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, INC. Defendants.	)	CA. No.

COMPLAINT

Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") file this Complaint against Defendants Watson Laboratories, Inc. ("Watson") and Actavis, 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 an Abbreviated New Drug Application ("ANDA") 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") and 8,017,150 ("the '150 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 Nevada corporation having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. On information and belief, Watson is a wholly-owned subsidiary of Actavis.

8. On information and belief, Actavis was formerly known as Watson Pharmaceuticals, Inc. ("WPI") until on or around January 24, 2013. On information and belief, Actavis is 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, through its own actions and through the actions of its agents and subsidiaries, including at least Watson.

9. On information and belief, Actavis organizes its operations by divisions including at least Generics, Brands, and Distribution and, before the name change, WPI reported its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions. On information and belief, WPI consolidated its financial results with subsidiaries in

its SEC filings at least since 2007 and did not file separate reports to the SEC for each subsidiary.

10. On information and belief, Actavis' Generics Division ("Generics Division") is involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals. On information and belief, each Defendant acts as an agent of the other and/or works in concert with each other as integrated parts of the Generics Division. On information and belief, the Generics Division develops and submits ANDAs to the FDA, relying on contributions from at least Watson.

11. On information and belief, the head of the Generics Division is an employee of Actavis, the Generic Division's products are developed and manufactured by at least Watson, and the Generic Division's products are marketed, sold, and distributed throughout the United States, including in Delaware, by at least Actavis or a wholly-owned subsidiary thereof. On information and belief, Watson and Actavis are parties to one or more contractual agreements regarding the distribution of generic pharmaceutical products.

12. On information and belief, each Defendant shares with the others at least some common employees, officers, and directors.

13. On information and belief, Watson is within the control of Actavis for purposes of responding to discovery in this action.

14. On information and belief, Defendants collaborated in the research and development of Defendants' ANDA No. 204383, continue to collaborate in seeking approval of that application by the FDA, and intend to collaborate in the commercial manufacture, marketing, offer for sale and sale of the generic product resulting from Defendants' ANDA No.

204383 throughout the United States, including the State of Delaware, in the event the FDA approves Defendants' ANDA No. 204383.

JURISDICTION AND VENUE

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

16. 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.

17. This Court has personal jurisdiction over Watson because of, *inter alia*, Watson's incorporation in Delaware, its continuous and systematic contacts with corporate entities within this judicial district, its previous submission to the jurisdiction of 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 generic pharmaceutical products to residents of this judicial district.

18. This Court has personal jurisdiction over Actavis because of, *inter alia*, Actavis' incorporation in Delaware, its continuous and systematic contacts with corporate entities within this judicial district, its previous submission to the jurisdiction of 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 generic pharmaceutical products to residents of this judicial district, and through its intent to market and sell the generic product resulting from Defendants' ANDA No. 204383, if approved, to residents of this judicial district.

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

THE PATENTS-IN-SUIT

20. Plaintiff RBP UK is the lawful owner 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.

21. 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.

SUBOXONE® SUBLINGUAL FILM

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

23. 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.

24. The '832 and '150 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering Suboxone® sublingual film.

DEFENDANT'S ANDA

25. Plaintiffs received a letter from Defendants 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.

26. The Notification Letter further states that Defendants 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.

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

COUNT I
(Infringement of the '832 Patent Under 35 U.S.C. § 271(e)(2))

28. Plaintiffs reallege paragraphs 1-27 above as if fully set forth herein.

29. On information and belief, Defendants' generic product is covered by one or more claims of the '832 patent.

30. By filing ANDA No. 204383 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of Defendants' generic product prior to the expiration of the '832 patent, Defendants have committed an act of infringement of the '832 patent under 35 U.S.C. § 271(e)(2).

31. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No.

204383 to be a date which is not any earlier than the expiration date of the '832 patent, including any extensions of that date.

COUNT II
(Declaratory Judgment of Infringement of the '832 Patent Under 35 U.S.C. § 271(a-c))

32. Plaintiffs reallege paragraphs 1-32 above as if fully set forth herein.

33. 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 with its proposed labeling immediately following approval of ANDA No. 204383.

34. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Defendants' generic product before the expiration of the '832 patent would infringe one or more claims of the '832 patent under 35 U.S.C. § 271(a)-(c).

35. On information and belief, by seeking approval to distribute Defendants' generic product with its proposed labeling, Defendants intend to cause others, specifically, for example, medical professionals and patients, to perform acts that Defendants knows will infringe one or more claims of the '832 patent.

36. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, actively induce infringement of one or more claims of the '832 patent immediately following approval of ANDA No. 204383.

37. On information and belief, unless enjoined by this Court, Defendants plan and intend to, and will, contribute to the infringement of one or more claims of the '832 patent immediately following approval of ANDA No. 204383.

38. On information and belief, Defendants know that Defendants' generic product and its proposed labeling are especially made or adapted for use in infringing one or more claims

of the '832 patent, and that Defendants' generic product and its proposed labeling are not suitable for any substantial noninfringing use.

39. 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 III
(Infringement of the '150 Patent Under 35 U.S.C. § 271(e)(2))

40. Plaintiffs reallege paragraphs 1-39 above as if fully set forth herein.

41. On information and belief, Defendants' generic product is covered by one or more claims of the '150 patent.

42. By filing ANDA No. 204383 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of Defendants' generic product prior to the expiration of the '150 patent, Defendants have committed an act of infringement of the '150 patent under 35 U.S.C. § 271(e)(2).

43. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, inter *alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 204383 to be a date which is not any earlier than the expiration date of the '150 patent, including any extensions of that date.

COUNT IV
(Declaratory Judgment of Infringement of the '150 Patent Under 35 U.S.C. § 271(a))

44. Plaintiffs reallege paragraphs 1-43 above as if fully set forth herein.

45. 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 with its proposed labeling immediately following approval of ANDA No. 204383.

46. On information and belief, Defendants' commercial importation, manufacture, use, sale, and/or offer for sale of Defendants' generic product before the expiration of the '150 patent would infringe one or more claims of the '150 patent under 35 U.S.C. § 271(a).

47. 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 judgment that Defendants have infringed the '832 and '150 patents under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 204383;

B. A declaratory judgment that Defendants' commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendants' generic product would infringe each of the patents-in-suit under 35 U.S.C. § 271(a);

C. A declaratory judgment that Defendants' commercial offer to sell or sale within the United States of Defendants' generic product would infringe the '832 patent under 35 U.S.C. § 271(b-c);

D. Preliminary and permanent injunctions, restraining and enjoining Defendants, its officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with it, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs and formulations, or from inducing and/or encouraging the use of methods, claimed in the patents-in-suit;

E. An order that the effective date of any approval of ANDA No. 204383 be a date that is not earlier than the expiration of the last to expire of the patents-in-suit, including any extensions thereof and any later expiration of exclusivity associated with those patents;

F. 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;

G. 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 manufactures, uses, offers to sell, or sells in the United States, or imports into the United States, Defendants' generic product before the expiration of each patent-in-suit that Defendants is found to infringe, including any extensions; and

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

Dated: October 8, 2013

Respectfully submitted,

WOMBLE CARLYLE SANDRIDGE & RICE, LLP

/s/ Mary W. Bourke
Mary W. Bourke (#2356)
Dana K. Severance (#4869)
222 Delaware Avenue, Suite 1501
Wilmington, DE 19801
(302) 252-4320
(302) 252-4330 (Fax)
mbourke@wcsr.com
dseverance@wcsr.com

Attorneys for Plaintiffs

Of Counsel:

Daniel A. Ladow
James M. Bollinger
TROUTMAN SANDERS LLP
405 Lexington Avenue
New York, NY 10174
(212) 704-6000
(212) 704-5929 (Fax)
daniel.ladow@troutmansanders.com
james.bollinger@troutmansanders.com

Troy S. Kleckley
Aaron J. Rugh
TROUTMAN SANDERS LLP
600 Peachtree Street, NE
Suite 5200
Atlanta, GA 30308
(404) 885-3000
(404) 885-3900
troy.kleckley@troutmansanders.com
aaron.rugh@troutmansanders.com

Attorneys for Plaintiffs
Reckitt Benckiser Pharmaceuticals, Inc.
and RB Pharmaceuticals Limited

Of Counsel:

James F. Hibey
Timothy C. Bickham
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, NW
Washington DC 20036
(202) 429-3000
(202) 429-3902 (Fax)
jhibey@steptoe.com
tbickham@steptoe.com

Attorneys for Plaintiff
MonoSol Rx, LLC