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.,	)	
Defendant.	)	

DEFENDANT'S ANSWER TO THE FIRST AMENDED COMPLAINT; AND COUNTERCLAIMS

Defendant Watson Laboratories, by and through its undersigned attorneys, answers the First Amended Complaint of Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC as follows:

NATURE OF THE ACTION

1. Defendant admits that Plaintiffs purport to bring this action under the Food and Drug Law and Patent Laws of the United States. Defendant further admits that Watson filed an ANDA 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 '832 patent, the '150 patent, and the '514 patent. Except as expressly admitted, Defendant denies the remaining allegations of paragraph 1.

THE PARTIES

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

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

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

5. Defendant admits that Watson is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 311 Bonnie Circle, Corona, California, 92880.

JURISDICTION AND VENUE

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

7. Defendant admits that Watson is a pharmaceutical company engaged in the business of developing, manufacturing, marketing, selling and distributing generic and brand-name pharmaceutical products, some of which are distributed, marketed, and/or sold in Delaware and throughout the United States. Except as expressly admitted, Defendant denies the remaining allegations in paragraph 7.

8. Defendant states that Watson does not contest this Court's personal jurisdiction over Watson for purposes of this action only. Except as expressly admitted, Defendant denies the allegations in paragraph 8.

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

THE PATENTS-IN-SUIT

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

further admits that the face of the '832 patent lists Garry L. Myers, Samuel D. Hillbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. Defendant further admits that Exhibit A to the Plaintiffs' First Amended Complaint purports to be the '832 patent. Defendant avers that the allegation that the '832 patent was duly and legally issued states a legal conclusion to which no response is required, but if a response is required Defendant denies the allegation. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 10 and therefore denies them.

11. Defendant admits that the face of the '150 patent identifies MonoSol as the assignee. Defendant admits that the '150 patent states that it issued on September 13, 2011. Defendant admits that the '150 patent is entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom." Defendant further admits that the face of the '150 patent lists Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. Defendant further admits that Exhibit B to the Plaintiffs' First Amended Complaint purports to be a true copy of the '150 patent. Defendant avers that the allegation that the '150 patent was duly and legally issued states a legal conclusion to which no response is required, but if a response is required Defendant denies the allegation. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 11 and therefore denies them.

12. Defendant admits that the face of the '514 patent identifies MonoSol as the assignee. Defendant admits that the '514 patent states that it issued on December 10, 2013. Defendant admits that the '514 patent is entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Marking Compositions." Defendant further admits that the face of the '514 patent lists Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuiz as

inventors. Defendant further admits that Exhibit C to the Plaintiffs' First Amended Complaint purports to be a true copy of the '514 patent. Defendant avers that the allegation that the '514 patent was duly and legally issued states a legal conclusion to which no response is required, but if a response is required Defendant denies the allegation. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 12 and therefore denies them.

SUBOXONE® SUBLINGUAL FILM

13. Defendant admits that the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") entry for New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film lists "Reckitt Beckiser" as the applicant. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 13 and therefore denies them.

14. Defendant states that the Orange Book entry for NDA No. 22-410 lists the FDA approval date as August 30, 2010. Defendant states that the labeling for Suboxone® sublingual film currently states that 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. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 14 and therefore denies them.

15. Defendant admits that the '832, '150, and '514 patents are listed in the Orange Book with respect to Suboxone® sublingual film. Defendant avers that RBP caused the '832, '150, and '514 patents to be listed in the Orange Book relative to Suboxone® sublingual film by filing a declaration with the FDA, and that the FDA published the '832, '150, and '514 patent

information as a ministerial act. Except as specifically admitted, Defendant denies the remaining allegations in paragraph 15.

DEFENDANT'S ANDA

16. Defendant admits that Watson sent to Plaintiffs a letter dated August 27, 2013 (the "Watson Notification Letter"), stating that ANDA No. 204383 contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification"), and explaining the reasons that claims of 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. Defendant lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 16 and therefore denies them.

17. Defendant admits that 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 a buprenorphine hydrochloride and naloxone hydrochloride sublingual film before expiration of the patents-in-suit. Defendant admits 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 ANDA product meets FDA requirements for bioequivalence with respect to Suboxone® sublingual film. Defendant lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 17 and therefore denies them.

18. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 and therefore denies them.

19. Defendant admits that Watson sent to Plaintiffs a letter dated February 4, 2014 (the "Watson '514 Notification Letter"), stating that ANDA No. 204383 contains a Paragraph IV certification, and explaining the reasons that claims of the '514 patent are invalid, unenforceable,

and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA. Defendant lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 19 and therefore denies them.

20. Defendant admits that 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 a buprenorphine hydrochloride and naloxone hydrochloride sublingual film before expiration of the '514 patent. Defendant admits 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 ANDA product meets FDA requirements for bioequivalence with respect to Suboxone® sublingual film. Defendant lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 20 and therefore denies them.

21. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 and therefore denies them.

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

22. Defendant repeats and incorporates by reference its answers to paragraphs 1-21 of the First Amended Complaint as if fully set forth here.

23. Defendant denies the allegations contained in paragraph 23 of the First Amended Complaint.

24. Defendant admits that the filing of ANDA No. 204383 is a technical act of infringement under 35 U.S.C. § 271(e)(2) that gives rise to subject matter jurisdiction. Defendant expressly denies that Watson's proposed ANDA product infringes any valid claim of the '832 patent.

25. Defendant denies the allegations in paragraph 25 of the First Amended Complaint.

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

26. Defendant repeats and incorporates by reference its responses to paragraphs 1-25 of the First Amended Complaint as if fully set forth here.

27. Defendant denies the allegations contained in paragraph 27 of the First Amended Complaint.

28. Defendant admits that the filing of ANDA No. 204383 is a technical act of infringement under 35 U.S.C. § 271(e)(2), that gives rise to subject matter jurisdiction. Defendant expressly denies that Watson's proposed ANDA product infringes any valid claim of the '150 patent.

29. Defendant denies the allegations contained in paragraph 29 of the First Amended Complaint.

COUNT III
(Infringement of the '514 Patent Under 35 U.S.C. § 271(e)(2))

30. Defendant repeats and incorporates by reference its responses to paragraphs 1-29 of the First Amended Complaint as if fully set forth here.

31. Defendant denies the allegations contained in paragraph 31 of the First Amended Complaint.

32. Defendant admits that the filing of ANDA No. 204383 is a technical act of infringement under 35 U.S.C. § 271(e)(2), that gives rise to subject matter jurisdiction. Defendant expressly denies that Watson's proposed ANDA product infringes any valid claim of the '514 patent.

33. Defendant denies the allegations contained in paragraph 33 of the First Amended Complaint.

PLAINTIFFS' PRAYER FOR RELIEF

The remainder of Plaintiffs' First Amended Complaint recites a prayer for relief for which no response is required. To the extent that a response is required, Defendant denies that Plaintiffs are entitled to any remedy or relief, including those requested.

AFFIRMATIVE DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or the truth of any allegation in Plaintiffs' First Amended Complaint, Defendant states the following affirmative defenses:

First Affirmative Defense

The claims of the '832,'150, and '514 patents are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, 111, 112, 116, 135, 256, and 287, and/or the doctrine of obviousness-type double patenting.

Second Affirmative Defense

The manufacture, use, sale, offer for sale, or importation of the buprenorphine hydrochloride and naloxone hydrochloride sublingual film that is the subject of ANDA No. 204383 will not infringe, directly or indirectly, any valid and/or enforceable claim of the '832, '150, and/or '514 patents.

Third Affirmative Defense

The filing of ANDA No. 204383 has not infringed, and will not infringe, directly or indirectly, any valid and/or enforceable claim of the '832, '150, and/or '514 patents.

Fourth Affirmative Defense

Plaintiffs' First Amended Complaint fails to state a claim upon which relief may be granted.

Fifth Affirmative Defense

Defendant's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Affirmative Defense

Defendant has not willfully infringed any claims of the '832, '150, and '514 patents.

Seventh Affirmative Defense

The relief requested in the First Amended Complaint is barred by the doctrines of estoppel and/or waiver.

Eighth Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal.

WHEREFORE, Defendant requests that Plaintiffs' First Amended Complaint be dismissed with prejudice and that Defendant be awarded the costs of this action, its attorney's fees, and all other relief this court deems just and proper.

COUNTERCLAIMS

For its counterclaims against Plaintiffs/Counterclaim-Defendants Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC (collectively, "Counterclaim-Defendants"), Watson Laboratories, Inc. alleges as follows:

THE PARTIES

1. Watson is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 311 Bonnie Circle, Corona, California, 92880.

2. On information and belief, as stated in its First Amended Complaint against Watson, RBP is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. On information and belief, as stated in its First Amended Complaint against Watson, RBP UK is a corporation organized and existing under the laws of the United Kingdom, having a principal place of business at 103-105 Bath Road, Slough, UK.

4. On information and belief, as stated in its First Amended Complaint against Watson, MonoSol is a limited liability corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 30 Technology Drive, Warren, New Jersey.

JURISDICTION AND VENUE

5. These counterclaims arise under the Patent Act, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. To the extent that the Court has subject matter jurisdiction over Counterclaim-Defendants' claims against Watson, this Court has subject

matter jurisdiction over these counterclaims under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over RBP because, among other reasons, it subjected itself to the jurisdiction of this Court by filing the First Amended Complaint against Watson here.

7. This Court has personal jurisdiction over RBP UK because, among other reasons, it subjected itself to the jurisdiction of this Court by filing the First Amended Complaint against Watson here.

8. This Court has personal jurisdiction over MonoSol because, among other reasons, it subjected itself to the jurisdiction of this Court by filing the First Amended Complaint against Watson here.

9. To the extent that venue is appropriate for Counterclaim-Defendants' claims against Watson, venue is also appropriate in this Court for Watson's counterclaims. Venue is also proper in this judicial district under 28 U.S.C. § 1391(b) and (c).

10. There is an actual and justiciable controversy between the parties as to the infringement, validity, and enforceability of United States Patent Nos. 8,475,832 ("the '832 patent"), 8,017,150 ("the '150 patent"), and 8,603,514 ("the '514 patent").

BACKGROUND

11. Upon information and belief, as stated in its First Amended Complaint against Watson, RBP holds approved New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

12. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. FDA lists

these patents in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book").

13. The '832 patent, entitled "Sublingual and Buccal Film Compositions," states that it issued on July 2, 2013.

14. Upon information and belief, as stated in the First Amended Complaint against Watson, RBP UK claims to be the assignee of the '832 patent.

15. The '150 patent, entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom," states that it issued on September 13, 2011.

16. Upon information and belief, as stated in the First Amended Complaint against Watson, MonoSol claims to be the assignee of the '150 patent.

17. Upon information and belief, as stated in the First Amended Complaint against Watson, RBP claims to hold an exclusive license to the '150 patent.

18. The '514 patent, entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Marking Compositions," states that it issued on December 10, 2013.

19. Upon information and belief, as stated in the First Amended Complaint against Watson, MonoSol claims to be the assignee of the '514 patent.

20. Upon information and belief, as stated in the First Amended Complaint against Watson, RBP claims to hold an exclusive license to the '514 patent.

21. Upon information and belief, Counterclaim-Defendants, including MonoSol and RBP, caused the '832, '150, and '514 patents to be listed in the Orange Book as patents that claim the drug and/or claim a method of using such a drug for which RBP submitted NDA No. 22-410.

22. Watson submitted its ANDA No. 204383 to obtain FDA approval to engage in the commercial manufacture, use, and sale of buprenorphine hydrochloride and naloxone hydrochloride sublingual film ("Watson's ANDA Products") before the expiration of the '832, '150, and '514 patents.

23. Watson's ANDA No. 204383 contains "Paragraph IV" certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the claims of the '832, '150, and '514 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Watson's ANDA Products.

24. On October 8, 2013, Counterclaim-Defendants filed their Complaint against Watson alleging infringement of the '832 and '150 patents.

25. On February 18, 2014, Counterclaim-Defendants filed their First Amended Complaint against Watson alleging infringement of the '832, '150, and '514 patents.

COUNT I
(Declaratory Judgment of Non-Infringement of the '832 Patent)

26. Watson repeats and realleges the allegations in paragraphs 1-25 above as if fully set forth here.

27. The manufacture, use, sale, offer for sale and/or importation of the Watson ANDA Products will not infringe, directly or indirectly, any valid or enforceable claim of the '832 patent.

28. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale or importation of the Watson ANDA Products will infringe the '832 patent.

29. Watson is entitled to a judicial declaration that it has not infringed and does not infringe—literally or under the doctrine of equivalents, directly or indirectly, by inducement or contribution—any valid claim of the '832 patent.

COUNT II
(Declaratory Judgment of Non-Infringement of the '150 Patent)

30. Watson repeats and realleges the allegations in paragraphs 1-29 above as if fully set forth here.

31. The manufacture, use, sale, offer for sale and/or importation of the Watson ANDA Products will not infringe, directly or indirectly, any valid or enforceable claim of the '150 patent.

32. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale or importation of the Watson ANDA Products will infringe the '150 patent.

33. Watson is entitled to a judicial declaration that it has not infringed and does not infringe—literally or under the doctrine of equivalents, directly or indirectly, by inducement or contribution—any valid claim of the '150 patent.

COUNT III
(Declaratory Judgment of Non-Infringement of the '514 Patent)

34. Watson repeats and realleges the allegations in paragraphs 1-33 above as if fully set forth here.

35. The manufacture, use, sale, offer for sale and/or importation of the Watson ANDA Products will not infringe, directly or indirectly, any valid or enforceable claim of the '514 patent.

36. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale or importation of the Watson ANDA Products will infringe the '514 patent.

37. Watson is entitled to a judicial declaration that it has not infringed and does not infringe—literally or under the doctrine of equivalents, directly or indirectly, by inducement or contribution—any valid claim of the '514 patent.

COUNT IV
(Declaratory Judgment of Invalidity of the '832 Patent)

38. Watson repeats and realleges the allegations in paragraphs 1-37 above as if fully set forth here.

39. On information and belief, the claims of the '832 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, 111, 112, 116, 132, 135, 256 and 287, and/or the doctrine of obviousness-type double patenting.

40. There is an actual and justiciable controversy between the parties concerning whether the '832 patent claims are invalid.

41. Watson is entitled to a judicial declaration that the claims of the '832 patent are invalid.

COUNT V
(Declaratory Judgment of the Invalidity of the '150 Patent)

42. Watson repeats and realleges the allegations in paragraphs 1-41 above as if fully set forth here.

43. On information and belief, the claims of the '150 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without

limitation, one or more of sections 101,102, 103, 111, 112, 116, 132, 135, 256 and 287, and/or the doctrine of obviousness-type double patenting.

44. There is an actual and justiciable controversy between the parties concerning whether the '150 patent claims are invalid.

45. Watson is entitled to a judicial declaration that the asserted claims of the '150 patent are invalid.

COUNT VI
(Declaratory Judgment of the Invalidity of the '514 Patent)

46. Watson repeats and realleges the allegations in paragraphs 1-45 above as if fully set forth here.

47. On information and belief, the claims of the '514 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of sections 101,102, 103, 111, 112, 116, 132, 135, 256 and 287, and/or the doctrine of obviousness-type double patenting.

48. There is an actual and justiciable controversy between the parties concerning whether the '514 patent claims are invalid.

49. Watson is entitled to a judicial declaration that the asserted claims of the '514 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Watson prays that the Court enter judgment in its favor and against Counterclaim-Defendants as follows:

a. Dismissing the First Amended Complaint with prejudice and denying each request for relief made by Plaintiffs;

b. Declaring that the filing of ANDA No. 204383 has not infringed, does not infringe, and would not infringe any valid and enforceable claims of the '832, '150, and/or '514 patents;

c. Declaring that the manufacture, use, sale, offer for sell, and/or importation in the United States of Watson's products that are the subject of ANDA No. 204383 do not, and will not, infringe any valid and enforceable claim of the '832, '150 and/or '514 patents;

d. Declaring that the claims of the '832, '150 and/or '514 patents are invalid;

e. Awarding Watson its costs and expenses in this action;

f. Awarding Watson its attorneys' fees pursuant to 35 U.S.C. § 285; and

g. Awarding other and further relief as this Court deems just and proper.

Dated: March 4, 2014

PHILLIPS, GOLDMAN & SPENCE, P.A.

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