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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MICHAEL W. BOBBING
CLERK, U.S. DISTRICT COURT

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NOVARTIS PHARMACEUTICALS :
CORPORATION, NOVARTIS AG, :
NOVARTIS PHARMA AG, :
NOVARTIS INTERNATIONAL :
PHARMACEUTICAL LTD., and :
PROTERRA AG, :
:

Plaintiffs, :
:

v. :
:

SUN PHARMACEUTICAL INDUSTRIES, :
LTD., :
:

Defendant. :
----- X

05C 4004

JUDGE NORGLÉ

MAGISTRATE JUDGE NOLAN

CIVIL ACTION NO.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd., and Protterra AG (hereinafter collectively "Plaintiffs"), by and through their attorneys, David C. Van Dyke and Christopher M. Welling of Cassidy, Schade & Gloor, LLP, and for their Complaint herein against Defendant, Sun Pharmaceutical Industries, Ltd. (hereinafter "Sun") allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation (“NPC”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG (“Novartis AG”) is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis Pharma AG (“Pharma AG”) is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Plaintiff Novartis International Pharmaceutical Ltd. (“NIP”) is a corporation organized and existing under the laws of Bermuda, having an office and place of business at Hurst Holme, 12 Trott Road, Hamilton HM 11, Bermuda.

6. Plaintiff Proterra AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Poststrasse 9, CH-6300 Zug, Switzerland.

7. On information and belief, Sun is a public limited liability company incorporated and existing under the laws of India and having a principal place of business at Acme Plaza, Andheri Kurla Road, Andheri (East) Mumbai 400059, Maharashtra, India.

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 under 28 U.S.C. §§ 1331 and 1338(a).

9. Sun has authorized James F. Hurst, Esq. of Winston & Strawn LLP, 35 West Wacker Drive, Chicago, Illinois 60601-9703, to accept service of process on behalf of Sun pursuant to 21 C.F.R. § 314.95(c)(7).

10. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF - PATENT INFRINGEMENT

11. Plaintiff NPC holds an approved new drug application (“NDA”) No. 20-823 for Exelon[®] capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg), which capsules contain the active ingredient rivastigmine tartrate (also known as rivastigmine hydrogen tartrate). Exelon[®] capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) were approved by the United States Food and Drug Administration (“FDA”) on April 21, 2000, for the treatment of mild to moderate dementia of the Alzheimer’s type, and are sold in the United States by Plaintiff NPC.

12. The active ingredient in the Exelon[®] capsules, rivastigmine tartrate, is known chemically as (S)-[N-ethyl-3-[(1-dimethylamino)ethyl]-N-methyl-phenyl-carbamate] tartrate and as (S)-N-ethyl-N-methyl-3-[1-(dimethylamino)ethyl]-phenyl carbamate hydrogen-(2R, 3R)-tartrate.

13. Proterra AG is the owner of United States Letters Patent No. 4,948,807 (“the ‘807 patent”). The ‘807 patent was duly and legally issued on August 14, 1990.

14. The ‘807 patent claims N-ethyl, N-methyl-3-[1-(dimethylamino)ethyl]phenyl carbamate and pharmaceutically acceptable salts thereof, as well as methods of treating patients that have Alzheimer’s disease. A true copy of the ‘807 patent is attached hereto as Exhibit A.

15. On information and belief, Sun submitted to the FDA an abbreviated new drug application (“ANDA”) under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules (hereinafter referred to as “the Sun Rivastigmine Tartrate Products”).

16. On information and belief, Sun submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Sun Rivastigmine Tartrate Products before the expiration of the ‘807 patent.

17. By filing the ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Sun Rivastigmine Tartrate Products before the expiration of the ‘807 patent, Sun has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of the Sun Rivastigmine Tartrate Products for which Sun seeks approval in its ANDA will also infringe one or more claims of the ‘807 patent.

18. On information and belief, the Sun Rivastigmine Tartrate Products if approved, will be administered to human patients in a therapeutically effective amount for treatment of mild to moderate dementia of the Alzheimer’s type, which administration

constitutes direct infringement of the '807 patent. On information and belief, this will occur at Sun's active behest, and with its intent, knowledge and encouragement. On information and belief, Sun will actively induce, encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '807 patent.

19. On information and belief, Sun made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in its opinion and to the best of its knowledge, the '807 patent is invalid, unenforceable or will not be infringed.

20. On information and belief, Sun's ANDA seeks approval to manufacture and sell the Sun Rivastigmine Tartrate Products, which infringe the '807 patent.

21. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to the Sun Rivastigmine Tartrate Products be a date which is not earlier than August 14, 2007, the current expiration date of the '807 patent,^{1/} and an award of damages for any commercial sale or use of the Sun Rivastigmine Tartrate Products, and any act committed by Sun with respect to the subject matter claimed in the '807 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

22. On information and belief, when Sun filed its ANDA, it was aware of the '807 patent and that the filing of its ANDA with the request for its approval prior to the expiration of the '807 patent was an act of infringement of this patent.

^{1/} Pursuant to 35.U.S.C. § 155 an extension of the patent term is being sought.

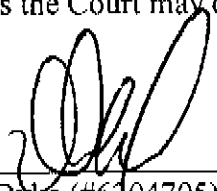
PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

- A. Judgment that Sun has infringed one or more claims of the '807 patent by filing the aforesaid ANDA relating to the Sun Rivastigmine Tartrate Products;
- B. A permanent injunction restraining and enjoining Sun and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the Sun Rivastigmine Tartrate Products as claimed in the '807 patent;
- C. An order that the effective date of any approval of the aforementioned ANDA relating to the Sun Rivastigmine Tartrate Products be a date which is not earlier than the expiration of the right of exclusivity under the '807 patent;
- D. Damages from Sun for the infringement of the '807 patent;
- E. The costs and reasonable attorney fees of Plaintiffs in this action; and

F. Such other and further relief as the Court may deem just and proper.

Dated: July 12, 2005



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