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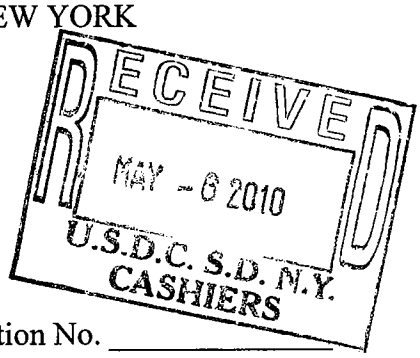
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK



NOVO NORDISK INC. and NOVO NORDISK A/S, Plaintiffs, v. LUPIN LTD., 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 Lupin Ltd. ("Lupin"), 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, Lupin is an alien corporation organized and existing under the laws of the Sovereign Nation of India, having a principal place of business at Laxmi Towers, "B" Wing, 5th Floor, Bandra Kurla Complex, Bandra (W), Mumbai, 400 051, India. Lupin Limited develops and manufactures prescription pharmaceutical drugs, including generic drug products.

Jurisdiction And Venue

5. This action arises under the patent laws of the United States. 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.

6. Personal jurisdiction over Lupin in New York is proper under N.Y. C.P.L.R. §§ 301 and 302(a), and because, *inter alia*, Lupin manufactures pharmaceuticals and pharmaceutical products that are sold and used throughout the United States, including within New York; Lupin 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 in this Judicial District; and Lupin derives substantial revenue from goods used or consumed or services rendered in New York, including in this Judicial District. Furthermore, Lupin's submission of ANDA No. 200-624, discussed below, indicates its intention to engage in the commercial manufacture, use, or sale of products that will compete directly with Novo Nordisk's PRANDIMET®, of which a significant portion of sales occur in the State of New York and this judicial district.

7. Venue is proper in this Judicial District pursuant to at least 28 U.S.C. §§ 1391 and 1400(b).

General Background

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. As a result, 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.,* 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 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.

11. 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.

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

13. 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").

14. 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.

15. Upon information and belief, Lupin 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

16. Novo Nordisk hereby realleges and incorporates by reference the allegations of paragraphs 1-15 of this Complaint.

17. Upon information and belief, Lupin filed Abbreviated New Drug Application ("ANDA") No. 200-624 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").

18. By its ANDA filing, Lupin 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 Lupin 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.

19. By its ANDA filing, Lupin 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.

20. By a letter dated March 22, 2010 (the "Notice Letter"), Lupin 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 March 23, 2010, NDA holder Novo Nordisk Inc. received the Notice Letter. On or about March 24, 2010, patent owner Novo Nordisk A/S received the Notice Letter.

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

22. Lupin's filing of ANDA No. 200-624 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).

23. Lupin's generic metformin hydrochloride/repaglinide tablets, 500 mg/1 mg and 500 mg/2 mg, will and are intended to compete directly with Novo Nordisk's PRANDIMET® (metformin hydrochloride/repaglinide) 500 mg/ 1mg and 500 mg/2 mg, respectively.

24. Upon information and belief, upon approval of ANDA No. 200-624, Lupin 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. 200-624 is stayed until the expiration of the '358 patent, and unless Lupin is preliminarily and permanently enjoined by this Court.

WHEREFORE, Novo Nordisk prays that this Court:

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

b. stay FDA approval of ANDA No. 200-624 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 Lupin'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 Lupin'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. 200-624 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 Lupin's activities make this an exceptional case under 35 U.S.C. § 285;

f. preliminarily and permanently enjoin and restrain Lupin 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. 200-624 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: May 6, 2010

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