### 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 LABORATORIES UT, INC.,	)
	)
Defendants.	)

CA. No. 13-1674-RGA

### PLAINTIFFS' ANSWER TO DEFENDANTS' 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 Defendants Watson Laboratories, Inc. ("Watson") and Actavis Laboratories UT ("Actavis") (collectively, "Defendants"), as alleged in Defendants' July 6, 2015 Answer and Counterclaims to Plaintiffs' Second Amended Complaint, 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. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 2 and, therefore, deny the same.
- 3. RBP admits that it is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.
- 4. RBP UK admits that it is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

5. 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

6. Paragraph 6 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 Defendants' counterclaims in this action relating to U.S. 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").

7. Paragraph 7 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 a civil action in this judicial district against Defendants.

8. Paragraph 8 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 a civil action in this judicial district against Defendants.

9. Paragraph 9 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 a civil action in this judicial district against Defendants.

10. Paragraph 10 states legal conclusions 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.

11. Plaintiffs admit an actual and justiciable controversy exists between the parties with respect to the patents-in-suit.

### **BACKGROUND**

12. Plaintiffs admit the allegations in paragraph 12.

13. Plaintiffs state that, to the extent the allegations contained in paragraph 13 characterize legal requirements and a Food and Drug Administration ("FDA") publication, the requirements and publication speak for themselves. Plaintiffs deny the allegations in paragraph 13, except that they admit that the FDA publishes *Approved Drug Products with Therapeutic Equivalence Evaluations* (a.k.a., the "Orange Book").

14. Plaintiffs admit that the '832 patent duly and legally issued on July 2, 2013.

15. Plaintiffs admit that RBP UK is the lawful owner of the '832 patent.

16. Plaintiffs admit that the '150 patent duly and legally issued on September 13,

2011.

17. Plaintiffs admit that MonoSol is the lawful owner of the '150 patent.

18. Plaintiffs admit that RBP is the exclusive licensee of the '150 patent.

19. Plaintiffs admit that the '514 patent duly and legally issued on December 10,

2013.

20. Plaintiffs admit that MonoSol is the lawful owner of the '514 patent.

21. Plaintiffs admit that RBP is the exclusive licensee of the '514 patent.

22. Plaintiffs deny the allegations in paragraph 22, except that they admit that the '832 patent, the '150 patent, and the '514 patent are listed in the Orange Book as covering Suboxone® sublingual film.

23. Plaintiffs lack sufficient knowledge or information to admit or deny paragraph 23 and, therefore, deny the same.

24. Plaintiffs deny the allegations in paragraph 24, except that they admit that Defendant's ANDA No. 20-4383 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '832 patent, the '150 patent, and 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.

25. Plaintiffs lack sufficient knowledge or information to admit or deny paragraph 25 and, therefore, deny the same.

26. Plaintiffs deny the allegations in paragraph 26, except that they admit that Defendant's ANDA No. 20-7087 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '832 patent, the '150 patent, and 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.

27. Plaintiffs admit the allegations in paragraph 27 except state they lack sufficient knowledge or information to admit or deny as to the current incorporation status of the Watson Laboratories, Inc. entity.

28. Plaintiffs admit the allegations in paragraph 28 except state they lack sufficient knowledge or information to admit or deny as to the current incorporation status of the Watson Laboratories, Inc. entity.

29. Plaintiffs lack sufficient knowledge or information to admit or deny paragraph 29 and, therefore, deny the same.

30. Plaintiffs admit the allegations in paragraph 30 except state they lack sufficient knowledge or information to admit or deny as to the current incorporation status of the Watson Laboratories, Inc. entity.

### <u>COUNT I</u> (Dismissal of Watson Laboratories, Inc. (Nevada))

31. Plaintiffs repeat the responses contained in paragraphs 1-30 of their Answer as if fully set forth herein.

32. Plaintiffs lack sufficient knowledge or information to admit or deny paragraph 32 and, therefore, deny the same.

33. Paragraph 33 states legal conclusions to which no reply is required. To the extent that a reply is required, Plaintiffs deny the allegations of Paragraph 33.

# (Declaratory Judgment of Non-infringement of the '832 Patent)

34. Plaintiffs repeat the responses contained in paragraphs 1-33 of their Answer as if fully set forth herein.

35. Plaintiffs deny the allegations of paragraph 35.

36. Plaintiffs admit an actual and justiciable controversy exists between the parties with respect to the '832 patent.

37. Plaintiffs deny the allegations of paragraph 37.

### <u>COUNT III</u> (Declaratory Judgment of Non-infringement of the '150 Patent)

38. Plaintiffs repeat the responses contained in paragraphs 1-37 of their Answer as if fully set forth herein.

39. Plaintiffs deny the allegations of paragraph 39.

40. Plaintiffs admit an actual and justiciable controversy exists between the parties

with respect to the '150 patent.

41. Plaintiffs deny the allegations of paragraph 41.

### <u>COUNT IV</u> (Declaratory Judgment of Non-infringement of the '514 Patent)

42. Plaintiffs repeat the responses contained in paragraphs 1-41 of their Answer as if

fully set forth herein.

43. Plaintiffs deny the allegations of paragraph 43.

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