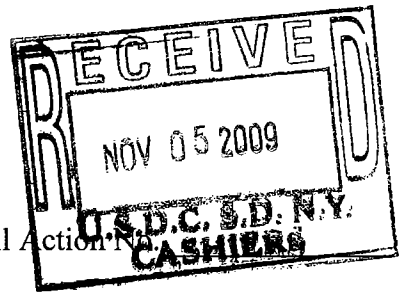
'09 CIV 9217

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVO NORDISK INC. and NOVO NORDISK A/S, Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No.



COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), for their Complaint against Defendant Sandoz Inc. ("Sandoz"), 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, having a 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, Sandoz Inc. is a Colorado corporation having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

5. Upon information and belief, Sandoz considers itself to be one of the largest manufacturers of generic pharmaceutical products in the United States, and it derives substantial revenue from goods used or consumed or services rendered in the State of New York and this Judicial District.

Jurisdiction And Venue

6. This action arises under the patent laws of the United States of America. 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.

7. Personal jurisdiction over Sandoz in New York is proper under N.Y. C.P.L.R. §§ 301 and 302(a) and because Sandoz is, *inter alia*, doing business in this jurisdiction. Sandoz is registered to do business in New York, and has designated Corporate Service Company at 80 State Street, Albany New York 12207-2543 for receipt of service, and maintains a place of business at 227-15 North Conduit Avenue, Laurelton, New York 11413. Sandoz manufactures pharmaceuticals and pharmaceutical products that are sold and used throughout the United States, including within New York. Sandoz regularly, systematically, and currently transacts business in the Southern District of New York, at least by making and shipping into this Judicial District, or by using, offering to sell, or selling, or by causing others to use, offer to sell, or sell, pharmaceutical products; sells various products throughout the United States, including within New York; derives substantial revenue from goods used or consumed or services rendered in New York; has contracted with one or more pharmaceutical bulk purchasing

organizations that supply generic drug products to the New York State Department of Health and other state agencies; and has filed claims and counterclaims in this Judicial District.

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. As a result, 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.,* 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.

11. Following a clinical trial commenced in Australia in 1995 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 May 2008, Novo Nordisk Inc. filed New Drug Application ("NDA") 22-386 with the Food and Drug Administration ("FDA"), seeking approval for the sale of repaglinide-metformin HCl combination tablets. In June 2008, the FDA approved that NDA. Novo Nordisk Inc. holds the approved NDA.

13. Since February 2009, Novo Nordisk has marketed PrandiMet®-brand repaglinide-metformin HCl combination tablets.

14. PrandiMet® is approved for use as an adjunct to diet and exercise to improve glycemic control in patients with Type 2 diabetes mellitus (also called "non-insulin dependent diabetes mellitus, or "NIDDM").

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

16. Upon information and belief, Sandoz is in the business of manufacturing, marketing, and distributing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

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

17. Novo Nordisk hereby realleges and incorporates by reference the allegations of paragraphs 1-16 of this Complaint.

18. Upon information and belief, Sandoz filed Abbreviated New Drug Application ("ANDA") No. 91-470 with the FDA under 21 U.S.C. § 355(j) seeking approval to market (i) tablets comprising a combination of 1 mg repaglinide and 500 mg metformin HCl and (ii) tablets comprising a combination of 2 mg repaglinide and 500 mg metformin HCl (collectively, the "Proposed Generic Products").

19. By its ANDA filing, Sandoz has indicated that it intends to engage, and there is a substantial likelihood that it will engage, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Generic Products, which Sandoz has alleged will be bioequivalent to Novo Nordisk's patented repaglinide-metformin combination drug products, immediately or imminently upon receiving FDA approval to do so.

20. By its ANDA filing, Sandoz seeks to obtain approval to manufacture, use, offer for sale, sell, and/or import the Proposed Generic Products, alleged equivalents of Novo Nordisk's PRANDIMET® drug products, prior to the expiration date of the '358 patent.

21. By a letter dated September 22, 2009 (the "Notice Letter"), Sandoz informed Novo Nordisk that it had filed a certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about September 23, 2009, NDA holder Novo Nordisk Inc. received the Notice Letter. On or about September 24, 2009, patent owner Novo Nordisk A/S received the Notice Letter.

22. The Notice Letter, purporting to be Sandoz's Notice of Certification under 21 U.S.C. § 355(j)(2)(B)(iv), alleges that, in Sandoz's opinion, the '358 patent is invalid, unenforceable, and/or will not be infringed by the Proposed Generic Products.

23. Sandoz's filing of ANDA No. 91-470 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of drug

products containing repaglinide and metformin, or salts thereof, before the expiration of the '358 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

24. Upon information and belief, upon approval of ANDA No. 91-470, Sandoz will directly and/or indirectly infringe the '358 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

25. 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. 91-470 is stayed until the expiration of the '358 patent, and unless Sandoz is preliminarily and permanently enjoined by this Court.

WHEREFORE, Novo Nordisk prays that this Court:

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

b. stay FDA approval of ANDA No. 91-470 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 Sandoz'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 Sandoz's manufacture, use, offer for sale, and/or sale in the United States, or importation into the United States, of the products that are the subject of ANDA No. 91-470 will infringe, induce infringement of, and/or contribute to the infringement of the '358 patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

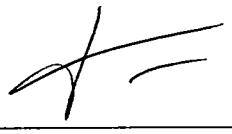
e. enter a judgment that Sandoz's activities make this an exceptional case under 35 U.S.C. § 285;

f. preliminarily and permanently enjoin and restrain Sandoz 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 products that are the subject of ANDA No. 91-470 and any other product that infringes, induces infringement of, or contributes to the infringement of the '358 patent, prior to the expiration of the '358 patent, including any extensions;

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

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

Dated: November 5, 2009



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