IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., and MONOSOL RX, LLC,	)	
Plaintiffs,	)	CA. No. 14-1574-RGA
v.	)	
WATSON LABORATORIES, INC. and ACTAVIS LABORATORIES UT, INC.,	)	
Defendants.	)	

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Reckitt Benckiser Pharmaceuticals Inc. ("RBP") and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") file this 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 related to United States Patent Nos. 8,900,497 ("the '497 patent") and 8,906,277 ("the '277 patent") (collectively, "the patents-in-suit") arising under the Patent Laws of the United States, Title 35 of the United States Code.

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

4. Defendant Watson is a Delaware corporation having a principal place of business at 311 Bonnie Circle, Corona, California, 92880.

5. 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

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

7. 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.

8. Watson has previously submitted to the jurisdiction of the United States District Court for the District of Delaware, for example by submitting to jurisdiction in *Reckitt Benckiser Pharmaceutical Inc. et. al. v. Watson Laboratories, Inc.*, Civil Action No. 1:13-cv-01674-RGA.

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.

SUBOXONE® SUBLINGUAL FILM

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

12. 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.

THE PENDING ANDA LITIGATION BETWEEN THE PARTIES

13. Plaintiffs and Defendant Watson (collectively "Parties") are involved in ongoing litigation in this District, C.A. 13-1674.

14. C.A. 13-1674 relates to Defendant's submission of an Abbreviated New Drug Application No. 20-4383 ("ANDA No. 20-4383") 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 three of Plaintiffs' patents, listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering Suboxone® sublingual film.

15. The patents at issue in C.A. 13-1674 include Patent Nos. 8,475,832 ("the '832 patent"), 8,017,150 ("the '150 patent"), and 8,603,514 ("the'514 patent").

16. Defendant's ANDA No. 20-4383 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the '832, '150, and '514 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

17. Plaintiffs commenced C.A. 13-1674, and subsequently filed an amended complaint, within 45 days of receiving the relevant notice letters from Defendant.

DEFENDANT'S ANDA No. 20-7087

18. Plaintiffs received a letter from Defendant Actavis dated April 22, 2015 (the "April 2015 Notice 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 '832, '150,

and ‘514 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

19. The April 2015 Notice 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 ‘832, ‘150,and ‘514 patents.

THE PATENTS-IN-SUIT

20. Plaintiff Monosol is the lawful owner of the ’497 patent, and Plaintiff RBP is an exclusive licensee of the ’497 patent. The ’497 patent, entitled “Process for Making a Film Having a Substantially Uniform Distribution of Components,” duly and legally issued on December 2, 2014, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the ’497 patent is attached hereto as Exhibit A.

21. Plaintiff Monosol is the lawful owner of the ’277 patent, and Plaintiff RBP is an exclusive licensee of the ’277 patent. The ’277 patent, entitled “Process for Manufacturing a Resulting Pharmaceutical Film,” duly and legally issued on December 9, 2014, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the ’277 patent is attached hereto as Exhibit B.

DEFENDANTS’ INFRINGING GENERIC PRODUCT

22. Defendants have submitted ANDA Nos. 20-4383 and 20-7087 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of Defendants’ generic product before expiration of the patents-in-suit.

23. ANDA Nos. 20-4383 and 20-7087 each refer to and rely on Plaintiff RBP's NDA for Suboxone® sublingual film and purport to contain data showing bioequivalence of Defendants' generic product with Suboxone® sublingual film.

24. On information and belief, Defendants' generic product will be produced using a method protected by the patents-in-suit.

COUNT I
(Declaratory Judgment of Infringement of the '497 Patent Under 35 U.S.C. § 271)

25. Plaintiffs reallege paragraphs 1-24 above as if fully set forth herein.

26. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic product immediately following approval of ANDA Nos. 20-4383 and 20-7087.

27. On information and belief, Defendants' commercial manufacture of Defendants' generic product before the expiration of the '497 patent would infringe one or more claims of the '497 patent under 35 U.S.C. § 271.

28. The acts of infringement by Defendants set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

COUNT II
(Declaratory Judgment of Infringement of the '277 Patent Under 35 U.S.C. § 271)

29. Plaintiffs reallege paragraphs 1-28 above as if fully set forth herein.

30. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or

importation of Defendants' generic product immediately following approval of ANDA Nos. 20-4383 and 20-7087.

31. On information and belief, Defendants' commercial manufacture of Defendants' generic product before the expiration of the '277 patent would infringe one or more claims of the '277 patent under 35 U.S.C. § 271.

32. The acts of infringement by Defendants set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A declaratory judgment that Defendants' commercial manufacture within the United States of Defendants' generic product would infringe the patents-in-suit under 35 U.S.C. § 271;

B. Preliminary and permanent injunctions, restraining and enjoining Defendants, their officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from infringement of the patents-in-suit;

C. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees;

D. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendants commercially manufacture, use, offer to sell, or sell in the United States, or import into the United States, Defendants' generic product before the expiration of each patent-in-suit that Defendants are found to infringe, including any extensions; and

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

Dated: June 3, 2015

Respectfully submitted,

/s/ Mary W. Bourke

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