IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 13-1674-RGA
WATSON LABORATORIES, INC. and ACTAVIS LABORATORIES UT, INC.,	)	
Defendants.	)	

DEFENDANTS' ANSWER AND COUNTERCLAIMS TO PLAINTIFFS' SECOND AMENDED COMPLAINT

Defendants Watson Laboratories, Inc. and Actavis Laboratories UT, Inc. (collectively "Defendants"), by and through their undersigned attorneys, answer the second amended complaint of Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc., RB Pharmaceuticals Limited, and MonoSol Rx, LLC (collectively "Plaintiffs") as follows:

AS TO THE NATURE OF THE ACTION

1. Defendants admit that Plaintiffs purport to bring this action under the Food and Drug Law and Patent Laws of the United States. Defendants further admit that Watson Laboratories, Inc. (also sometimes referred to as "Watson Laboratories, Inc. (Nevada)" and hereinafter referred to as same) filed ANDA No. 204383 and ANDA No. 207087 with the FDA seeking approval to manufacture and sell a generic version of Suboxone®, a sublingual film containing buprenorphine hydrochloride and naloxone hydrochloride, before the expiration of the patents-in-suit. Except as expressly admitted, Defendants deny the remaining allegations in paragraph 1.

AS TO THE PARTIES

2. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore deny them.

3. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore deny them.

4. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore deny them.

5. Denied. Further responding, Defendant Watson Laboratories, Inc. (Nevada) is a Nevada corporation having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

6. Defendants admit that Actavis Laboratories UT, Inc. (formerly known as Watson Laboratories, Inc. or 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

7. Defendant Actavis Laboratories UT, Inc. does not contest that the Court has subject matter jurisdiction over this action. Watson Laboratories, Inc. (Nevada), on the other hand, transferred ownership of ANDA Nos. 204383 and 207087 to Actavis Laboratories UT, Inc. Accordingly, Defendant Watson Laboratories, Inc. (Nevada) contests subject matter jurisdiction because it is no longer the owner of the accused ANDAs.

8. Defendants admit 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, Defendants deny the remaining allegations in paragraph 8.

9. Defendants do not contest this Court's personal jurisdiction over them for purposes of this action only. Except as expressly admitted, Defendants deny the remaining allegations in paragraph 9.

10. Defendants do not contest that venue is proper in this District for purposes of this action only.

AS TO THE PATENTS-IN-SUIT

11. Defendants admit that the face of the '832 patent identifies RBP UK as the assignee. Defendants further admit that the '832 patent states on its face that it issued on July 2, 2013. Defendants also admit that the '832 patent is entitled "Sublingual and Buccal Film Compositions." Defendants further admit 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. Defendants also admit that Exhibit A to the second amended complaint appears to be a copy of the '832 patent. Defendants aver that the allegation the '832 patent was duly and legally issued states a legal conclusion to which no response is required, but if a response is required Defendants deny the same. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 11 and therefore deny them.

12. Defendants admit that the face of the '150 patent identifies MonoSol as the assignee. Defendants further admit that the '150 patent states on its face that it issued on September 13, 2011. Defendants admit that the '150 patent is entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom." Defendants further admit that the face of the '150 patent identifies Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. Defendants further admit that Exhibit B to the second amended complaint appears to be a copy of the '150 patent. Defendants aver that the allegation the '150 patent was duly and legally issued states a legal conclusion to which no response is required, but if a response is

required, Defendants deny the same. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 12 and therefore deny them.

13. Defendants admit that the face of the '514 patent identifies MonoSol as the assignee. Defendants further admit that the '514 patent states on its face that it issued on December 10, 2013. Defendants also admit that the '514 patent is entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions." Defendants further admit that the face of the '514 patent identifies Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. Defendants further admit that Exhibit C to the second amended complaint appears to be a copy of the '514 patent. Defendants aver that the allegation the '514 patent was duly and legally issued states a legal conclusion to which no response is required, but if a response is required, Defendants deny the same. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 13 and therefore deny them.

AS TO SUBOXONE® SUBLINGUAL FILM

14. Defendants admit that the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") entry for NDA No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film identifies Plaintiff Reckitt Benckiser as the applicant. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 14 and therefore deny them.

15. Defendants admit that the Orange Book entry for NDA No. 22-410 identifies the FDA approval date as August 30, 2010. Defendants further admit that the labeling for Suboxone® sublingual film indicates the product is "indicated for maintenance treatment of opioid dependence" when used as part of a complete treatment plan to include counseling and psychosocial support. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 15 and therefore deny them.

16. Defendants admit that the patents-in-suit are listed in the Orange Book with respect to Suboxone® sublingual film. Defendants aver that Plaintiff RBP caused the patents-in-suit to be listed in the Orange Book relative to Suboxone® sublingual film by filing a declaration with the FDA, and that the FDA published this patent information for Suboxone® sublingual film as a purely ministerial act. Except as specifically admitted, Defendants deny the remaining allegations in paragraph 16.

AS TO ACTAVIS' ANDAS

17. Defendants admit that Watson Laboratories, Inc. (Nevada) sent Plaintiffs a notice letter dated August 27, 2013, stating that ANDA No. 204383 contains a Paragraph IV certification, and explaining the reasons that the claims of the '832 and '150 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the proposed ANDA products. Defendants lack knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 17 and therefore deny them.

18. Defendants admit that Watson Laboratories, Inc. (Nevada) submitted ANDA No. 204383 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of the proposed ANDA products before expiration of the patents-in-suit. Defendants further admit that ANDA No. 204383 identifies Plaintiff RBP's NDA for Suboxone® sublingual film as the Reference Listed Drug, and that ANDA No. 204383 contains data demonstrating that the proposed ANDA products meet FDA requirements for bioequivalence with respect to Suboxone® sublingual film. Defendants lack knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 18 and therefore deny them.

19. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 and therefore deny them.

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