IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INDIVIOR INC., INDIVIOR UK LTD., and MONOSOL RX, LLC,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. 16-1009-RGA
ACTAVIS LABORATORIES UT, INC.,	)	
Defendant.	)	

DEFENDANT'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Defendant Actavis Laboratories UT, Inc., by and through its undersigned attorneys, answers the complaint of plaintiffs Indivior Inc., Indivior UK Ltd., and MonoSol Rx, LLC as follows:

AS TO THE NATURE OF THE ACTION

1. Defendant admits that plaintiffs purport to bring this action under the patent laws of the United States. Defendant further admits that it submitted ANDA No. 204383 to the FDA seeking approval to manufacture and sell a generic version of the 4 mg/1 mg (buprenorphine/naloxone) dosage strength of Suboxone® sublingual film prior to expiration of U.S. Patent No. 8,475,832, U.S. Patent No. 8,017,150, and U.S. Patent No. 8,603,514. Except as expressly admitted, defendant denies the remaining allegations of paragraph 1.

AS TO THE PARTIES

2. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 2 and therefore denies them.

3. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 3 and therefore denies them.

4. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 4 and therefore denies them.

5. Defendant admits that Actavis Laboratories UT, Inc., formerly known as Watson Laboratories, Inc. (Delaware), is a Delaware corporation having a place of business at 577 Chipeta Way, Salt Lake City, Utah 84108.

AS TO JURISDICTION AND VENUE

6. Defendant does not contest that the Court has subject matter jurisdiction over this action.

7. Defendant admits that Actavis Laboratories UT, Inc. is a pharmaceutical company engaged in the business of developing and manufacturing generic pharmaceutical products, some of which are ultimately distributed, marketed, and/or sold in Delaware and throughout the United States. Except as expressly admitted, defendant denies any remaining allegations contained in paragraph 7.

8. Defendant does not contest personal jurisdiction for purposes of this action only. Except as expressly admitted, defendant denies any remaining allegations contained in paragraph 8.

9. Defendant does not contest that venue is proper in this District for purposes of this action only.

AS TO THE PATENTS-IN-SUIT

10. Defendant admits that the face of the '832 patent states that it issued on July 2, 2013, and that it is entitled "Sublingual and Buccal Film Compositions." Defendant further admits

that the face of the ’832 patent identifies Garry L. Myers, Samuel D. Hilbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors, and also identifies RB Pharmaceuticals Limited as the assignee. Defendant also admits that Exhibit A to the complaint appears to be a copy of the ’832 patent. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 10 and therefore denies them.

11. Defendant admits that the face of the ’150 patent states that it issued on September 13, 2011, and that it is entitled “Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom.” Defendant further admits that the face of the ’150 patent identifies Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors, and also identifies MonoSol Rx, LLC as the assignee. Defendant also admits that Exhibit B to the complaint appears to be a copy of the ’150 patent. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 11 and therefore denies them.

12. Defendant admits that the face of the ’514 patent states that it issued on December 10, 2013, and that it is entitled “Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions.” Defendant further admits that the face of the ’514 patent identifies Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors, and also identifies MonoSol Rx, LLC as the assignee. Defendant also admits that Exhibit C to the complaint appears to be a copy of the ’514 patent. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 12 and therefore denies them.

AS TO SUBOXONE® SUBLINGUAL FILM

13. Defendant admits that the Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) entry for NDA No. 22410 for Suboxone® sublingual film identifies Indivior Inc. as the applicant holder. Except as expressly admitted, defendant lacks

knowledge or information sufficient to form a belief about the truth of any remaining allegations in paragraph 13 and therefore denies them.

14. Defendant admits that the Orange Book entry for NDA No. 22410 identifies the FDA approval date as August 30, 2010 for the 2 mg/0.5 mg and 8 mg/2 mg (buprenorphine/naloxone) dosage strengths of the Suboxone® sublingual film. Defendant further admits 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. Defendant lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in paragraph 14 and therefore denies them.

15. Defendant admits that the Orange Book entry for NDA No. 22410 identifies the FDA approval date as August 30, 2010 for the 2 mg/0.5 mg and 8 mg/2 mg (buprenorphine/naloxone) dosage strengths of the Suboxone® sublingual film. Except as expressly admitted, defendant denies any remaining allegations contained in paragraph 15.

16. Defendant admits that the Orange Book entry for NDA No. 22410 identifies the FDA approval date as August 10, 2012 for the 4 mg/1 mg and 12 mg/3 mg (buprenorphine/naloxone) dosage strengths of the Suboxone® sublingual film. Except as expressly admitted, defendant denies any remaining allegations contained in paragraph 16.

17. Defendant admits that the ’832 patent, the ’150 patent, and the ’514 patent are listed in the Orange Book entry for NDA No. 22410. Except as otherwise expressly admitted, defendant denies any remaining allegations contained in paragraph 17.

AS TO THE DRUG APPROVAL PROCESS

18. Defendant answers that paragraph 18 states a legal conclusion to which no response is required, but if a response is required defendant admits that 21 U.S.C. § 355 *et seq.* sets forth

the federal statutory framework commonly known as the Hatch-Waxman Act. Except as expressly admitted, defendant denies any remaining allegations contained in paragraph 18.

19. Defendant answers that paragraph 19 states a legal conclusion to which no response is required, but if a response is required defendant admits that 21 U.S.C. § 355 *et seq.* sets forth the federal statutory framework commonly known as the Hatch-Waxman Act. Except as expressly admitted, defendant denies any remaining allegations contained in paragraph 19.

20. Defendant answers that paragraph 20 states a legal conclusion to which no response is required, but if a response is required defendant admits that 21 U.S.C. § 355 *et seq.* sets forth the federal statutory framework commonly known as the Hatch-Waxman Act. Except as expressly admitted, defendant denies any remaining allegations contained in paragraph 20.

21. Defendant answers that paragraph 21 states a legal conclusion to which no response is required, but if a response is required defendant admits that 21 U.S.C. § 355 *et seq.* sets forth the federal statutory framework commonly known as the Hatch-Waxman Act. Defendant further answers that 21 C.F.R. § 314.101 sets forth certain regulations implementing the Hatch-Waxman Act. Except as expressly admitted, defendant denies any remaining allegations contained in paragraph 21.

22. Defendant answers that paragraph 22 states a legal conclusion to which no response is required, but if a response is required defendant admits that 21 U.S.C. § 355 *et seq.* sets forth the federal statutory framework commonly known as the Hatch-Waxman Act. Except as expressly admitted, defendant denies any remaining allegations contained in paragraph 22.

23. Defendant answers that paragraph 23 states a legal conclusion to which no response is required, but if a response is required defendant admits that 21 U.S.C. § 355 *et seq.* sets forth

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