

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

CUMBERLAND PHARMACEUTICALS INC.,)	
)	
Plaintiff,)	No. 1:12-cv-03846
)	
v.)	JUDGE REBECCA PALLMEYER
)	
MYLAN INSTITUTIONAL LLC, AND)	MAGISTRATE JUDGE MARIA VALDEZ
MYLAN INC.,)	
)	
Defendants.)	
)	

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

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

Parties

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

2. On information and belief Mylan Institutional LLC is a Delaware corporation having its corporate offices and a place of business at 4901 Hiawatha Drive, Rockford, IL 61103. On information and belief, Mylan is engaged in the development, manufacture, marketing, and distribution of generic pharmaceutical products for sale throughout the United States.

3. On information and belief, Mylan Inc. is the parent company of Mylan Institutional LLC. Mylan Inc. is a Pennsylvania corporation having corporate offices and a principal place of business at 1500 Corporate Drive, Canonsburg, PA, 15317. Upon information and belief, Mylan Inc. is a large and diverse generic drug manufacturing and sales company that distributes and sells its products throughout the United States, including substantial sales in the State of Illinois.

Jurisdiction and Venue

4. 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.

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

6. Mylan Institutional LLC resides in this district.

7. Mylan Inc. distributes and sells its products throughout the United States, including substantial sales in the State of Illinois and the Northern District of Illinois. Mylan Inc.'s wholly owned subsidiary and agent, Mylan Institutional LLC, 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. On information and belief, Mylan Inc. and Mylan Institutional LLC will market and distribute the infringing product if approved by the FDA in this district.

8. On information and belief, Mylan has maintained continuous and systematic contacts with Illinois and has purposefully availed itself of the privileges of doing business under the laws of Illinois. Thus, Mylan is subject to personal jurisdiction in this judicial district.

Claim for Relief

9. 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), a valid patent, duly and legally issued on April 3, 2012. Cumberland is also the owner of U.S. Patent No. 8,399,445 (“the ’445 patent”), entitled “Acetylcysteine Composition and Uses Therefor” (attached as Exhibit B), a valid patent, duly and legally issued on March 19, 2013. The ’445 patent is a divisional of the ’356 patent.

10. Commercial embodiments encompassed by the patents-in-suit are a formulation of acetylcysteine and method of using an acetylcysteine formulation currently sold by Cumberland pursuant to New Drug Application (“NDA”) No. 021539 under the trademark Acetadote®. Cumberland is the holder of NDA No. 021539 for Acetadote®.

11. 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.

12. On information and belief, Mylan filed Abbreviated New Drug Application (“ANDA”) No. 203624 with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic Acetadote® formulation, which contains 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

13. Cumberland realleges and incorporates by reference paragraphs 1-12.

14. By submitting its ANDA and Paragraph IV Certification under § 505(j) of the Federal Food, Drug, and Cosmetic Act 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, Mylan has infringed one or more claims of the '356 patent under 35 U.S.C. § 271(e)(2).

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

16. As a result of Mylan'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 - Patent Infringement of the '445 Patent

17. Cumberland realleges and incorporates by reference paragraphs 1-16.

18. By submitting its ANDA 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 '445 patent, Mylan has infringed one or more claims of the '445 patent under 35 U.S.C. § 271(e)(2).

19. Mylan has knowledge of the '445 patent, and Mylan's actions constitute knowing and willful infringement of the valid '445 patent.

20. As a result of Mylan's infringement of the '445 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.

Relief Requested

Wherefore, Cumberland prays for judgment and relief including:

- (A) A declaration that United States Patent Nos. 8,148,356 and 8,399,445 are valid and enforceable;
- (B) A declaration that Mylan's submission of ANDA No. 203624 constitutes an act of infringement of one or more claims of the '356 and '445 patents under § 271(e)(2);
- (C) A declaration that Mylan will infringe one or more claims of the '356 and '445 patents by importing, using, offering to sell, and selling of its acetylcysteine formulation drug product prior to expiration of the '356 and '445 patents;
- (D) A declaration that the effective date of any approval of Mylan's acetylcysteine formulation drug product is not to be earlier than the expiration of the '356 and '445 patents under 35 U.S.C. § 271(e)(4)(A);
- (E) A declaration that Mylan 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 Mylan 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 and/or '445 patents under 35 U.S.C. § 271(e)(4)(B).

- (G) An accounting and award of damages incurred by Cumberland as a result of Mylan'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: May 7, 2013

/s/ Lynn H. Murray

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CERTIFICATE OF SERVICE

The undersigned certifies that on May 7, 2013, a true and correct copy of the foregoing **AMENDED COMPLAINT FOR PATENT INFRINGEMENT** was filed with the Clerk of the Court using the Electronic Case Filing (ECF) system, which will send notification of such filing via electronic mail to the following counsel of record:

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