IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

RHODES PHARMACEUTICALS L.P.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
INDIVIOR INC.,	)	**DEMAND FOR JURY TRIAL**
	)	
Defendant.	)	

COMPLAINT

Plaintiff Rhodes Pharmaceuticals L.P. ("Rhodes" or "Plaintiff") for its Complaint against Defendant Indivior Inc. ("Indivior" or "Defendant") hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. The patent-in-suit (see paragraph 9) recognizes that treating opioid addiction with buprenorphine and naloxone is an important public health issue, which Plaintiff seeks to address through research and development. As it is entitled to, Plaintiff seeks an award of damages no less than a reasonable royalty from Defendant for use of the inventions claimed in the patent in suit.

THE PARTIES

2. Rhodes is a limited partnership organized and existing under the laws of the State of Delaware, having a principal place of business at 498 Washington Street, Coventry, Rhode Island.

3. On information and belief, Defendant Indivior is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

SUBJECT MATTER JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

PERSONAL JURISDICTION

6. This Court has personal jurisdiction over Defendant because of, *inter alia*: Defendant's incorporation in Delaware; its continuous and systematic contacts with corporate entities within this Judicial District; and its marketing and sales activities in this Judicial District, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of Suboxone® Sublingual Film to residents of this Judicial District. Accordingly, Indivior should have reasonably anticipated that its actions would cause injury in Delaware and that it would be subject to suit in Delaware to redress that injury.

7. This Court further has personal jurisdiction over Defendant by virtue of the fact that Defendant has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Rhodes, which is a limited partnership organized and existing under the laws of the State of Delaware.

8. This Court also has personal jurisdiction over Defendant because Defendant has purposely availed itself of the rights and benefits of the laws of this State and Judicial District by, *inter alia*, filing patent infringement actions in this District, including four lawsuits regarding its Suboxone Sublingual Film described in paragraphs 10-17 below: *Indivior Inc. et al v. Actavis Laboratories UT, Inc.*, C.A. No. 1:2016cv01009; *Indivior Inc. et al. v. Teva Pharmaceuticals USA,*

Inc., C.A. No. 1:2016cv00178; *Indivior Inc. et al. v. Sandoz Inc.*, C.A. No. 1:2015cv01051 and *Indivior Inc. et al. v. Mylan Technologies Inc. et al.*, C.A. No. 1:2015cv01016.

THE PATENT-IN-SUIT

9. United States Patent No. 9,370,512 ("the '512 Patent"), entitled "Buprenorphine-Wafer For Drug Substitution Therapy," was duly and legally issued by the United States Patent and Trademark Office on June 21, 2016. Plaintiff Rhodes is the owner of the entire right, title, and interest in the '512 Patent by assignment, and possesses the right to sue for and obtain equitable relief and damages, including past damages, for infringement of the '512 Patent. A true and correct copy of the '512 Patent is attached as Exhibit A.

SUBOXONE SUBLINGUAL FILM

10. Defendant Indivior is the holder of New Drug Application ("NDA") No. 22-410 for SUBOXONE® (buprenorphine and naloxone) Sublingual Film ("Suboxone Sublingual Film").

11. On August 30, 2010, the FDA approved NDA No. 22-410 Suboxone Sublingual Film for the treatment of opioid dependence.

12. Defendant has sold and continues to sell Suboxone Sublingual Film in the United States under NDA No. 22-410 since its approval.

13. Defendant has provided information and instructions to healthcare professionals and/or patients regarding its Suboxone Sublingual Film, including but not limited to Prescribing Information and Medication Guides. A true and correct copy of Defendant's Prescribing Information is attached as Exhibit B.

14. Defendant's Prescribing Information for its Suboxone Sublingual Film, provided to healthcare professionals and/or patients, states that "SUBOXONE sublingual film is indicated for treatment of opioid dependence and should be used as part of a complete treatment plan to

include counseling and psychosocial support." (Exh. B at 3).

15. The Prescribing Information also states "Sublingual Administration: Place one film under the tongue, close to the base on the left or right side, and allow to completely dissolve." (*Id.* at 1).

16. The Prescribing Information also states that Suboxone Sublingual Film "contains polyethylene oxide, hydroxypropyl methylcellulose, maltitol, acesulfame potassium, lime flavor, citric acid, sodium citrate, FD&C yellow #6, and white ink." (*Id.* at 18).

17. The Prescribing Information also states that Defendant's 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.*).

FIRST CLAIM FOR RELIEF
(INFRINGEMENT OF THE '512 PATENT)

18. Plaintiff incorporates by reference and realleges paragraph 1 through 17 above as though fully restated herein.

19. The 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 under 35 U.S.C. § 271(a), including but not limited to independent claims 1 and 19.

20. As required by claim 1, Defendant's Suboxone Sublingual Film is a "sublingual film dosage form," containing (depending on dosage strength) somewhere between 2 mg of buprenorphine and 12 mg of buprenorphine, within the claimed rage of "approximately 0.1 mg to approximately 16 mg buprenorphine, or an equivalent amount of a pharmaceutically acceptable

salt thereof," and also containing "naloxone or a pharmaceutically acceptable salt thereof" and containing "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," including but not limited to polyethylene oxide and/or hydroxypropyl methylcellulose, and containing buprenorphine and naloxone in a 4:1 weight ratio, within the claimed range of "1:1 to 10:1." On information and belief, healthcare professionals and patients acting in accordance with Defendant's Prescribing Information and/or other instructions provided by Defendant perform the claimed method, including "contacting the sublingual mucosa of a patient in need thereof" with Defendant's Suboxone Sublingual Film "such that within less than 5 minutes after contacting the sublingual mucosa of the patient" with Defendant's Suboxone Sublingual Film, "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 $AUC_{0\text{-}48}$ 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 $AUC_{0\text{-}48}$ 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 $AUC_{0\text{-}48}$ 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."

21. As required by claim 19, Defendant's Suboxone Sublingual Film is a "sublingual film dosage form," containing "an amount of buprenorphine, . . . [and] naloxone or a

pharmaceutically acceptable salt thereof," and "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," including but not limited to polyethylene oxide and/or hydroxypropyl methylcellulose, and containing buprenorphine and naloxone in a 4:1 weight ratio, within the claimed range of "1:1 to 10:1." On information and belief, the buprenorphine or pharmaceutically acceptable salt thereof present in Defendant's Suboxone Film is "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." On information and belief, healthcare professionals and patients acting in accordance with Defendant's Prescribing Information and/or other instructions provided by Defendant perform the claimed method, including "contacting the sublingual mucosa of a patient in need thereof with a sublingual film dosage form . . . 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."

22. Through its commercial manufacture, sale, offer for sale, and instructions for use of the four dosage strengths of Defendant's Suboxone Sublingual Film and other actions, Defendant has indirectly infringed and continues to indirectly infringe one or more claims of the '512 patent, including but not limited to independent claims 1 and 19, under 35 U.S.C. § 271(b) & (c).

23. On information and belief, Defendant has had knowledge of the '512 patent since at least June 21, 2016, including knowledge of the claims of the '512 patent.

24. Defendant has induced and continues to induce infringement of the '512 patent.

25. 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. Defendant has explicitly instructed and continues to instruct healthcare professionals and/or patients to use its Suboxone Sublingual Film in a manner that directly infringes one or more claims of the '512 patent by, *inter alia*, providing 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, wherein said contacting achieves the pharmacokinetic parameters of at least claims 1 and 19.

26. On information and belief, 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. Defendant has, *inter alia*, intentionally provided 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.

27. On information and belief, Defendant's affirmative acts, including its commercial manufacture, sale, offer for sale, and/or its provision of instructions for Suboxone Sublingual Film to healthcare professionals and/or patients have induced and/or caused, and continue to induce and/or cause, direct infringement by healthcare professionals and/or patients.

28. Defendant has contributed to, and continues to contribute to, infringement of the '512 patent.

29. 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.

30. Defendant's Suboxone Sublingual Film constitutes 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.

31. On information and belief, since at least the date that 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. Defendant's 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.

32. On 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.

33. Defendant's infringement of the '512 patent has been willful since at least the issuance of the '512 patent, and justifies an increase in damages of up to three times in accordance with 35 U.S.C. § 284. 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.

DEMAND FOR JURY TRIAL

Plaintiff respectfully demands a jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter:

A. A judgment that Defendant has infringed one or more claims of the ’512 patent;

B. A judgment that Defendant has induced infringement of one or more claims of the ‘512 patent;

C. A judgment that Defendant has contributed to infringement of one or more claims of the ‘512 patent;

D. A judgment that the ’512 patent is valid and enforceable;

E. A judgment that Defendant’s infringement has been willful and increasing damages up to three times pursuant to 35 U.S.C. § 284;

F. A judgment finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding Plaintiff its reasonable attorneys’ fees;

G. A judgment granting Plaintiff compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendant is found to infringe; and

H. Any and all other relief as the Court deems just and proper.

Respectfully submitted,

/s/ Jeffrey T. Castellano

John W. Shaw (No. 3362)
Jeffrey T. Castellano (No. 4837)
SHAW KELLER LLP
300 Delaware Ave., Suite 1120
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
jcastellano@shawkeller.com
Attorneys for Plaintiff Rhodes Pharmaceuticals L.P.

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