David E. De Lorenzi
Carrie A. Longstaff
GIBBONS, P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Telephone: (973) 596-4500
Facsimile: (973) 596-0545

Josh A. Krevitt
Charles J. Boudreau
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue, 48th Floor
New York, New York 10166-0193
Telephone: (212) 351-4000
Facsimile: (212) 351-4035

Wayne M. Barsky
Michael A. Sitzman
GIBSON, DUNN & CRUTCHER LLP
2029 Century Park East
Los Angeles, California 90067-4276
Telephone: (310) 557-8183
Facsimile: (310) 552-7010

Attorneys For Plaintiffs
Novo Nordisk, Inc. and Novo Nordisk A/S

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK INC. and NOVO NORDISK A/S, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	Civil Action No. 3:09-CV-02445-FLW-DEA **PLAINTIFFS' FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their attorneys Gibson, Dunn & Crutcher LLP and Gibbons P.C., for their First Amended Complaint against defendant Mylan Pharmaceuticals Inc. ("Mylan"), hereby allege as follows:

Nature Of The Action

1. This is a civil action for the infringement of United States Patent No. 6,677,358 pursuant to the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

The Parties

2. Plaintiff Novo Nordisk Inc. is a Delaware corporation, and has its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

3. Plaintiff Novo Nordisk A/S is a corporation organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark.

4. Upon information and belief, defendant Mylan is a corporation organized and existing under the laws of the state of West Virginia, and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

5. Upon information and belief, defendant Mylan is registered to do business in New Jersey and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628 as its registered agent in New Jersey for the receipt of service of process.

Jurisdiction And Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and 35 U.S.C. § 271(e)(2).

7. This Court has personal jurisdiction over Mylan by virtue of, *inter alia*, Mylan's continuous and systematic contacts with New Jersey, its sale of prescription drugs in New Jersey, its registration of prescription drug products in the *New Jersey Generic Formulary* of the New Jersey Department of Health and Senior Services, its consent to being sued in New Jersey, as evidenced by its registration to do business in New Jersey and its appointment of a registered agent in New Jersey, and its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

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

General Background

9. Type 2 diabetes mellitus, also known as non-insulin dependent diabetes mellitus ("NIDDM"), is the most common form of diabetes, and affects millions of children and adults throughout the world. It is a chronic disorder characterized by hyperglycemia—elevated blood glucose levels in the body—typically as a result of insufficient insulin production in the pancreas, excessive glucose production in the liver, or a resistance to the effects of insulin at the cellular level. Hyperglycemia inhibits the normal functioning of the body's cells, and if left uncontrolled, can severely damage the kidneys, eyes, nervous system, heart, and blood vessels. Type 2 diabetes is among the leading causes of death in the United States.

10. Founded in 1923, Novo Nordisk has pioneered many key breakthroughs in diabetes treatment, and spends well in excess of $1 billion annually on research and development in the field of diabetes care. Up until the mid-1990s, type 2 diabetic patients were generally treated with monotherapy, *i.e.,* treatment with a single oral antidiabetic drug ("OAD"). At the

time, combination therapy—the treatment of diabetes with two or more OAD's—was not the standard of care and was, in fact, quite rare.

11. Following a clinical trial in Australia in 1996 that produced unexpected and surprising results, Novo Nordisk pursued patent protection in 1997 relating to an important breakthrough in the treatment of type 2 diabetes: combination therapy with repaglinide and metformin. On January 13, 2004, United States Patent No. 6,677,358, entitled "NIDDM Regimen" (the "'358 patent") was duly and legally issued by the United States Patent and Trademark Office to Novo Nordisk A/S as assignee. Novo Nordisk A/S has at all times been, and continues to be, the sole owner of the '358 patent. A copy of the '358 patent is attached hereto and incorporated herein by reference as Exhibit A.

12. In June 1997, Novo Nordisk filed a New Drug Application ("NDA") with the Food and Drug Administration ("FDA"), seeking approval for the sale of repaglinide. The FDA ultimately approved repaglinide for use in the treatment of type 2 diabetes, both as a monotherapy as well as in combination with metformin or thiazolidinediones ("TZD's"). Novo Nordisk Inc. holds the approved NDA for repaglinide.

13. Since 1997, Novo Nordisk has manufactured and sold repaglinide under the brand name PRANDIN®.

14. The listing for PRANDIN® in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") includes the '358 patent.

FDA Requires Simplified OAD Labeling

15. In 2007, the FDA reevaluated the labeling for all oral anti-diabetic drugs. On or about November 21, 2007, the FDA directed Novo Nordisk that the indicated use of PRANDIN®

be merged into a unified statement that it is to be used "as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." The FDA specifically instructed Novo Nordisk that this statement of use for PRANDIN® was to "[r]eplace all the separate indications (e.g., monotherapy, combination therapy, and initial or second-line therapy)." The FDA further directed Novo Nordisk to submit revised labeling in accordance with this simplified statement of use.

16. In response to this FDA directive, Novo Nordisk submitted a supplement to its NDA on January 11, 2008, requesting that the label for PRANDIN® be changed accordingly. Effective July 14, 2008, Novo Nordisk's revised labeling for PRANDIN® was approved by the FDA. The revised Indications and Usage statement required and approved by the FDA now reads as follows: "PRANDIN® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."

17. On May 6, 2009, Novo Nordisk amended the use code for PRANDIN® to conform to the FDA's directive regarding simplified labeling for all OADs. The use code for PRANDIN® accurately describes its approved indication as "[a] method for improving glycemic control in adults with type 2 diabetes mellitus."

Mylan Knowingly Submits An Improper ANDA To The FDA

18. On information and belief, Mylan submitted Abbreviated New Drug Application ("ANDA") No. 90-252 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of generic 0.5, 1, and 2 mg oral repaglinide tablets prior to the expiration of the '358 patent.

19. On information and belief, Mylan received filing confirmation of its ANDA from the FDA in February 2008.

20. On information and belief, ANDA No. 90-252 refers to and relies upon Novo Nordisk's NDA for PRANDIN® and purports to contain data showing bioequivalence of Mylan's repaglinide with PRANDIN®.

21. On information and belief, Mylan initially submitted a statement to the FDA pursuant to 21 U.S.C. §355(j)(2)(A)(viii) (a "Section viii statement") in connection with the '358 patent. On information and belief, Mylan knew that this was improper at the time it made this filing, because Section viii statements can only be filed for method of use claims, as the plain language of Section viii makes clear. Only one of the five claims of the '358 patent (claim 4) is a method claim; all of the remaining claims of the '358 patent (claims 1-3 and 5) are composition claims.

22. On April 7, 2009, Novo Nordisk Inc. received from Mylan a letter dated April 6, 2009, stating that ANDA No. 90-252 had been amended to include a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (commonly known as a "Paragraph IV certification") alleging that claims 1-3 and 5 of the '358 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Mylan's repaglinide. In that letter, Mylan states that "its [proposed] labeling does not include indications to treat diabetes with a combination of repaglinide and metformin."

23. Based on a May 19, 2009 discussion with the FDA, Novo Nordisk understood that the FDA would not permit any ANDA filer for generic repaglinide to omit information from its labeling regarding the use of repaglinide in combination with metformin, nor would it permit any ANDA filer for generic repaglinide to rely upon a Section viii statement in connection with claim 4 of the '358 patent.

24. On June 16, 2009, the FDA issued a formal ruling consistent with the information the FDA provided on May 19, 2009. The import of this ruling is that, in view of the amended use code for PRANDIN®, the FDA will not permit any ANDA filer for generic repaglinide to omit information from its labeling regarding the use of repaglinide in combination with metformin.

25. As a direct and necessary consequence of FDA's actions, Mylan's Section viii statement with respect to claim 4 of the '358 patent is of no force and effect, and its proposed labeling will be rejected by the FDA. Based on information known as early as May 19, 2009, and as confirmed by subsequent actions of the FDA, it is Novo Nordisk's understanding and belief that in order to proceed with its ANDA, Mylan will be required to: a) abandon its Section viii statement with respect to claim 4 and substitute a Paragraph IV certification with respect to all claims of the '358 patent; and b) propose new labeling that includes instructions for the use of repaglinide in combination with metformin.

26. On information and belief, Mylan intends to proceed with its ANDA filing for generic repaglinide despite the FDA's requirement that Mylan abandon its Section viii statement with respect to claim 4, and notwithstanding the FDA's further requirement that any labeling for repaglinide include instructions for use in combination with metformin.

27. On information and belief, Mylan's initial, proposed label for generic repaglinide does not restrict the use of repaglinide to monotherapy, or to combination therapy with compounds other than metformin. On information and belief, Mylan's initial, proposed label for generic repaglinide does not instruct physicians not to prescribe repaglinide in combination with metformin.

28. In the event the FDA approves Mylan's ANDA, it will necessarily include labeling which recites instructions for the use of repaglinide in combination with metformin.

Mylan's Intent to Induce, Promote and Encourage Infringement of the '358 Patent

29. On information and belief, Mylan knows that the predominant use of repaglinide today is in combination with metformin for the treatment of type 2 diabetes mellitus. On information and belief, Mylan further knows that it stands to reap huge profits by supporting, promoting and encouraging the infringement of the '358 patent. On information and belief, Mylan currently manufactures, markets and sells generic metformin in the United States and elsewhere, and is now seeking approval from the FDA to manufacture, market and sell generic repaglinide in the United States.

30. On information and belief, Mylan filed and is pursuing its ANDA for generic repaglinide with the knowledge and intent that its product, if approved, would predominantly be used in combination with metformin for the treatment of type 2 diabetes mellitus.

31. On information and belief, Mylan intends to and will support, promote and encourage the use of its generic repaglinide in combination with metformin for the treatment of type 2 diabetes mellitus.

32. On information and belief, Mylan intends to and will support, promote and encourage the manufacture, use and sale of its generic repaglinide in a kit with metformin for the treatment of type 2 diabetes mellitus.

33. On information and belief, Mylan does not intend to take any actions to discourage the use of its generic repaglinide in combination with metformin for the treatment of type 2 diabetes mellitus.

First Cause of Action for Infringement of U.S. Patent No. 6,677,358

34. Novo Nordisk hereby realleges and incorporates by reference the allegations of paragraphs 1-33 of this Amended Complaint.

35. Mylan's submission of ANDA 90-252 to the FDA with a Paragraph IV certification regarding the '358 patent, with the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of repaglinide before the expiration of the '358 patent, constitutes infringement of the '358 patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon information and belief, upon approval of ANDA No. 90-252, Mylan will directly and/or indirectly infringe the '358 patent under 35 U.S.C. § 271(a), (b), and (c).

37. The acts of infringement set forth above will cause Novo Nordisk irreparable harm for which it has no adequate remedy at law, and will continue unless the FDA's approval of ANDA No. 90-252 is stayed until the expiration of the '358 patent, and unless Mylan is preliminarily and permanently enjoined by this Court.

WHEREFORE, Novo Nordisk prays that this Court:

a. Enter a judgment that Mylan has infringed and is infringing the '358 patent under 35 U.S.C. § 271(e)(2)(A);

b. Stay FDA approval of Mylan's ANDA for at least thirty months, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii);

c. Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mylan's generic repaglinide shall be a date not earlier than the date of the expiration of the '358 patent, including any extensions;

d. Enter a judgment that Mylan's manufacture, use, offer for sale, or sale in the United States or importation into the United States of the repaglinide products that are the

subject of ANDA No. 90-252 will infringe and actively induce infringement of the '358 patent under 35 U.S.C. § 271(a) and (b);

e. Enter a judgment that Mylan's activities make this an exceptional case under 35 U.S.C. § 285;

f. Preliminarily and permanently enjoin and restrain Mylan and its respective officers, directors, agents, servants, employees, and attorneys, and those in active concert or participation with them, from the manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the repaglinide products that are the subject of ANDA No. 90-252 and any other product that infringes or induces infringement of the '358 patent, prior to the expiration of the '358 patent, including any extensions;

g. Grant Novo Nordisk compensatory damages in an amount to be determined at trial including both prejudgment and postjudgment interest if Mylan commercially manufactures, uses, offers for sale, or sells in the United States, or imports into the United States, the repaglinide products that are the subject of ANDA 90-252, or any other product that infringes or induces infringement of the '358 patent, prior to the expiration of the '358 patent, including any extensions;

h. Award Novo Nordisk enhanced damages;

i. Award Novo Nordisk its costs, expenses, and attorney fees that it incurs in prosecuting this action; and

j. Grant Novo Nordisk such additional and further relief as the Court may deem just and proper.

Dated: June 26, 2009

s/ David E. De Lorenzi

David E. De Lorenzi
Carrie A. Longstaff
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 017102-5310
Telephone: (973) 596-4500
Facsimile: (973) 596-0545

Josh A. Krevitt
Charles J. Boudreau
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue, 47th Floor
New York, New York 10166-0193
Telephone: (212) 351-4000
Facsimile: (212) 351-4035

Wayne M. Barsky
Michael A. Sitzman
GIBSON, DUNN & CRUTCHER LLP
2029 Century Park East
Los Angeles, California 90067
Telephone: (310) 557-8183
Facsimile: (310) 552-7010

Attorneys for Plaintiffs
Novo Nordisk, Inc. and Novo Nordisk A/S

CERTIFICATE OF SERVICE

I, Carrie A. Longstaff, hereby certify that on June 26, 2009, I caused to be served via electronic mail a true and correct copy of Plaintiffs' First Amended Complaint for Patent Infringement upon all counsel of record.

Date: June 26, 2009

By: C. Longstaff
Carrie A. Longstaff