosage form.
271(c) Element 2: "constituting a material part of the invention, . . ."	Suboxone Sublingual Film is "a material part of the inventions covered by the claims of the '512 patent, because, *inter alia*, it is used in the claimed methods of opioid substitution therapy for 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 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 parameters of at least claims 1 and 19." (¶30).
271(c) Element 3: "knowing the same to be especially made or especially adapted for use in an infringement of such patent, . . ."	"[S]ince at least the date that the '512 patent issued, [Indivior] 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[,]" at least because the "Prescribing Information and other instructions instruct healthcare professionals and/or patients to use Defendant's Suboxone Sublingual Film in a manner that directly infringes one or more claims of the '512 patent, including claimed methods of opioid substitution therapy for 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 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 parameters of at least claims 1 and 19." (¶31). Moreover, "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 intended to cause such infringement." (¶26). Indivior's knowledge and intent are shown by, *inter alia*: "intentionally provid[ing] Prescribing Information and other instructions to healthcare professionals and/or patients that instruct the healthcare professionals and/or patients to perform the claimed methods of at least independent claims 1 and 19 of the '512 patent, with knowledge of the '512 patent and with knowledge that use by healthcare professionals and/or patients in accordance with the Prescribing Information and other instructions directly infringes the '512 patent." (¶26). The Prescribing Information provided by Indivior includes specific instructions that, when followed, result in infringement of at least claims 1 and 19 of the '512 patent (*see* discussion of direct infringement, *supra*; *see also* ¶¶13, 14, 15, 16, 17).
271(c) Element 4: "and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer."	"[S]ince at least the date that the '512 patent issued, [Indivior] has known that there is no substantial non-infringing use" for Suboxone Sublingual Film. (¶32). Suboxone Sublingual Film is indicated for infringing sublingual use. (¶15).

D. <u>Willful Infringement by Indivior</u>

The Complaint alleges facts sufficient to make out a plausible claim of willful infringement against Indivior. Indivior admits knowledge of the '512 patent since its issuance on June 21, 2016 (more than six months before this case was filed). (D.I. 12 at 17). The Complaint alleges that Indivior has "continu[ed] to knowingly cause widespread direct infringement of the '512 patent, and fail[ed] to provide a good faith response or analysis of its non-infringement or invalidity positions in response to licensing communications[.]" (D.I. 1, ¶33). Moreover, the Complaint is

replete with factual descriptions of Indivior's ongoing instructions to healthcare professionals and patients that establish knowing and willful indirect infringement. (*See*, *e.g.*, *id.*, ¶¶22-32).

ARGUMENT

No plaintiff is required to prove its case in the complaint. *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1339 (Fed. Cir. 2012) (pleading a plausible claim for relief "does not mean . . . that [plaintiff] must prove its case at the pleading stage"). Rather, the Court must review the Complaint drawing all reasonable inferences in Rhodes' favor. *Id.* at 1340. The Court may not "choose among competing inferences as long as there are sufficient facts alleged to render the non-movant's asserted inferences plausible." *Id.* "Absent specific guidance from the Federal Circuit directing the court to front-load the litigation process by requiring a detailed complaint in every instance, the court declines to do so." *DermaFocus LLC v. Ulthera, Inc.*, 201 F. Supp. 3d 465, 469 (D. Del. 2016) (Robinson, J.).

I. The Complaint States a Claim for Inducement

Indivior argues that Rhodes' Complaint does not state a claim for inducement because the Complaint (1) does not sufficiently allege direct infringement; and (2) does not sufficiently allege Indivior's intent to induce infringement. Indivior's arguments on both points are wrong.

A. The Complaint Sufficiently Alleges Direct Infringement by Healthcare Professionals and Patients

As set forth in the Statement of Facts, the Complaint contains detailed allegations of direct infringement, including factual allegations related to each element for the '512 patent's independent claims. Indivior argues these allegations are insufficient because the Complaint does not explain "how" the claims are infringed – in other words, the Complaint does not link Indivior's Prescribing Information (Complaint Exhibit B) to the claim elements. (D.I. 12 at 9).

In *DermaFocus LLC v. Ulthera, Inc.*, this Court rejected an argument – just like the one made by Indivior here – that plaintiff had failed to explain "how" the claimed method steps were performed. 201 F. Supp. 3d at 470. The challenged complaint in *DermaFocus* included only a cursory description of direct infringement (Exh. 2 at ¶10) that did not mention several claim elements, including requirements for certain temperature parameters. *Id.* at 469-70. Nonetheless, the Court upheld the direct infringement claim. Here, the Complaint not only describes each element of the infringed claims, it provides factual allegations – drawn in part from Indivior's package insert – to support infringement of each claim element. (*See supra* at 2-4).

Indivior faults Rhodes for not naming a specific direct infringer, rather than healthcare providers and patients who use Suboxone® Sublingual Film. (D.I. 12 at 8). Unsurprisingly, Indivior cites no support for this alleged fault, because "[t]o state a claim for indirect infringement . . . a plaintiff need not identify a *specific* direct infringer if it pleads facts sufficient to allow an inference that at least one direct infringer exists." *Bill of Lading*, 681 F.3d at 1336 (emphasis original). Given that Suboxone® must be prescribed (hence the Prescribing Information attached to the Complaint) and is sold commercially (D.I. 1, ¶12), it is reasonable to infer that at least one directly infringing healthcare provider or patient exists.[4]

Indivior also challenges the sufficiency of allegations related to certain claim elements (D.I. 12 at 9), but none of these challenges holds water. First, Indivior argues that the Complaint does not allege the active ingredients are "dissolved or homogenously dispersed." On the contrary, paragraphs 16 and 17 identify the relevant active and inactive ingredients, and paragraphs 20 and

[4] FDA regulations require that all packages of Suboxone Film sold contain detailed labeling including directions for use. *See, e.g.*, 21 CFR §§ 201.56; 201.57 & 201.100.

21 explain that the active ingredients are "dissolved or homogeneously dispersed" in a "non-gelatin polymeric film-forming material" as required by the claims.

Next, Indivior argues the Complaint does not allege that the active ingredients will contact the sublingual mucosa less than five minutes after the film contacts the sublingual mucosa. But the Complaint alleges both that the Prescribing Information instructs users to place the film under the tongue where the sublingual mucosa is located in a method of "Sublingual Administration" (D.I. 1, ¶15) and that the active ingredients will contact the sublingual mucosa less than five minutes after that, as required by the claims.[5] (D.I. 1, ¶¶20, 21).

Finally, Indivior asserts that the Complaint does not allege that the claimed pharmacokinetic parameters will be achieved by the healthcare professionals and patients identified in the Complaint. But again, the Complaint includes exactly these allegations in paragraphs 20 and 21 (as well as in paragraphs alleging facts showing inducement and contributory infringement, such as 25, 30 and 31).

To the extent Indivior is challenging the amount of factual support in support of Rhodes' allegations, Rhodes is not required to "prove its case" at this stage. *Bill of Lading*, 681 F.3d at 1339. Moreover, many of the factual allegations challenged by Indivior are made upon information and belief because key facts are contained in non-public information held by Indivior. *See McDermott v. Clondalkin Grp., Inc.*, 649 Fed. Appx. 263, 267-68 (3d Cir. 2016) (permitting pleading on information and belief where "requisite factual information is peculiarly within the defendant's knowledge or control"). As the Court held in *DermaFocus*, "[a] defendant cannot

[5] The prescribing information for Suboxone® Sublingual Tablets indicates a dissolution time of 5 to 10 minutes. (Exh. 1 at 47 (Section 14, "CLINICAL STUDIES")). In light of this fact and the disclosures in the patents covering the film licensed to Indivior (*see infra* at n.6), it is reasonable to infer that the Sublingual Film will dissolve in less than five minutes.

shield itself from a complaint . . . by operating in such secrecy that the filing of a complaint itself is impossible." 201 F. Supp. 3d at 469-70 (quoting *K-Tech Telecommunications, Inc. v. Time Warner Cable, Inc.*, 714 F.3d 1277, 1286 (Fed. Cir. 2013)); *see also id.* at 470 (finding reasonable notice of a plausible claim for direct infringement where it was not clear that "the information demanded by defendant is in the public domain and, therefore, reasonably available to plaintiff").

In any event, most – if not all – of the authoritative facts related to the aspects of Indivior's Suboxone® Sublingual Film and its use that Indivior challenges (including its constitution, dissolution times, and pharmacokinetics) are uniquely within the possession of Indivior. Contrary to Indivior's suggestion (D.I. 12 at 9 n.3), these facts cannot simply be gleaned from users or prescribers of Suboxone® – they are, to be sure, closely guarded confidential information held by Indivior in the form of clinical study reports, internal analyses, etc. These facts can be developed in discovery, but in the meantime, Rhodes should not be kept out of court while Indivior "shield[s] itself" by "operating in . . . secrecy." *DermaFocus*, 201 F. Supp. 3d at 469-70.[6]

[6] There are, nonetheless, snippets of details about Indivior's product that are available in the public record and that further support the direct infringement allegations of the Complaint, including Orange Book patents for Suboxone® Sublingual Film and (heavily redacted) reports by the FDA's Center for Drug Evaluation and Research based on clinical trial data for Suboxone® Sublingual Film. For example, the Orange Book patents, which have been licensed to Indivior since before the '512 patent issued (*see* March 2016 complaint filed by Indivior in C.A. No. 16-178-RGA (Exh. 3) at ¶¶10-12) discuss the uniform distribution of active ingredients (Exh. 4, U.S. Patent No. 8,603,514 at claim 1 (referring to "uniformity" of active ingredients in film)), dissolution time (Exh. 5, U.S. Patent No. 8,475,832 at 6:65-7:3 (film dissolves "within about 3 minutes" preferably less)), and claimed pharmacokinetic properties (*id.* at Tables 6, 8, and 10 (showing C_{max} and AUC_{inf} – which exceeds $AUC_{0\text{-}48}$ – below the maximums in claim 19)). Fed. R. Evid. 201(b)(2); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509 (2007) (court may take judicial notice of facts in deciding Rule 12(b)(6) motions); *Foster Poultry Farms v. Alkar-Rapidpak-MP Equip., Inc.*, 868 F. Supp. 2d 983, 990 (E.D. Cal. 2012) ("Court[s] have also found the contents of patents to be the appropriate subject of judicial notice because patents are documents issued by the U.S. Patent and Trademark Office, a source whose accuracy cannot be reasonably questioned.") (citing cases). As noted above, however, because the definitive, unredacted information regarding these claim elements is peculiarly within Indivior's possession, Rhodes' Complaint, as pleaded, is sufficient to permit the case to proceed. *McDermott*, 649 Fed. Appx. at 267-68.

For these reasons, the Complaint provides reasonable notice of the allegation of direct infringement supporting Rhodes' claims of indirect infringement.

B. The Complaint Sufficiently Alleges Inducement of Infringement by Indivior

Indivior argues that the Court should dismiss the Complaint because it does not include facts that show Indivior provided express instructions to the direct infringers to perform each method step. (D.I. 12 at 11-12). But the methods of claims 1 and 19 contain ***only one step***: "contacting the sublingual mucosa of a patient in need thereof with a sublingual film dosage form . . . ." As the Complaint alleges, the Prescribing Information provided by Indivior to healthcare providers and/or patients ***does*** expressly instruct users to contact the sublingual mucosa with the sublingual film dosage, to hold the film under the tongue until it dissolves, and further includes specific information about the dosage form itself (including the claimed ingredients and ratios). (*See supra* at 2-5; *see also* Exh. 1 at 1, 3, 18). Once the step of contacting the sublingual mucosa is performed in accordance with the Prescribing Information, the remaining claim elements (including contact of the sublingual mucosa by the active ingredients, and claimed pharmacokinetic parameters) are the inevitable and natural result. Thus, Indivior's intent to bring about the claimed method is evident – it provides express instructions on how to perform ***the method's only step***.[7]

Even a complaint that does not expressly touch on intent to induce with respect to each element of a patent claim, adequately pleads inducement. In *Bill of Lading*, defendant argued that

[7] The Complaint also alleges that Indivior had *knowledge* that its affirmative acts would cause infringement of the '512 patent, including the limitations directed to the active ingredients contacting the sublingual mucosa within less than five minutes and the resulting pharmacokinetic parameters (*see supra* at 4-5). Indivior does not challenge the allegations of knowledge on their merits, instead arguing that it cannot have had knowledge or intent because the patent issued after Indivior obtained FDA approval. That argument is addressed below.

the complaint did not include statements that "specifically instruct [the direct infringers] to perform all of the steps of the patented method." 681 F.3d at 1341. The court rejected that argument, explaining that plaintiff's complaint is ***not*** required to "allege facts that prove all aspects of its claims, or [even] make those claims probable." *Id.* Instead, plaintiff must simply allege "'enough fact[s] to raise a reasonable expectation that discovery will reveal' that the defendant is liable for the misconduct alleged." *Id.* (quoting *Bell Atlantic v. Twombly*, 550 U.S. 544, 556 (2009)); *see also Braintree Labs., Inc. v. Breckenridge Pharm., Inc.*, 2016-1731, 2017 U.S. App. LEXIS 7980, at *11-12 (Fed. Cir. May 5, 2017) (finding that defendant's label showed intent to induce infringement even where it did not discuss the claimed use, because the claimed use was the "*means* by which the approved indication achieves its result" (emphasis original)); *GlaxoSmithKline LLC v. Glenmark Generics Inc., USA*, C.A. No. 14-877-LPS-CJB, 2015 U.S. Dist. LEXIS 52525, at *22-23 (D. Del. Apr. 22, 2015) ("There is no requirement that Defendants need to have mimicked the precise wording of [the claims]. 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] in a manner that would meet the claim limitations."); *DermaFocus*, 201 F. Supp. 3d at 471 (denying motion to dismiss inducement claim where defendant's educational materials were provided to direct infringers and thus it was "plausible to infer that defendant knew that the intended use of the [accused system] (for which defendant's customers received instructions) was infringing" and that defendant had the requisite intent to induce that infringement); *Walker Digital, LLC v. Facebook, Inc.*, 852 F. Supp. 2d 559, 564-66 (D. Del. 2012) (denying motion to dismiss inducement claim where plaintiff generally alleged that defendant "instructs its users and/or customers on using the infringing apparatuses in a manner

that is accused herein to infringe" and otherwise induced infringing activity without tying the intent to specific claim elements).[8]

The main case cited by Indivior (*Takeda*) does not help its cause. *Takeda* concerned an "off-label" use of a drug product, such that the prescribing information did not on its face instruct the use according to the patented method. *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 188 F. Supp. 3d 367, 377 (D. Del. 2016) . In fact, the court in *Takeda* distinguished its off-label use situation from cases like this one, where the label instructs the users to perform the patented method. *Id*. at 376. Significantly, the Prescribing Information here *does* instruct users to perform the claimed method "on its face," and thus, *Takeda* refutes Indivior's position.[9] *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) (affirming district court grant of preliminary injunction to prevent inducement based on finding that the label would "inevitably lead some consumers to practice the claimed method."); *Braintree*, 2017 U.S. App. LEXIS 7980, at *11-12.

II. The Complaint States a Claim for Contributory Infringement

Indivior challenges Rhodes' contributory infringement claim in several ways. First, Indivior argues that the Complaint does not allege that Indivior sells "a component . . . of an

[8] In addition, public information described above in footnote 6 (including patents on Suboxone® Sublingual Film licensed to Indivior since before the '512 patent issued) – in combination with Indivior's admitted knowledge of the '512 patent since it issued – supports a reasonable inference that Indivior had knowledge of infringement and the requisite intent to induce infringement.

[9] The other cases cited by Indivior are also inapposite. Here, unlike in *RainDance*, Rhodes has alleged infringement of each limitation of claims 1 and 19 of the '512 patent. Moreover, unlike the plaintiff in *RainDance* who could examine the accused product and analyze all elements of the claim, C.A. No. 15-152-RGA, 2016 U.S. Dist. LEXIS 33875, at *4-7 (D. Del. Mar. 4, 2016), much of the information here is Indivior's confidential information and thus unavailable for Rhodes' review. *See DermaFocus*, 201 F. Supp. 3d at 470. Likewise, in light of the Complaint's substantial and straightforward factual allegations regarding inducement, *Atlas*, which dealt with plainly contradictory allegations in a twice-amended complaint, does not apply. 189 F. Supp. 3d 768, 771 (N.D. Ill. 2016).

infringing combination." (D.I. 12 at 12). But § 271(c) includes ***two*** paths for liability: sale of a "component" to be used in a "patented machine, manufacture, combination or composition, ***or*** a material or apparatus for use in practicing a patented process, . . ." 35 U.S.C. § 271(c) (emphasis added). Rhodes is asserting liability under the latter path. (D.I. 1, ¶29 ("Defendant's Suboxone Sublingual Film is a material or apparatus for use in practicing the methods of the '512 patent")). Therefore, Indivior's assertions that the Complaint lacks allegations about "components" and "combinations," including "who made it, where it was sold, or who else contributed to it," miss the mark entirely. Even if they were required, the Complaint alleged manufacture by Indivior, sales by Indivior and direct infringement by others. The Complaint also includes factual allegations required to establish knowledge of the patent and of infringement, as well as the statutory requirements of § 271(c) . (*See supra* at 6-7). *See GlaxoSmithKline*, 2015 U.S. Dist. LEXIS 52525, at *30-34. Nothing else is required.

Indivior next argues that buccal administration is a substantial non-infringing use that precludes Rhodes' contributory infringement claim, but this is a liability issue, not a pleading issue, as "the Court accepts all of Plaintiff's allegations as true." *TeleSign Corp. v. Twilio, Inc.*, C.A. No. 16-2106-PSG-SSX, 2016 U.S. Dist. LEXIS 123516, at *8-10 (C.D. Cal. Aug. 3, 2016) (citing *Iqbal*, 556 U.S. at 679-80). The Complaint specifically alleges that Indivior has known since the issuance of the '512 patent that there were no substantial non-infringing uses. (D.I. 1, ¶32). *See GlaxoSmithKline*, 2015 U.S. Dist. LEXIS 52525, at *30-34 (holding that complaint stated a claim for contributory infringement despite lack of data regarding extent of non-infringing use because it contained "enough factual specificity to put Defendants on notice of the claim of contributory infringement, and to sufficiently suggest that any non-infringing use of carvedilol was occasional and non-substantial."). As the Court explained in *GSK*, "'[Q]uestions' about a party's liability

need not be definitively 'answer[ed]' at the pleading stage." *Id.* Moreover, unlike in *Bill of Lading*, the Complaint does not "make clear on [its] face" that buccal administration is a substantial non-infringing use. Buccal administration is simply an alternative route of administration that may or may not infringe (the claims do not expressly require that the film be placed initially under the tongue).

III. The Complaint States a Claim for Willful Infringement

The Complaint alleges knowledge of the patent since it issued (admitted by Indivior), continued knowing and widespread infringement by Indivior, and Indivior's failure to respond to licensing entreaties for the '512 patent (which creates a reasonable inference that Indivior knew that its ongoing conduct created a risk of infringement). (D.I. 1, ¶¶22-33). These are facts, not legal conclusions, and they adequately support the willfulness allegations of the Complaint. *DermaFocus*, 201 F. Supp. 3d at 473 (D. Del. 2016) (denying motion to dismiss post-filing willfulness claims where complaint simply stated that defendant had knowledge of the patent and knowledge of the risk of infringement (Exh. 2 at ¶17)).

Indivior nonetheless argues – without support from any case – that ignoring licensing efforts does not create a plausible inference of willful infringement. (D.I. 12 at 14). Yet again, Indivior's failure to cite any case is telling, as just months ago this Court found similar allegations more than adequate to state a claim for willful infringement. *See Bio-Rad Labs. Inc. v. Thermo Fisher Sci. Inc.*, C.A. No. 16-358-RGA, 2017 U.S. Dist. LEXIS 13548, at *3-4 (D. Del. Jan. 31, 2017) (upholding willful infringement claim post-*Halo*, and noting that defendant's continued sales after receiving licensing terms from plaintiff was "highly relevant").

IV. Indivior's Futility Argument Fails and Does Not Support a Dismissal with Prejudice

Indivior argues that it cannot have had intent to induce infringement before the patent issued (D.I. 12 at 15-17) or after the patent issued (*id.* at 17-19) as a matter of law. There is no need to address Indivior's argument about pre-issuance intent, because Rhodes does not allege that infringement occurred prior to patent issuance.[10] Thus, Indivior's professed inability to have the requisite intent prior to patent issuance is of no moment.[11]

As for post-issuance intent, Indivior appears to argue that its intent is frozen in time as of the date of submission of its NDA (or perhaps the approval of the NDA). Because it could not have had the intent to induce infringement in 2010, the argument goes, it cannot have intent to induce infringement now.

The *L.A. Biomedical* case cited by Indivior directly contradicts its argument. There, defendant argued (like Indivior does here) that pre-patent-issuance activity with respect to its label could not support an allegation of intent to induce infringement. *L.A. Biomedical Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co.*, C.A. No. 13-857-JAK, 2014 U.S. Dist. LEXIS 185431, at *8 (C.D. Cal. May 12, 2014). The Court rejected defendants' argument because plaintiff "alleges that Defendants' label continues to instruct physicians and patients to prescribe and use [the accused product]" in an infringing manner (like Rhodes alleges here). *Id.* The court explained that "[b]ecause the complaint contains allegations of continued culpable conduct after

[10] Rhodes reserves its rights to seek pre-issuance damages if the facts uncovered in discovery support such a claim under 35 U.S.C. § 154(d) or otherwise.

[11] Ultimately, Indivior's pre-issuance conduct may be relevant to its post-issuance inducement. *See, e.g., GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, C.A. No. 14-878-LPS-CJB, 2016 U.S. Dist. LEXIS 94438, at *34-35 (D. Del. July 20, 2016) ("In contrast to the facts at issue in *Nat'l Presto Indus.*, where there are acts of inducement that *continue* after the issuance of a patent, courts have indicated that acts occurring prior to the patent's issuance could still be relevant to an induced infringement claim.") (emphasis original). But for the purposes of this motion, Indivior's pre-issuance intent is irrelevant.

the issuance of the patent, dismissal is not warranted." *Id.* Other courts have likewise found intent to induce where a party continues to instruct or promote the infringing use of its products. *See AstraZeneca*, 633 F.3d at 1058 (affirming finding of intent to induce based on defendant's failure to alter drug label after learning of patent); *CreAgri, Inc. v. Pinnaclife Inc.,* C.A. No. 11–06635–LHK, 2013 U.S. Dist. LEXIS 105952, at *11-16 (N.D. Cal. July 29, 2013) ("In choosing to continue its activities, despite having knowledge of the '599 Patent, Pinnaclife is taking an affirmative action to induce infringement of the '599 Patent.").

None of the other cases cited by Indivior supports its tortured logic. *Takeda* does not even discuss the proposition that Indivior advances here. Setting aside its limited relevance in a non-Hatch-Waxman context, *Takeda* simply holds that the label submitted to the FDA by a defendant is evidence of its intent. *See* 188 F. Supp. 3d at 376. It does not hold or even suggest that the intent is frozen in time such that the label could not be used as evidence of inducement of a later-issued patent. *Id. National Presto Indus. v. West Bend Co.*, is also unhelpful to Indivior, because it involved the question of exclusively pre-issuance activity, as opposed to ongoing, continued post-issuance actions. 76 F.3d 1185, 1196 (Fed. Cir. 1996). Indivior's reliance on *Nazomi Comms., Inc. v. Nokia Corp.* is similarly misplaced. In that case, the user instructions in the form of a manual were distributed once, prior to the issuance of the patent, unlike the Prescribing Information here, which is continually provided to users and was updated after the patent issued. 2011 U.S. Dist. LEXIS 76057, at *7 (N.D. Cal. July 14, 2011); *see infra* at n.13. The *Evolved Wireless* holding is based on the straightforward proposition that intent is evaluated at the time of the alleged infringement, and therefore a claim for pre-suit inducement requires an allegation of pre-suit intent. C.A. No. 15-545-SLR-SRF, 2016 U.S. Dist. LEXIS 32794, at *18-19 (D. Del. Mar. 15, 2016). In this case, unlike in *Evolved Wireless*, Indivior is alleged to have both knowledge

and intent – based on ongoing provision of instructions to practice the claimed method – since the patent issued in June 2016, months before this case was filed.

Likewise, *Catapano* is inapposite. In that case, the Court found that intent was implausible where the vaccine that was alleged to directly infringe was referenced in the patent. 88 F. Supp. 2d 27, 30-31 (E.D.N.Y. 2000). Here, Indivior incorrectly argues that the infringing Suboxone® Sublingual ***Film*** is mentioned in the '512 patent. (D.I. 12 at 18). It is not. The patent refers to the prior Suboxone® ***Tablet*** formulation, which the '512 patent invention and Suboxone® Film are improvements on. (D.I. 1 Exh. A at 2:1-24 (describing various "sublingual tablets")). Thus, there is no logical inconsistency in Indivior's intent to cause infringement of the sublingual film formulation, which arose after Rhodes' original application was filed.[12]

Indivior also seems to argue that the fact that it ***has not*** changed the Prescribing Information since the '512 patent issued means that it cannot have intent to infringe. The truth is exactly the opposite – Indivior's intent is established by the fact that it continues to provide the Prescribing Information and other instructions directing users to perform the claimed method of administration, despite knowing about the patent.[13] *See AstraZeneca*, 633 F.3d at 1058; *L.A. Biomedical*, 2014 U.S. Dist. LEXIS 185431, at *8; *CreAgri*, 2013 U.S. Dist. LEXIS 105952, at

[12] Indivior states that the application for the '512 patent was filed in 2015, but that application was a divisional of an application filed in 2009, which was itself the national stage entry of an application filed in 2007, claiming priority to a 2006 foreign application. (D.I. 1 at Exh. A). Thus, a number of patent applications were filed on this invention before Suboxone® Sublingual Film was submitted to, or approved by, the FDA.

[13] In fact, Indivior amended its Prescribing Information in December 2016, once again declining to remove instructions to perform the claimed method of sublingual administration. (*See* Exh. 6 at 1 (highlighting added)). Indivior's continued affirmative instruction of users to perform the infringing methods and even updating of those instructions without changing the offending portions supports a finding of intent; Indivior's liability is not based on "mere sale of a drug product". (D.I. 12 at 15 (quoting *Acorda Therapeutics Inc. v. Apotex Inc.*, C.A. No. 07-4937-GEB-MCA, 2011 U.S. Dist. LEXIS 102875, at *39 (D.N.J. Sept. 6, 2011))).

*11-16. Thus, the Court can reject Indivior's assertion that it was not alleged to have undertaken any affirmative act after issuance of the '512 patent that induced infringement. (D.I. 12 at 17).

Finally, the cases cited by Indivior for the proposition that dismissal should be with prejudice do not support its position. *Alston v. Parker* did not endorse dismissal with prejudice on its facts, instead vacating the district court's dismissal. 363 F.3d 229, 236 (3d Cir. 2004). In *Brown v. Aponte,* the court dismissed with prejudice because "the essence of the plaintiff's claim . . . is simply incorrect as a matter of black-letter contract law." C.A. No. 06-2096, 2006 U.S. Dist. LEXIS 72684, at *10 (E.D. Pa. Oct. 3, 2006). Unlike in *Brown*, the proposition that Indivior is advancing – that intent cannot change with the circumstances – is anything but "black-letter law." *See AstraZeneca*, 633 F.3d at 1058.

CONCLUSION

For the above reasons, Indivior's motion to dismiss should be denied. If the Court dismisses some or all of Rhodes' claims, the dismissal should be without prejudice to amend.

Respectfully submitted,

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