UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NUMBER: **09-60609-CIV-DIMITROULEAS/SNOW**

RECKITT BENCKISER INC.

Plaintiff,

v.

WATSON LABORATORIES, INC. - FLORIDA and WATSON PHARMACEUTICALS, INC.

Defendants.
_____/

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Reckitt Benckiser Inc. ("Reckitt") brings this complaint against Defendant Watson Laboratories, Inc. – Florida and Watson Pharmaceuticals, Inc. ("collectively Watson") and hereby alleges as follows:

THE PARTIES

1. Plaintiff Reckitt Benckiser Inc. is a corporation incorporated and existing under the laws of the State of Delaware, having its principal place of business at 399 Interpace Parkway, Parsippany, New Jersey 07054.

2. Upon information and belief, Defendant Watson Laboratories, Inc. – Florida is a corporation incorporated under the laws of the State of Florida and having its principal place of business at 4955 Orange Drive, Davie, Florida 33314.

3. Upon information and belief, Defendant Watson Pharmaceuticals, Inc. is a corporation incorporated under the laws of the State of Nevada and having its principal place of business at 311 Bonnie Circle, Corona, California, 92880. Defendant Watson Pharmaceuticals,

Inc. develops, manufactures and markets generic pharmaceutical products through its operating subsidiary Defendant Watson Laboratories, Inc. – Florida.

4. Upon information and belief, Defendant Watson Laboratories, Inc. – Florida is a wholly-owned subsidiary of Defendant Watson Pharmaceuticals, Inc., and the two have common officers and directors.

5. Upon information and belief, Defendant Watson Pharmaceuticals, Inc. directed, authorized, participated in, assisted and cooperated with Defendant Watson Laboratories, Inc. – Florida in all of the acts complained of herein. Hereinafter Defendants Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. – Florida are collectively referred to as "Watson."

6. Upon information and belief, the acts complained of herein were done by, at the direction of, with the authorization, cooperation, participation or assistance of, or least in part for the benefit of Watson.

JURISDICTION AND VENUE

7. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Watson at least by virtue of the fact that it conducts business in the State of Florida, has availed itself of the rights and benefits of Florida law, and has engaged in substantial and continuing contacts with the State.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391 (b) and (c) and 28 U.S.C. 1400(b).

FIRST COUNT

10. Reckitt is the holder of New Drug Application ("NDA") No. 21-282 by which the United States Food and Drug Administration ("FDA") granted approval for 600 mg and 1200 mg extended release tablets including the active ingredient guaifenesin. These tablets are marketed in the United States under the tradename Mucinex®, and are indicated to help loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

11. Reckitt is also the holder of New Drug Application ("NDA") No. 21-620 by which the United States Food and Drug Administration ("FDA") granted approval for 30mg/600 mg and 60mg/1200 mg dextromethorphan HBr/guaifenesin extended release tablets. These tablets are marketed in the United States under the tradename Mucinex® DM, and are indicated to help loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

12. On April 16, 2002, U.S. Patent No. 6,372,252 ("the '252 patent") issued.

13. On October 18, 2005, U.S. Patent No. 6,955,821 ("the '821 patent") issued.

14. Reckitt is the owner of the '252 Patent. A copy of the '252 Patent is attached as Exhibit A.

15. Reckitt is the owner of the '821 Patent. A copy of the '821 Patent is attached as Exhibit B.

16. The '252 Patent and the '821 Patent cover Mucinex® and Mucinex® DM and have been listed in the FDA Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for those products.

17. Upon information and belief, Watson submitted to the FDA an Abbreviated New Drug Application ("ANDA"), filed under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of guaifenesin extended release tablets, 600mg and 1200mg, prior to the expiration of the '252 Patent and the '821 Patent. Watson's ANDA for Mucinex® has been assigned ANDA No. 91-009.

18. Upon information and belief, Watson submitted to the FDA an ANDA, filed under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of dextromethorphan HBr/guaifenesin extended release tablets, 30mg/600mg and 60mg/1200mg, prior to the expiration of the '252 Patent and the '821 Patent. Watson's ANDA for Mucinex® DM has been assigned ANDA No. 91-070.

19. Upon information and belief, Watson's ANDA No. 91-009 includes a certification with respect to the '252 Patent and '821 Patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '252 Patent and '821 Patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Watson's guaifenesin extended release tablets, 600mg and 1200mg.

20. Upon information and belief, Watson's ANDA No. 91-070 includes a certification with respect to the '252 Patent and '821 Patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '252 Patent and '821 Patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Watson's dextromethorphan HBr/guaifenesin extended release tablets, 30mg/600mg and 60mg/1200mg.

21. Upon information and belief, Watson sent notice of those certifications to Reckitt on or about March 11, 2009. Reckitt received a copy of Watson's notice letter on or about March 12, 2009.

22. Upon information and belief, the Watson products that are the subject of ANDA No. 91-009 will infringe at least one of the '252 Patent claims and at least one of the '821 Patent claims.

23. Upon information and belief, the Watson products that are the subject of ANDA No. 91-070 will infringe at least one of the '252 Patent claims and at least one of the '821 Patent claims.

24. Because Watson has submitted its ANDAs under 21 U.S.C. § 355(j), in order to obtain approval from the FDA to engage in the commercial manufacture, use or sale of a drug product claimed in the '252 Patent before its expiration, Watson has committed acts of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

25. Because Watson has submitted its ANDAs under 21 U.S.C. § 355(j), in order to obtain approval from the FDA to engage in the commercial manufacture, use or sale of a drug product claimed in the '821 Patent before its expiration, Watson has committed acts of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

26. Reckitt is entitled to relief provided by 35 U.S.C. § 271 (e)(4), including an order from this Court that the effective date of the approval of Watson's ANDAs be a date that is not earlier than the expiration date of the '252 Patent or the '821 Patent, or any later expiration of exclusivity for the '252 Patent or the '821 Patent to which Reckitt is or becomes entitled.

27. Watson's certification to the FDA that the '252 Patent was not infringed, invalid and/or unenforceable was baseless, and therefore this case is exceptional under 35 U.S.C. § 285.

28. Watson's certification to the FDA that the '821 Patent was not infringed, invalid and/or unenforceable was baseless, and therefore this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter a Judgment that:

(a) Watson infringed one or more claims of the '252 Patent by submitting the aforesaid ANDAs;

(b) Watson infringed one or more claims of the '821 Patent by submitting the aforesaid ANDAs;

(c) A permanent injunction be issued, pursuant to 35 U.S.C. § 271 (e)(4)(B), restraining and enjoining Defendant Watson, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions as claimed in the '252 Patent;

(d) A permanent injunction be issued, pursuant to 35 U.S.C. § 271 (e)(4)(B), restraining and enjoining Defendant Watson, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions as claimed in the '821 Patent;

(e) An order be issued pursuant to 35 U.S.C. § 271 (e)(4)(A) that the effective date of any approval of Watson's ANDA No. 91-009 be a date that is not earlier than the expiration of the '252 Patent or the '821 Patent, or any later expiration of exclusivity for the '252 Patent or the '821 Patent to which Plaintiff is or becomes entitled;

(f) An order be issued pursuant to 35 U.S.C. § 271 (e)(4)(A) that the effective date of any approval of Watson's ANDA No. 91-070 be a date that is not earlier than the expiration of the '252 Patent or the '821 Patent, or any later expiration of exclusivity for the '252 Patent or the '821 Patent to which Plaintiff is or becomes entitled; and

(g) Watson made a baseless certification to the FDA, which makes this case exceptional under 35 U.S.C. § 285, and Reckitt therefore is entitled to reasonable attorneys fees; and for such other and further relief as the Court may deem just and proper under the circumstances.

Dated, April 24, 2009.

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