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Therapeutics, Inc., Adams Respiratory
Operations, Inc. and Adams Respiratory Products, Inc.

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ADAMS RESPIRATORY)
THERAPEUTICS, INC., ADAMS)
RESPIRATORY OPERATIONS, INC.)
and ADAMS RESPIRATORY)
PRODUCTS, INC.)
)
Plaintiffs,)
)
v.)
)
PERRIGO COMPANY, L. PERRIGO)
COMPANY and PERRIGO RESEARCH)
AND DEVELOPMENT COMPANY,)
)
Defendants.)

Civil Action No. _____

**COMPLAINT AND
LOCAL RULE 11.2 CERTIFICATION**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Adams Respiratory Therapeutics, Inc., Adams Respiratory Operations, Inc. and Adams Respiratory Products, Inc. (collectively “Adams”), bring this complaint against Defendants Perrigo Company, L. Perrigo Company and Perrigo Research and Development Company (collectively “Perrigo”) and hereby allege as follows:

THE PARTIES

1. Plaintiff Adams Respiratory Therapeutics, Inc. is a corporation incorporated and existing under the laws of the State of Delaware, having its principal place of business at 4 Mill Ridge Lane, Chester, New Jersey 07930.

2. Plaintiff Adams Respiratory Operations, Inc. is a corporation incorporated and existing under the laws of the State of Delaware, having its principal place of business at 14841 Sovereign Road, Fort Worth, Texas 76155.

3. Plaintiff Adams Respiratory Products, Inc. is a corporation incorporated and existing under the laws of the State of Delaware, having its principal place of business at 4 Mill Ridge Lane, Chester, New Jersey 07930.

4. On April 16, 2002, U.S. Patent No. 6,372,252 (“the ‘252 Patent”) issued.

5. The ‘252 patent was assigned to Plaintiff Adams Respiratory Operations, Inc., which is a wholly-owned subsidiary of Plaintiff Adams Respiratory Therapeutics, Inc. Plaintiff Adams Respiratory Products, Inc. is the exclusive licensee under the ‘252 patent. Plaintiffs are collectively referred to as “Adams.”

6. Upon information and belief, Defendant Perrigo Company is a corporation incorporated under the laws of the State of Michigan and having its principal place of business as 515 Eastern Avenue, Allegan, Michigan, 49010.

7. Upon information and belief, Defendant Perrigo Company is registered to conduct business and does business in the State of New Jersey, and owns a place of business at 71 Suttons Lane, Piscataway, New Jersey, 08854.

8. Upon information and belief, Defendant L. Perrigo Company is a company incorporated under the laws of the State of Michigan, having a principal place of business at 900 Brooks Avenue, Holland, Michigan 49423.

9. Upon information and belief, Defendant Perrigo Research and Development Company is a corporation incorporated under the laws of the State of Michigan, having its principal places of business at 515 Eastern Avenue, Allegan, Michigan, 49010.

10. 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 Perrigo Company, L. Perrigo Company and Perrigo Research and Development.

11. Defendants are collectively referred to as "Perrigo."

JURISDICTION AND VENUE

12. 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).

13. This Court has personal jurisdiction over Perrigo Company, L. Perrigo Company and Perrigo Research and Development at least by virtue of the fact that they conduct business in the State of New Jersey, have availed themselves of the rights and benefits of New Jersey law, have engaged in substantial and continuing contacts with the State, and/or because

one or more are a wholly-owned subsidiary of Perrigo Company, having common officers and directors, and operating as a single-entity.

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

FIRST COUNT

15. Adams 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.

16. Adams is the owner of the ’252 Patent, which was lawfully granted on April 16, 2002. A copy of the ’252 Patent is attached as Exhibit A.

17. The ’252 Patent covers Mucinex® and has been listed in the FDA Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for that product.

18. Upon information and belief, Perrigo 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 prior to the expiration of the ’252 Patent. Perrigo’s ANDA has been assigned ANDA No. 78-912.

19. Upon information and belief, Perrigo’s ANDA No. 78-912 includes a certification with respect to the ’252 Patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the

Federal Food, Drug and Cosmetic Act that the '252 Patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Perrigo's guaifenesin product.

20. Upon information and belief, Perrigo sent a notice of that certification to Adams on or about August 17, 2007. Adams received a copy of Perrigo's notice letter on or about August 20, 2007.

21. Upon information and belief, the Perrigo product that is the subject of ANDA No. 78-912 will infringe at least one of the '252 Patent claims.

22. Because Perrigo has submitted an ANDA 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, Perrigo has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

23. Adams 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 Perrigo's ANDA be a date that is not earlier than the expiration date of the '252 Patent, or any later expiration of exclusivity for the '252 Patent to which Adams is or becomes entitled.

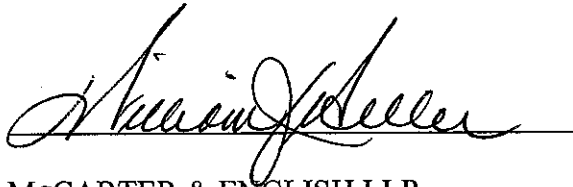
24. Perrigo's certification to the FDA that the '252 Patent was not infringed, invalid and/or unenforceable was baseless, and therefore this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

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

- (a) Perrigo infringed one or more claims of the '252 Patent by submitting the aforesaid ANDA;
- (b) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants Perrigo Company, L. Perrigo Company and Perrigo Research and Development Company, 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;
- (c) An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Perrigo's ANDA No. 78-912 be a date that is not earlier than the expiration of the '252 Patent, or any later expiration of exclusivity for the '252 Patent to which Plaintiff is or becomes entitled; and
- (d) To the extent Perrigo committed any acts with respect to the compositions claimed in the '252 Patent, other than those expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiff be awarded damages for such acts;
- (e) Perrigo made a baseless certification to the FDA, which makes this case exceptional under 35 U.S.C. § 285, and Adams therefore is entitled to reasonable attorneys fees; and
- (f) For such other and further relief as the Court may deem just and proper under the circumstances.

Dated: September 27, 2007



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