UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Novo Nordisk Inc. and Novo Nordisk A/S, **Plaintiffs,** **vs.** **Paddock Laboratories, Inc.,** **Defendant.**	Civil No. _____ **COMPLAINT**

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S ("Novo Nordisk"), by their attorneys, for their Complaint against defendant Paddock Laboratories, Inc. ("Paddock"), hereby allege as follows:

Nature of The Action

1. This is a civil action for (i) the infringement of United States Patent No. 6,677,358 (the "'358 patent"), pursuant to the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; and (ii) a declaration, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), that Novo Nordisk has not violated the Antitrust Laws of the United States, 15 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, Paddock is a corporation organized and existing under the laws of the State of Minnesota, and has its principal place of business at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427.

Jurisdiction And Venue

5. 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).

6. This Court has personal jurisdiction over Paddock by virtue of its incorporation, continuous presence and principal place of business in the State of Minnesota.

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

Type 2 Diabetes And The ’358 Patent

8. 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.

9. 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 OADs – was not the standard of care and was, in fact, quite rare.

10. 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.

11. The '358 patent is directed to and claims a pharmaceutical composition which includes repaglinide, metformin and a carrier (claim 1) in the form of a tablet (claim 2) or a capsule (claim 3); a method for treating non-insulin dependent diabetes mellitus ("NIDDM") by administering repaglinide and metformin to a patient in need of treatment (claim 4); and a kit that includes repaglinide and metformin (claim 5).

12. 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.

FDA-Approved Uses Of Repaglinide

13. Novo Nordisk Inc. holds the FDA-approved New Drug Application ("NDA") for repaglinide, and manufactures and sells repaglinide under the brand name PRANDIN®.

14. The FDA has approved repaglinide for three uses in the treatment of type 2 diabetes: (1) repaglinide by itself (*i.e.*, monotherapy); (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones.

15. The predominant approved use of PRANDIN® is in combination therapy with metformin.

FDA Orange Book Listing For PRANDIN®

16. After an NDA is approved by the FDA, the NDA holder must submit FDA Form 3542 ("Patent Information Submitted Upon and After Approval of an NDA or Supplement").

17. On Form 3542, the FDA requests that an NDA holder propose a "use code" narrative for an approved drug based on a description of either the "approved indication" or "method of use."

18. The FDA publishes use codes and information about patent protection for each approved drug in a book called "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

19. The Orange Book listing for PRANDIN® includes the '358 patent.

20. When the '358 patent was issued in 2004, the "Indications and Usage" section of the FDA-approved label for PRANDIN® contained a separate indication for FDA-approved uses of repaglinide in combination therapy: "PRANDIN is also indicated for combination therapy use (with metformin or thiazolidinediones) to lower blood glucose in patients whose hyperglycemia could not be controlled by diet and exercise, plus monotherapy with metformin, sulfonylureas, repaglinide, or thiazolidinediones."

21. Consistent with the FDA-approved label for PRANDIN® in 2004**,** Novo submitted on Form 3542 the following proposed use code description for PRANDIN®: "Use of repaglinide in combination with metformin to lower blood glucose."

22. The FDA assigned use code U-546 to the proposed use code description for PRANDIN® and published the U-546 use code and description in the Orange Book.

23. In November 2007, the FDA decided that separate indications of usage for PRANDIN® – whether for monotherapy or combination therapy – should be eliminated and directed Novo Nordisk to submit revised labeling with a single approved indication:

> Under **INDICATIONS AND USAGE**
>
> Replace all the separate indications (e.g., monotherapy, combination therapy, and initial or second-line therapy) with the following sentence:
>
> "Prandin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."

24. Novo Nordisk submitted a proposed new label in January 2008, and the FDA approved the new PRANDIN® label in July 2008. The "Indications and Usage"

section of the FDA-approved label now states that "PRANDIN is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."

25. In late February 2009, regulatory counsel for Novo Nordisk met with attorneys from the FDA's Office of Chief Counsel. During a discussion about the new unitary indication in the approved revised labeling for PRANDIN®, FDA counsel inquired about the then existing use code for PRANDIN®. Regulatory counsel for Novo Nordisk advised the FDA attorneys that Novo Nordisk was considering amending its use code narrative to reflect the new approved indication for PRANDIN®. The FDA attorneys did not raise any objection.

26. In May 2009, Novo Nordisk submitted to the FDA a proposed amended use code description for PRANDIN® to track the approved indication for PRANDIN® in the revised labeling for PRANDIN®:

FDA-Approved Indication In Revised Label	**Proposed Amended Use Code**
PRANDIN is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	A method for improving glycemic control in adults with type 2 diabetes mellitus.

27. The FDA assigned use code U-968 to the proposed amended use code description for PRANDIN® and published the U-968 use code and description in the Orange Book. The U-968 use code accurately describes the "approved indication" for PRANDIN®.

The Federal Circuit Decision On The Use Code For PRANDIN®

28. In a decision dated April 14, 2010, the United States Court of Appeals for the Federal Circuit addressed a dispute over the amended use code description for PRANDIN®. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359 (Fed. Cir. 2010).

29. In *Novo Nordisk A/S, et al. v. Caraco Pharm. Labs., Ltd., et al.*, Civil Action No. 2:05 CV 40188 (E.D. Mich.), the district court had ordered Novo Nordisk to request that the FDA restore the original use code for PRANDIN®.

30. A divided panel of the Federal Circuit vacated the district court injunction. Writing for the majority, the Honorable Randall R. Rader held that the use code description for PRANDIN® was not subject to the district court's revision. In his concurring opinion, the Honorable Raymond C. Clevenger noted that "Novo did nothing that was illegal or forbidden" and that "there is nothing illegal, or even incorrect, about Novo's current use code." *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359 (Fed. Cir. 2010).

Paddock's Intent To Induce, Promote And Encourage Infringement Of The '358 Patent

31. On information and belief, Paddock submitted Abbreviated New Drug Application ("ANDA") No. 201189 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.

32. On information and belief, ANDA No. 201189 refers to and relies upon Novo Nordisk's NDA for PRANDIN® and purports to contain data showing bioequivalence of Paddock's repaglinide with PRANDIN®.

33. On April 16, 2010, Novo Nordisk Inc. received from Paddock a letter dated April 15, 2010 (the "Notification Letter"), stating that ANDA No. 201189 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (commonly known as a "Paragraph IV certification") alleging that the '358 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Paddock's repaglinide.

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

35. Based on discussions with the FDA, Novo Nordisk understands that the FDA will not permit any ANDA filer for generic repaglinide, including Paddock, to omit information from its labeling regarding the use of repaglinide in combination with metformin. In the event the FDA approves Paddock's ANDA, it will necessarily include labeling which recites instructions for the use of repaglinide in combination with metformin.

36. On information and belief, Paddock 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, Paddock further knows that it stands to reap huge profits by supporting, promoting and encouraging the infringement of the '358 patent.

37. On information and belief, Paddock 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.

38. On information and belief, Paddock 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.

39. On information and belief, Paddock 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.

40. On information and belief, Paddock 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.

Paddock Threatens Novo Nordisk That It Will Assert An Antitrust Claim If It Is Sued For Patent Infringement

41. In an attachment to its Notification Letter dated April 15, 2010, Paddock asserted that the amended use code description for PRANDIN® misrepresents the scope of the '358 patent and that Novo Nordisk had amended the use code description to unlawfully monopolize the market for repaglinide.

42. Just one day earlier, on April 14, 2010, the Honorable Raymond C. Clevenger of the United States Court of Appeals for the Federal Circuit had noted that "there is nothing illegal, or even incorrect, about Novo's current use code." *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1368 (Fed. Cir. 2010) (Clevenger, J., concurring).

43. On May 13, 2010, counsel for Paddock contacted counsel for Novo Nordisk and stated in essence that, if Novo Nordisk sued Paddock for patent infringement, Paddock would assert an antitrust counterclaim against Novo Nordisk. In a subsequent meeting, counsel for Paddock made clear that the antitrust claim would be premised on the change in the use code description for PRANDIN®.

Count 1: Infringement of U.S. Patent No. 6,677,358

44. Novo Nordisk hereby realleges and incorporates by reference the allegations of paragraphs 1-43 of this Complaint.

45. Paddock's submission of ANDA No. 201189 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).

46. On information and belief, upon approval of ANDA No. 201189, Paddock will directly and/or indirectly infringe the '358 patent under 35 U.S.C. § 271(a), (b), and (c).

47. 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. 201189 is stayed until the expiration of the '358 patent, and unless Paddock is preliminarily and permanently enjoined by this Court.

Count 2: Declaratory Relief Pursuant To 28 U.S.C. § 2201

48. Novo Nordisk hereby realleges and incorporates by reference the allegations of paragraphs 1-47 of this Complaint.

49. This Court has subject matter jurisdiction over any asserted antitrust issues in this case because Paddock could have brought an independent antitrust action under 15 U.S.C. § 26 in this Court seeking injunctive relief against Novo Nordisk for alleged violations of the Sherman Act.

50. There is an actual controversy between Novo Nordisk, on the one hand, and Paddock, on the other, concerning Paddock's infringement of Novo Nordisk's '358 patent and Paddock's allegation that Novo Nordisk has engaged in conduct designed to improperly and illegally monopolize an alleged market for repaglinide.

51. Pursuant to 28 U.S.C. § 2201, this Court may "declare the rights and legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

52. Novo Nordisk is an interested party who seeks a declaration of its rights and legal relations vis-à-vis Paddock with regard to Paddock's allegations that Novo Nordisk has engaged in conduct that Paddock may contend violates Section 2 of the Sherman Act.

53. Paddock's allegation that Novo Nordisk misrepresented the scope of its '358 patent so as to illegally leverage its patent rights in order to unlawfully maintain dominant control of an alleged market for repaglinide is unfounded.

54. Novo Nordisk has never told the FDA that the '358 patent claims the use of repaglinide in monotherapy or in combination therapy with thiazolidinediones.

55. Novo Nordisk's actions in revising the use code for PRANDIN® were done in response to FDA actions and were ultimately held not to be unlawful or otherwise contrary to Novo Nordisk's rights.

56. Novo Nordisk's requests and various petitions to the FDA regarding ANDAs for repaglinide have not been mere shams or fraudulent misrepresentations. For example, in June 2008, to address an attempt by a generic manufacturer to omit or "carve out" from its product label information regarding the predominant approved use of repaglinide (*i.e.*, in combination therapy with metformin), Novo Nordisk filed with the FDA a Citizen Petition stating that the exclusion of such information would render the use of repaglinide less safe and less effective. In early December 2008, the FDA issued a Response in which it denied Novo Nordisk's Citizen Petition. Shortly thereafter, Novo Nordisk submitted a Petition for Reconsideration, asking the FDA to reconsider its position given information and evidence that allowing a carve-out would render generic repaglinide less safe and less effective. The Petition for Reconsideration was subsequently denied as moot. These were legitimate requests for governmental action based on legitimate concerns about the safety and efficacy of repaglinide.

57. Paddock cannot allege, as is necessary to state a sham litigation/petitioning claim under Section 2 of the Sherman Act, that Novo Nordisk's claim for infringement of the '358 patent is objectively baseless.

Conclusion

WHEREFORE, Novo Nordisk prays that this Court:

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

b. Stay FDA approval of Paddock'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 Paddock'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 Paddock'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. 201189 will infringe and actively induce the infringement of the '358 patent under 35 U.S.C. § 271(a);

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

f. Preliminarily and permanently enjoin and restrain Paddock 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. 201189 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 Paddock 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 201189, 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;

j. Declaring, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), that Novo Nordisk’s actions did not constitute a violation of U.S. Antitrust Laws, including, but not limited to, Section 2 of the Sherman Act; and

k. Grant Novo Nordisk any such other and further relief as the Court may deem just and proper.

Dated: May 28, 2010

s/ Kenneth A. Liebman

Kenneth A. Liebman, #236731
Chad Drown, #319053
Christopher J. Burrell, #386475
FAEGRE & BENSON LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, Minnesota 55402
Telephone: (612) 766-7000
Fax: (612) 766-1600
kliebman@faegre.com
cdrown@faegre.com
cburrell@faegre.com

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

Of Counsel:

Josh A. Krevitt
Aric H. Wu
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, New York 10166
Telephone: (212) 351-4000
Facsimile: (212) 351-4035
jkrevitt@gibsondunn.com
awu@gibsondunn.com

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
msitzman@gibsondunn.com
wbarsky@gibsondunn.com

W. Todd Miller
BAKER & MILLER PLLC
2401 Pennsylvania Ave., NW., Suite 300
Washington, D.C. 20037
Telephone: (202) 663-7820
Facsimile: (202) 663-7849
tmiller@bakerandmiller.com