

William J. Heller  
McCARTER & ENGLISH, LLP  
Four Gateway Center  
100 Mulberry Street  
Newark, New Jersey 07102  
(973) 622-4444

OF COUNSEL:  
Bruce M. Wexler  
Joseph M. O'Malley, Jr.  
Eric W. Dittmann  
Angela C. Ni  
PAUL, HASTINGS, JANOFSKY & WALKER LLP  
75 East 55th Street  
New York, NY 10022  
(212) 318-6000

*Attorneys for Plaintiffs,  
Boehringer Ingelheim International GmbH  
and Boehringer Ingelheim Pharmaceuticals, Inc.*

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

BOEHRINGER INGELHEIM  
INTERNATIONAL GMBH and  
BOEHRINGER INGELHEIM  
PHARMACEUTICALS, INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC. and  
MYLAN INC.,

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively, “Boehringer”), by their undersigned attorneys, bring this action against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, “Mylan”) and hereby allege as follows:

**THE PARTIES**

1. Plaintiff Boehringer Ingelheim International GmbH (“BII”) is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

2. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

3. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

4. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

5. Upon information and belief, Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan, Inc.

6. Upon information and belief, the acts of Mylan Pharmaceuticals Inc. were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of and at least in part for the benefit of Mylan Inc.

**JURISDICTION AND VENUE**

7. This action arises under the patent laws of the United States of America. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

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

9. Mylan is subject to the jurisdiction of this Court based upon, *inter alia*, its presence in, and continuous and systematic contacts with, this District. Upon information and belief, Mylan Pharmaceuticals Inc. is registered to do business in New Jersey, has appointed a registered agent in New Jersey for the receipt of service of process, has registered its generic drugs in the *New Jersey Generic Formulary* of the New Jersey Department of Health and Senior Services, and sells a substantial volume of such drugs and otherwise transacts business within this District. Mylan has also on numerous occasions submitted to this Court's jurisdiction by virtue of its presence in, and continuous and systematic contacts with, New Jersey and filed counterclaims in this Court seeking declaratory judgments of patent noninfringement and invalidity.

**CLAIM FOR RELIEF**

10. Boehringer is the holder of New Drug Application ("NDA") No. 20-667, by which the United States Food and Drug Administration ("FDA") first granted approval for a pharmaceutical composition containing pramipexole dihydrochloride. The pramipexole dihydrochloride composition described in Boehringer's NDA is used for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Boehringer sells pramipexole dihydrochloride tablets in the United States under the tradename "MIRAPEX®."

11. BII owns United States Patent No. 4,886,812 ("the '812 patent"), which was duly and legally issued on December 12, 1989, and is titled "Tetrahydro-Benzthiazoles, the

Preparation Thereof and Their Use as Intermediate Products or as Pharmaceuticals.” BIPI has a license under the ’812 patent in the United States from BII.

12. A copy of the ’812 patent is attached as Exhibit A.

13. Upon information and belief, Mylan filed with the FDA Abbreviated New Drug Application (“ANDA”) No. 90-764, which included a certification with respect to the ’812 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to commercially manufacture, use, and sell 0.75 mg pramipexole dihydrochloride tablets (“the ANDA product”) prior to the expiration of that patent.

14. On or about December 15, 2008, Mylan sent a letter (“Notice Letter”) to Boehringer in which Mylan represented that it had filed an ANDA for the ANDA product, including the certification with respect to the ’812 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

15. Because Mylan seeks approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug claimed in the ’812 patent before its expiration, Mylan has infringed the ’812 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

16. The ANDA product is within the literal scope of at least claims 1-5, 7, 9, and 10 of the ’812 patent. Mylan has no defense to Boehringer’s claim of patent infringement as to claims 1-5, 7, 9, and 10 of the ’812 patent other than an assertion of nonstatutory double patenting.

17. On Sept. 18, 2008, the United States District Court for the District of Delaware entered judgment that claims 3-5, 7, 9, and 10 of the ’812 patent are invalid for nonstatutory double patenting. Boehringer has timely appealed from that judgment, and the appeal is presently pending. (*See* Exhibit B.) In doing so, Boehringer has presented substantial

arguments that the Delaware district court's judgment is in error. Because the Delaware court judgment is in error, Boehringer has sought reversal by the United States Court of Appeals for the Federal Circuit. (*See* Exhibit C.)

18. Boehringer is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Mylan's ANDA be a date that is not earlier than the expiration of the patent term extension granted by the United States Patent and Trademark Office pursuant to 35 U.S.C. § 156 on October 13, 1999, or any later expiration of exclusivity for the '812 patent to which Boehringer is or becomes entitled.

**PRAYER FOR RELIEF**

19. Plaintiffs request that:

a. Judgment be entered that Defendants have infringed the '812 patent by submitting the aforementioned ANDA;

b. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining said Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the drugs or methods of administering drugs claimed in the '812 patent;

c. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 90-764 be a date that is not earlier than the expiration of the patent term extension granted by the United States Patent and Trademark Office pursuant to 35 U.S.C. § 156 on October 13, 1999, or any later expiration of exclusivity for the '812 patent to which Plaintiffs are or become entitled; and

d. For such other and further relief as the Court may deem just and proper under the circumstances.

Dated: January 26, 2009

By: /s William J. Heller

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McCARTER & ENGLISH, LLP  
Four Gateway Center  
100 Mulberry Street  
Newark, New Jersey 07102  
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