

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MEDICIS PHARMACEUTICAL	)	
CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
NYCOMED U.S. INC. and NYCOMED	)	
GMBH,	)	
	)	
Defendants.	)	

**COMPLAINT**

Plaintiff Medicis Pharmaceutical Corporation (“Medicis”), for its Complaint against Defendants Nycomed U.S. Inc. (“Nycomed U.S.”) and Nycomed GmbH (collectively, “Nycomed”), alleges as follows:

**PARTIES**

1. Plaintiff Medicis is a corporation organized and existing under the laws of the State of Delaware having a place of business at 7720 North Dobson Road, Scottsdale, Arizona 85256. Medicis is the leading independent specialty pharmaceutical company in the United States, focusing primarily on the treatment of dermatological and podiatric conditions and aesthetics medicine. Medicis has developed and commercialized leading brand name prescription drug products in numerous therapeutic categories. Because of their clinical effectiveness and high quality, Medicis’ products have earned wide acceptance by both physicians and patients.

2. Upon information and belief, Defendant Nycomed U.S., formerly known as Altana, Inc., is a corporation organized and existing under the laws of the State of New York having a place of business at 60 Baylis Road, Melville, New York 11747.

3. Upon information and belief, Defendant Nycomed GmbH is a corporation organized and existing under the laws of Germany having a place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

4. Upon information and belief, Nycomed U.S. is a wholly-owned subsidiary of Nycomed GmbH.

5. Upon information and belief, Nycomed GmbH conducts operations through international subsidiaries, including Nycomed U.S.

6. Upon information and belief, Nycomed U.S. acts under the direction, control, and influence of Nycomed GmbH, including with respect to the acts and conduct alleged in this Complaint.

#### **JURISDICTION AND VENUE**

7. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202.

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§1331 and 1338(a).

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§1391(b) and (c) and 1400(b).

10. This Court has personal jurisdiction over Nycomed U.S. and Nycomed GmbH by virtue of, *inter alia*, their transaction of business and derivation of substantial revenue from services or things used or consumed in this judicial district, their substantial and continuous contacts with this judicial district, and their purposeful availment of the rights and benefits of Delaware law. Upon information and belief, Nycomed U.S. and Nycomed GmbH engage in the

marketing, sale, and distribution of pharmaceutical products within the United States generally and the State of Delaware specifically.

### **BACKGROUND**

11. On July 20, 2004, the United States Patent and Trademark Office (“PTO”) duly and legally issued United States Patent No. 6,765,001 (“the ‘001 patent”), entitled “Compositions And Methods For Enhancing Corticosteroid Delivery,” to Medicis as the assignee of the inventors named therein. Medicis is the owner of all right, title, and interest in and to the ‘001 patent, including the right to sue and recover for infringement thereof. A copy of the ‘001 patent is attached hereto as Exhibit A.

12. On May 22, 2007, the PTO duly and legally issued United States Patent No. 7,220,424 (“the ‘424 patent”), entitled “Compositions And Methods For Enhancing Corticosteroid Delivery,” to Medicis as the assignee of the inventors named therein. Medicis is the owner of all right, title, and interest in and to the ‘424 patent, including the right to sue and recover for infringement thereof. A copy of the ‘424 patent is attached hereto as Exhibit B.

13. On May 15, 2007, the PTO duly and legally issued United States Patent No. 7,217,422 (“the ‘422 patent”), entitled “Compositions And Methods For Enhancing Corticosteroid Delivery,” to Medicis as the assignee of the inventors named therein. Medicis is the owner of all right, title, and interest in and to the ‘422 patent, including the right to sue and recover for infringement thereof. A copy of the ‘422 patent is attached hereto as Exhibit C.

14. Medicis is the holder of New Drug Application (“NDA”) No. 21-758 approved by the United States Food and Drug Administration (“FDA”) for Vanos<sup>®</sup> (fluocinonide) 0.1% cream. The ‘001 and ‘424 patents are listed in the entry for Vanos<sup>®</sup>

(fluocinonide) 0.1% cream in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

15. Medicis' Vanos<sup>®</sup> drug product is extremely successful and widely used in the United States, including this judicial district, and throughout the world to treat psoriasis, atopic dermatitis, and corticosteroid responsive dermatoses.

16. Pursuant to 21 U.S.C. §355(j), Nycomed filed Abbreviated New Drug Application ("ANDA") No. 20-735 seeking FDA approval to engage in the commercial manufacture, use, or sale of fluocinonide cream, 0.1%, before expiration of the '001, '424, and '422 patents. Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Nycomed included in ANDA No. 20-735 a certification ("the Paragraph IV Certification") alleging that the '001 and '424 patents will not be infringed by the commercial manufacture, use, or sale of Nycomed's fluocinonide cream, 0.1%.

17. On or about April 7, 2010, Medicis received a letter ("the Notice Letter") from Nycomed notifying Medicis of the filing of ANDA No. 20-735 and purporting to provide information pursuant to 21 U.S.C. §355(j)(2)(B).

**COUNT I**  
**INFRINGEMENT OF THE '001 PATENT**

18. Medicis incorporates by reference the averments of Paragraphs 1-17 as if fully set forth herein.

19. Pursuant to 35 U.S.C. §271(e)(2)(A), Nycomed's submission of ANDA 20-735 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of Nycomed's fluocinonide cream, 0.1%, was an act of infringement of the '001 patent.

20. Upon information and belief, Nycomed intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into

the United States, of Nycomed's fluocinonide cream, 0.1%, upon receipt of final FDA approval of ANDA No. 20-735.

21. Pursuant to 35 U.S.C. §§271(a), (b), and/or (c), Nycomed's commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States, of Nycomed's fluocinonide cream, 0.1%, will constitute infringement of the '001 patent.

22. Unless Nycomed is enjoined by the Court, Medicis will be substantially and irreparably harmed by Nycomed's infringement of the '001 patent. Medicis has no adequate remedy at law.

23. Nycomed was aware of the '001 patent but nevertheless infringed and is continuing to infringe that patent by seeking FDA approval to engage in the commercial manufacture, use, or sale of Nycomed's fluocinonide cream, 0.1%.

**COUNT II**  
**INFRINGEMENT OF THE '424 PATENT**

24. Medicis incorporates by reference the averments of Paragraphs 1-23 as if fully set forth herein.

25. Pursuant to 35 U.S.C. §271(e)(2)(A), Nycomed's submission of ANDA 20-735 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of Nycomed's fluocinonide cream, 0.1%, was an act of infringement of the '424 patent.

26. Upon information and belief, Nycomed intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States, of Nycomed's fluocinonide cream, 0.1%, upon receipt of final FDA approval of ANDA No. 20-735.

27. Pursuant to 35 U.S.C. §§271(a), (b), and/or (c), Nycomed's commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States, of Nycomed's fluocinonide cream, 0.1%, will constitute infringement of the '424 patent.

28. Unless Nycomed is enjoined by the Court, Medicis will be substantially and irreparably harmed by Nycomed's infringement of the '424 patent. Medicis has no adequate remedy at law.

29. Nycomed was aware of the '424 patent but nevertheless infringed and is continuing to infringe that patent by seeking FDA approval to engage in the commercial manufacture, use, or sale of Nycomed's fluocinonide cream, 0.1%.

**COUNT III**  
**INFRINGEMENT OF THE '422 PATENT**

30. Medicis incorporates by reference the averments of Paragraphs 1-29 as if fully set forth herein.

31. Pursuant to 35 U.S.C. §271(e)(2)(A), Nycomed's submission of ANDA 20-735 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of Nycomed's fluocinonide cream, 0.1%, was an act of infringement of the '422 patent.

32. Upon information and belief, Nycomed intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States, of Nycomed's fluocinonide cream, 0.1%, upon receipt of final FDA approval of ANDA No. 20-735.

33. Pursuant to 35 U.S.C. §§271(a), (b), and/or (c), Nycomed's commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States, of Nycomed's fluocinonide cream, 0.1%, will constitute infringement of the '422 patent.

34. Unless Nycomed is enjoined by the Court, Medicis will be substantially and irreparably harmed by Nycomed's infringement of the '422 patent. Medicis has no adequate remedy at law.

35. Upon information and belief, Nycomed was aware of the '422 patent but nevertheless infringed and is continuing to infringe those patents by seeking FDA approval to engage in the commercial manufacture, use, or sale of Nycomed's fluocinonide cream, 0.1%.

**PRAYER FOR RELIEF**

WHEREFORE, Medicis respectfully requests that judgment be entered:

A. Declaring that Nycomed has infringed one or more claims of the '001, '424, and '422 patents;

B. Declaring that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States, of Nycomed's fluocinonide cream, 0.1%, will infringe one or more claims of the '001, '424, and '422 patents;

C. Ordering that the effective date of any approval of ANDA 20-735 shall not be earlier than the latest expiration date of the '001, '424, and '422 patents, including any extensions;

D. Preliminarily and permanently enjoining Nycomed, its officers, agents, servants, and employees, all other persons acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States, of Nycomed's fluocinonide cream, 0.1%;

E. In the event that Nycomed engages in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States, of

Nycomed's fluocinonide cream, 0.1%, awarding Medicis damages to the full extent provided by 35 U.S.C. §§271(e)(4)(C) and 284;

F. Declaring that this is an exceptional case entitling Medicis to an award of its reasonable attorneys' fees, costs, and expenses as provided in 35 U.S.C. §285; and

G. Granting such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Karen Jacobs Louden*

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May 19, 2010