IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. ALVOGEN PINE BROOK, INC., Defendant.	CA. No. 13-CV-2003 RGA

PLAINTIFFS' ANSWER TO DEFENDANT ALVOGEN PINE BROOK, INC.'S COUNTERCLAIMS

Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively "Plaintiffs"), herein reply to the numbered paragraphs of the Counterclaims of Defendant Alvogen Pine Brook, Inc. ("Alvogen") as alleged in Alvogen's February 4, 2014 Answer, as follows:

THE PARTIES

1. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 1 and, therefore, deny the same.

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

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

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

JURISDICTION AND VENUE

5. Paragraph 5 states a legal conclusion to which no reply is required. To the extent a reply is required, Plaintiffs admit that this Court has subject matter jurisdiction over Alvogen's Counterclaims in this action relating to 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").

6. Paragraph 6 states a legal conclusion to which no reply is required. To the extent a reply is required, RBP admits that this Court has personal jurisdiction over RBP in this action due to Plaintiffs' filing of this civil action in this judicial district against Defendant.

7. Paragraph 7 states a legal conclusion to which no reply is required. To the extent a reply is required, RBP UK admits that this Court has personal jurisdiction over RBP UK in this action due to Plaintiffs' filing of this civil action in this judicial district against Defendant.

8. Paragraph 8 states a legal conclusion to which no reply is required. To the extent a reply is required, MonoSol admits that this Court has personal jurisdiction over MonoSol in this action due to Plaintiffs' filing of this civil action in this judicial district against Defendant.

9. Paragraph 9 states a legal conclusion to which no reply is required. To the extent a reply is required, Plaintiffs admit that venue for this action is proper in this Court.

10. Paragraph 10 states a legal conclusion to which no reply is required. To the extent a reply is required, Plaintiffs aver that this action was commenced against Defendant because Defendant served Plaintiffs with what purport to be notice letters stating that Defendant's ANDA No. 205954 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (commonly, referred to as a Paragraph IV certification) alleging that the

'832, '150 and '514 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic product proposed in the ANDA. Plaintiffs take no position at this time as to whether those notice letters were timely, proper or otherwise effective to trigger the 45 day period to file suit pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and fully reserve their rights in that regard.

BACKGROUND

11. MonoSol lacks sufficient knowledge or information to admit or deny the allegations in paragraph 11 and, therefore, denies the same. RBP and RBP UK admit that RBP is the holder of New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film. RBP and RBP UK admit that, 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.

12. Plaintiffs state that, to the extent the allegations contained in paragraph 12 characterize legal requirements and a Food and Drug Administration ("FDA") publication, the requirements and publication speak for themselves. Plaintiffs deny the allegations in paragraph 12, except that they admit that the FDA publishes *Approved Drug Products with Therapeutic Equivalence Evaluations* (a.k.a., the "Orange Book").

13. Plaintiffs state that to the extent the allegations in paragraph 13 characterize the '832 patent, the patent speaks for itself. Plaintiffs deny the allegations in paragraph 13, except that they admit that the '832 patent, entitled "Sublingual and Buccal Film Compositions," was duly and legally issued on July 2, 2013.

14. MonoSol lacks sufficient knowledge or information to admit or deny the allegations in paragraph 14 and, therefore, denies the same. RBP and RBP UK state that to the extent the allegations in paragraph 14 characterize Plaintiffs' First Amended Complaint dated January 24, 2014 ("the First Amended Complaint"), the pleading speaks for itself. RBP and RBP UK deny the allegations of paragraph 14, except that they admit that RBP UK is the lawful owner of the '832 patent, and that RBP is an exclusive licensee of the '832 patent.

15. Plaintiffs state that to the extent the allegations in paragraph 15 characterize the '150 patent, the patent speaks for itself. Plaintiffs deny the allegations of paragraph 15, except that they admit that the '150 patent, entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom," was duly and legally issued on September 13, 2011.

16. RBP and RBP UK lack sufficient knowledge or information to admit or deny the allegations in paragraph 16 and, therefore, deny the same. MonoSol states that to the extent the allegations in paragraph 16 characterize the First Amended Complaint, the pleading speaks for itself. MonoSol denies the allegations in paragraph 16, except that it admits that it is the lawful owner of the '514 patent.

17. Plaintiffs state that to the extent the allegations in paragraph 17 characterize the First Amended Complaint, the pleading speaks for itself. Plaintiffs deny the allegations in paragraph 17, except that they admit that RBP is an exclusive licensee of the '514 patent.

18. Plaintiffs state that to the extent the allegations in paragraph 18 characterize the '514 patent, the patent speaks for itself. Plaintiffs deny the allegations in paragraph 18, except that they admit that the '514 patent, entitled "Uniform Films for Rapid Dissolve Dosage Forms Incorporating Taste-Masking Compositions," was duly and legally issued on December 10, 2013.

19. RBP and RBP UK lack sufficient knowledge or information to admit or deny the allegations in paragraph 19 and, therefore, deny the same. MonoSol states that to the extent the allegations in paragraph 19 characterize the First Amended Complaint, the pleading speaks for itself. MonoSol denies paragraph 19 of the complaint, except that it admits that it is the lawful owner of the '514 patent.

20. Plaintiffs state that to the extent the allegations in paragraph 20 characterize the First Amended Complaint, the pleading speaks for itself. Plaintiffs deny paragraph 20 of the complaint, except that they admit that RBP is an exclusive licensee of the '514 patent.

21. Plaintiffs deny the allegations in paragraph 21, except that they admit that the patents-in-suit are listed in the Orange Book as covering Suboxone® sublingual film.

22. Plaintiffs state that to the extent the allegations in paragraph 22 characterize Abbreviated New Drug Application ("ANDA") No. 205954, the ANDA speaks for itself. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 22 and, therefore, deny the same, except that they admit that, on information and belief, Alvogen submitted ANDA No. 205954 to the FDA seeking approval to manufacture, use, and sell a generic version of Plaintiff RBP's Suboxone® sublingual film prior to the expiration of the patents-in-suit.

23. Plaintiffs state that to the extent the allegations in paragraph 23 characterize ANDA No. 205954, the ANDA speaks for itself. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 23 and, therefore, deny the same, except that they admit that they received letters from Alvogen collectively indicating that ANDA No. 205954 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the patents-in-suit are invalid, unenforceable, and/or will not be

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.