IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. WATSON LABORATORIES, INC. and ACTAVIS LABORATORIES UT, INC., Defendants.	)	CA. No. 1:13-cv-01674-RGA

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Reckitt Benckiser Pharmaceuticals Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") file this Amended Complaint against Defendant Watson Laboratories, Inc. ("Watson") and Actavis Laboratories UT, Inc. ("Actavis") (collectively "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submission of Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiff RBP's Suboxone® sublingual film prior to the expiration of United States Patent Nos. 8,475,832 ("the '832 patent"), 8,017,150 ("the '150 patent"), and 8,603,514 ("the '514 patent") (collectively, "the patents-in-suit").

THE PARTIES

2. Plaintiff RBP is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. Plaintiff RBP UK is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

4. Plaintiff MonoSol is a Delaware limited liability corporation having a principal place of business at 30 Technology Drive, Warren, New Jersey.

5. On information and belief, Defendant Watson is a Delaware corporation having a principal place of business at 311 Bonnie Circle, Corona, California, 92880.

6. On information and belief, Defendant Actavis is a Delaware corporation having a principal place of business at 577 East Chipeta Way, Salt Lake City, Utah, 84108.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. On information and belief, Defendants are in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products in Delaware and throughout the United States.

9. This Court has personal jurisdiction over Defendants because of, *inter alia*, Defendants' incorporation in Delaware, their continuous and systematic contacts with corporate entities within this judicial district, their previous submission to the jurisdiction of this judicial district, and their marketing and sales activities in this judicial district, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

10. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400.

THE PATENTS-IN-SUIT

11. Plaintiff RBP UK is the lawful owner of the ’832 patent, and Plaintiff RBP is an exclusive licensee of the ‘832 patent. The ’832 patent, entitled “Sublingual and Buccal Film Compositions,” duly and legally issued on July 2, 2013, naming Garry L. Myers, Samuel D. Hillbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. A true copy of the ’832 patent is attached hereto as Exhibit A.

12. Plaintiff MonoSol is the lawful owner of the ’150 patent, and Plaintiff RBP is an exclusive licensee of the ’150 patent. The ’150 patent, entitled “Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom,” duly and legally issued on September 13, 2011, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the ’150 patent is attached hereto as Exhibit B.

13. Plaintiff MonoSol is the lawful owner of the ’514 patent, and Plaintiff RBP is an exclusive licensee of the ’514 patent. The ’514 patent, entitled “Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions,” duly and legally issued on December 10, 2013, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the ’514 patent is attached hereto as Exhibit C.

SUBOXONE® SUBLINGUAL FILM

14. Plaintiff RBP is the holder of New Drug Application (“NDA”) No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

15. On August 30, 2010, the FDA approved NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the maintenance treatment of opioid dependence. Plaintiff RBP has sold Suboxone® sublingual film under NDA No. 22-410 since its approval.

16. The patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering Suboxone® sublingual film.

DEFENDANTS' ANDAS

17. Plaintiffs received a letter from Defendant Watson dated August 27, 2013 (the "Notification Letter"), stating that ANDA No. 204383 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the '832 and '150 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

18. The Notification Letter further states that Defendant Watson 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 buprenorphine hydrochloride and naloxone hydrochloride sublingual film ("Defendants' generic product") before expiration of the patents-in-suit. On information and belief, ANDA No. 204383 refers to and relies on Plaintiff RBP's NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Defendants' generic product with Suboxone® sublingual film.

19. Plaintiffs commenced this action within 45 days of receiving the Notification Letter.

20. Plaintiffs received another letter from Defendant Watson dated February 4, 2014 ("the '514 Notification Letter"), stating that ANDA No. 204383 contains a Paragraph IV certification alleging that the '514 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic product proposed in the ANDA.

21. The '514 Notification Letter further states that ANDA No. 204383 seeks approval for Defendant Watson to engage in commercial manufacture, use, or sale of Defendants' generic product before expiration of the '514 patent. On information and belief, ANDA No. 204383 refers to and relies on Plaintiff RBP's NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Defendants' generic product with Suboxone® sublingual film.

22. Plaintiffs filed an Amended Complaint within 45 days of receiving the '514 Notification Letter.

23. Plaintiffs received another letter from Defendant Actavis dated April 22, 2015 (the "April 2015 Notification Letter"), stating that ANDA No. 20-7087 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the '514, '150, and '832 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

24. The April 2015 Notification Letter further states that Defendant Actavis submitted ANDA No. 20-7087 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of a buprenorphine hydrochloride and naloxone hydrochloride sublingual film Defendants' generic product before expiration of the patents-in-suit. On information and belief, ANDA No. 20-7087 refers to and relies on Plaintiff RBP's NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Defendants' generic product with Suboxone® sublingual film.

25. Plaintiffs filed this Second Amended Complaint within 45 days of receiving the April 2015 Notification Letter.

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