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. 13-2003-RGA
ALVOGEN PINE BROOK, INC.,	)	
Defendant.	)	

ANSWER AND COUNTERCLAIMS FOR DEFENDANT ALVOGEN PINE BROOK, INC.

Defendant Alvogen Pine Brook, Inc. ("Alvogen"), by and through its undersigned attorneys, hereby answers each of the numbered paragraphs of the First Amended Complaint, filed January 24, 2014 by Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK") and MonoSol Rx, LLC (individually "MonoSol") (collectively "Plaintiffs"). Except as expressly admitted below, Alvogen denies each allegation of Plaintiffs' First Amended Complaint.

NATURE OF THE ACTION

1. Alvogen admits that Plaintiffs purport to bring this action under the Food and Drug Laws and the Patent Laws of the United States. Alvogen further admits that Alvogen Pine Brook Inc. submitted ANDA No. 205954 to the Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j) to obtain approval to market buprenorphine hydrochloride and naloxone hydrochloride sublingual film ("the Alvogen product") 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"). Alvogen denies the remaining allegations in paragraph 1.

THE PARTIES

2. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 and therefore Alvogen denies same.

3. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 and therefore Alvogen denies same.

4. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 and therefore Alvogen denies same.

5. Alvogen admits the allegations in paragraph 5.

6. Alvogen admits the allegations in paragraph 6.

JURISDICTION AND VENUE

7. Alvogen does not contest that this Court has subject matter jurisdiction over this action.

8. Alvogen does not contest that this Court has personal jurisdiction over Alvogen Pine Brook Inc. for the purposes of this action. Alvogen denies the remaining allegations in paragraph 8.

9. Alvogen does not contest venue in this district for purposes of this action.

THE PATENTS-IN-SUIT

10. Alvogen admits that the '832 patent states that it issued on July 2, 2013. Alvogen admits that the '832 patent is entitled "Sublingual and Buccal Film Compositions." Alvogen admits that Garry L. Myers, Samuel D. Hillbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi,

and Madhusudan Hariharan are listed as inventors on the face of the '832 patent. Alvogen admits that Plaintiff RBP is listed as the assignee on the face of the '832 patent. Alvogen admits that a purported copy of the '832 patent is attached to the First Amended Complaint as Exhibit A. Alvogen denies that the '832 patent was duly and legally issued. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 10 of the First Amended Complaint and therefore denies them.

11. Alvogen admits that the '150 patent states that it issued on September 13, 2011. Alvogen admits that the '150 patent is entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom." Alvogen admits that Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz are listed as inventors on the face of the '150 patent. Alvogen admits that Plaintiff MonoSol is listed as the assignee on the face of the '150 patent. Alvogen admits that a purported copy of the '150 patent is attached to the First Amended Complaint as Exhibit B. Alvogen denies that the '150 patent was duly and legally issued. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 11 of the First Amended Complaint and therefore denies them.

12. Alvogen admits that the '514 patent states that it issued on December 10, 2013. Alvogen admits that the '514 patent is entitled "Uniform Films for Rapid Dissolve Dosage Forms Incorporating Taste-Masking Compositions." Alvogen admits that Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz are listed as inventors on the face of the '514 patent. Alvogen admits that Plaintiff MonoSol is listed as the assignee on the face of the '514 patent. Alvogen admits that a purported copy of the '514 patent is attached to the First Amended Complaint as Exhibit C. Alvogen denies that the '514 patent was duly and legally

issued. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 12 of the First Amended Complaint and therefore denies them.

SUBOXONE® SUBLINGUAL FILM

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

14. Alvogen admits that the Orange Book identifies August 30, 2010 as the approval date for NDA No. 22-410 directed to the 2 mg/0.5 mg and 8 mg/2 mg dosages of Suboxone sublingual film. Alvogen admits that the labeling for Suboxone® sublingual film currently states that Suboxone® sublingual film is "indicated for maintenance treatment of opioid dependence." Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 14 of the First Amended Complaint and therefore denies them.

15. Alvogen admits that the '832, '150, and '514 patents are identified in the Orange Book for Suboxone® sublingual film. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15 of the First Amended Complaint and therefore denies them.

DEFENDANT'S ANDA

16. Alvogen admits that Alvogen Pine Brook, Inc. sent letters, dated October 25, 2013, and November 21, 2013, to Plaintiffs, and that such letters stated that ANDA No. 205954 contains a Paragraph IV certification stating 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. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 16 of the First Amended Complaint and therefore denies them.

17. Alvogen admits that it submitted ANDA No. 205954 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of the Alvogen product before expiration of the patents-in-suit. Alvogen admits that ANDA No. 205954 identifies the NDA for Suboxone® sublingual film as the Reference Listed Drug. To the extent that paragraph 17 of the First Amended Complaint contains additional allegations, Alvogen denies them.

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

19. Alvogen admits that Alvogen Pine Brook, Inc. sent a letter, dated December 10, 2013, to Plaintiffs, and that such letter stated that ANDA No. 205954 contains a Paragraph IV certification stating that the '514 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 19 of the First Amended Complaint and therefore denies them.

DOCKET ALARM

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