

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

CUMBERLAND PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	No.
v.	)	
	)	
PERRIGO COMPANY,	)	
	)	
Defendant.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, Cumberland Pharmaceuticals Inc. (hereinafter “Cumberland”), brings this Complaint for patent infringement against Defendant, Perrigo Company (“Perrigo”). This action concerns a patent related to Cumberland’s product Acetadote®, an intravenous formulation of N-acetylcysteine, widely used to treat suspected acetaminophen overdose to prevent or lessen hepatic injury.

**Parties**

1. Plaintiff Cumberland is a Tennessee corporation having its corporate offices and principal place of business at 2525 West End Avenue, Suite 950, Nashville, TN 37203. Cumberland is engaged in the business of development, manufacture, and sale of pharmaceutical products.

2. Defendant Perrigo is a Michigan corporation having its corporate offices and a principal place of business at 515 Eastern Avenue, Allergan MI 49010. Upon information and belief Perrigo is a global healthcare supplier that develops, manufactures, and distributes over-the-counter and generic prescription pharmaceuticals, nutritional products, active pharmaceutical

ingredients, and pharmaceutical and medical diagnostic products throughout the United States, including substantial sales in the State of Illinois.

**Jurisdiction and Venue**

3. This is a complaint for patent infringement and for declaratory judgment of patent infringement. The jurisdiction of this Court is properly founded under 28 U.S.C. §§ 1331 and 1338(a) as well as 28 U.S.C. §§ 2201 and 2202.

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

5. On information and belief, Perrigo filed its Abbreviated New Drug Application (“ANDA”) for the infringing product and issued a certification under 21 U.S.C. § 355(j)(2)(B)(ii)—the acts which give rise to the instant litigation—with knowledge that Cumberland would be injured by such actions in Illinois.

6. On information and belief, Perrigo manufactures, sells, offers for sale, and causes to be supplied or sold throughout the United States, including within Illinois, various products, including prescription and over-the-counter pharmaceuticals and nutritional products.

7. On information and belief, Perrigo derives substantial revenue from the sales of those products in Illinois.

8. On information and belief, Perrigo holds a current and valid “Drug Distributor” license from the Illinois Department of Financial and Professional Regulation.

9. Perrigo is subject to personal jurisdiction in this District, as Perrigo has engaged in substantial and/or continuous and systematic contacts with the State of Illinois, which satisfy due process and confer personal jurisdiction over this Defendant.

**Claim for Relief**

10. Cumberland is the owner of U.S. Patent No. 8,148,356 (“the ’356 patent”), entitled “Acetylcysteine Composition and Uses Therefor” (attached as Exhibit A), which was duly and legally issued by the United States Patent and Trademark Office on April 3, 2012.

11. A commercial embodiment of the patent-in-suit is a formulation of acetylcysteine currently sold by Cumberland under the trademark Acetadote® pursuant to New Drug Application (“NDA”) No. 021539. Cumberland is the holder of NDA No. 021539 for Acetadote®, for which The Food and Drug Administration (“FDA”) “Orange Book” lists the ’356 patent.

12. Acetadote® is an intravenous formulation of N-acetylcysteine. Acetadote® is currently used in hospital emergency departments to prevent or lessen potential liver damage resulting from suspected overdose of acetaminophen. Acetaminophen overdose continues to be the leading cause of poisonings reported by hospital emergency rooms in the United States, and Acetadote® has become a standard of care for treating this potentially life-threatening condition.

13. On information and belief, Perrigo filed Abbreviated New Drug Application (“ANDA”) No. 204191 with the FDA seeking approval to market a generic Acetadote® formulation, with a certification under 21 U.S.C. § 355(j)(2)(B)(i) and (ii) (“Paragraph IV” Certification) that the ’356 patent is invalid, unenforceable, and/or not infringed.

**The Infringing Conduct by Defendants**

**Count I - Patent Infringement of the '356 Patent**

14. Cumberland realleges and incorporates by reference paragraphs 1-13.

15. By submitting its ANDA and Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, or importation of its acetylcysteine formulation before the expiration of the '356 patent, Perrigo has infringed the '356 patent under 35 U.S.C. § 271(e)(2).

16. Perrigo has knowledge of the '356 patent, and Perrigo's actions constitute knowing and willful infringement of the valid '356 patent.

17. As a result of Perrigo's infringement of the '356 patent, Cumberland has been and will continue to be damaged unless said infringement is enjoined by this Court. Cumberland presently has no adequate remedy of law.

**Count II - Declaratory Judgment of Infringement of the '356 Patent**

18. Cumberland realleges and incorporates by reference paragraphs 1-17.

19. Perrigo has filed or caused to be filed an application with the FDA, seeking authorization to import, market, use, and sell its proposed acetylcysteine formulation for one or more indications before the expiration of the '356 patent. Perrigo had knowledge of the '356 patent at least as of the date of its Paragraph IV Certification.

20. On information and belief, Perrigo is expecting approval of its ANDA.

21. On information and belief, Perrigo plans to begin marketing, selling, and offering to sell its acetylcysteine formulation drug product soon after FDA approval.

22. Such conduct will constitute infringement of one or more claims of the '356 patent under 35 U.S.C. § 271(a), and will induce infringement of the '356 patent under 35 U.S.C. § 271(b).

23. Perrigo's infringing activity complained of herein is imminent and will begin following FDA approval of its ANDA application.

24. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Cumberland on the one hand and Perrigo on the other as to liability for the infringement of the '356 patent. Perrigo's actions constitute a knowing and willful infringement of the '356 patent. Perrigo's actions have created in Cumberland's mind a reasonable apprehension of irreparable harm and loss resulting from Perrigo's threatened imminent actions.

### **Relief Requested**

Wherefore, Cumberland prays for judgment and relief including:

- (A) A declaration that United States Patent No. 8,148,356 is valid and enforceable;
- (B) A declaration that Perrigo's submission of ANDA No. 204191 constitutes an act of infringement of the '356 patent under § 271(e)(2);
- (C) A declaration that Perrigo will infringe one or more claims of the '356 patent by importing, using, offering to sell, and selling of its acetylcysteine formulation drug product prior to expiration of the '356 patent;
- (D) A declaration that the effective date of any approval of Perrigo's acetylcysteine formulation drug product is not to be earlier than the expiration of the '356 patent under 35 U.S.C. § 271(e)(4)(A);
- (E) A declaration that Perrigo has no legal or equitable defense to Cumberland's allegations of infringement.
- (F) A preliminary and permanent injunction pursuant to 35 U.S.C. § 283, enjoining Perrigo and its officers, agents, servants, employees, privies, and others acting

for, on behalf of, or in concert with any of them from infringing any claims of the '356 patent under 35 U.S.C. § 271(e)(4)(B).

- (G) An accounting and award of damages incurred by Cumberland as a result of Perrigo's infringement if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States under 35 U.S.C. § 271(e)(4)(C).
- (H) An award declaring this case exceptional pursuant to 35 U.S.C. § 285 and granting Cumberland its attorneys' fees in pursuing this case and reasonable costs and expenses incurred in this case; and
- (I) Such further and other relief as this Court may deem just and proper.

Date: August 9, 2012

/s/ Lynn H. Murray

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