UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVO NORDISK INC. and NOVO NORDISK A/S, Plaintiffs, v. ACTAVIS PHARMA MANUFACTURING PVT. LTD. LLC and ACTAVIS INC. Defendants.	Civil Action No. 09 CV 8939

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), for their Complaint against Defendants Actavis Pharma Manufacturing Pvt. Ltd. LLC and Actavis Inc. (collectively, "Actavis"), 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, Actavis Pharma Manufacturing Pvt. Ltd. LLC ("Actavis Pharma") is a corporation organized under the laws of India, having a principal place of business at No. 15, 80 Feet Road, Koramangala, Bangalore 560 095, India.

5. Upon information and belief, Actavis Inc. is a Delaware corporation having a principal place of business at 60 Columbia Turnpike, Bldg. B, Morristown, New Jersey 07960.

6. Upon information and belief, Actavis Inc. is an affiliate of Actavis Pharma.

7. Upon information and belief, Actavis Inc. considers itself to be the eighth largest generic pharmaceutic company in North America by value and the fifth largest by volume, and derives substantial revenue from goods used or consumed or services rendered in the State of New York and this Judicial District.

Jurisdiction And Venue

8. 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.

9. Personal jurisdiction over the Defendants in New York is proper under N.Y. C.P.L.R. §§ 301 and 302(a) and because the Defendants are, *inter alia*, doing business in this jurisdiction. Actavis Pharma manufactures pharmaceuticals and pharmaceutical products that are sold and used, including by Actavis Inc., throughout the United States, including within New York. Actavis Inc. 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 previously submitted to the jurisdiction of this Court.

10. Actavis Pharma is additionally subject to jurisdiction in the United States under principles of general jurisdiction, and specifically in New York, pursuant to Fed. R. Civ. P. 4(k)(2). Actavis Pharma has contacts within the United States by, *inter alia*, having filed ANDA No. 91-400 with the FDA.

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

General Background

12. 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.

13. 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.

14. 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.

15. 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.

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

17. 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").

18. 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.

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

20. Upon information and belief, Actavis filed Abbreviated New Drug Application ("ANDA") No. 91-400 with the FDA under 21 U.S.C. § 355(j) on May 11, 2009, seeking approval to engage in the commercial manufacture, use, and sale of (i) generic tablets comprising a combination of 1 mg repaglinide and 500 mg metformin HCl and (ii) generic tablets comprising a combination of 2 mg repaglinide and 500 mg metformin HCl (collectively, the "Proposed Generic Products") prior to the expiration of the '358 patent.

21. Upon information and belief, ANDA No. 91-400 refers to and relies upon Novo Nordisk Inc.'s NDA for PrandiMet® and purports to contain data showing bioequivalence of the Proposed Generic Products with PrandiMet®.

22. Upon information and belief, Actavis Inc. actively encouraged and/or directed Actavis Pharma to file ANDA No. 91-400 with the FDA, and/or participated in the work related to the submission of ANDA No. 91-400.

23. On September 10, 2009, Novo Nordisk Inc. received from Actavis Inc. a letter dated September 9, 2009 (the "Notice Letter"), stating that Actavis Pharma had filed a certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Statement") alleging that the claims of the '358 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the Proposed Generic Products.

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

24. Novo Nordisk hereby realleges and incorporates by reference the allegations of paragraphs 1-23 of this Complaint.

25. Actavis's submission of ANDA No. 91-400 to the FDA with a Paragraph IV certification regarding the '358 patent, with the purpose of obtaining FDA approval to engage in the commercial manufacture, use, and sale 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).

26. Upon information and belief, upon approval of ANDA No. 91-400, Actavis will directly and/or indirectly infringe the '358 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

27. 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. 91-400 is stayed until the expiration of the '358 patent, and unless Actavis is preliminarily and permanently enjoined by this Court.

WHEREFORE, Novo Nordisk prays that this Court:

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

b. stay FDA approval of ANDA No. 91-400 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 Actavis'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 Actavis'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. 91-400 will infringe, actively 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 Actavis's activities make this an exceptional case under 35 U.S.C. § 285;

f. preliminarily and permanently enjoin and restrain Actavis Pharma and Actavis Inc., and their 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. 91-400 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: October 22, 2009

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