IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

CEPHALON, INC., Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES, INC., and SUN PHARMACEUTICAL INDUSTRIES LTD. Defendants.	Civil Action No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Cephalon, Inc., for its Complaint against Defendants Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries Ltd., (collectively, "Sun"), alleges as follows.

This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(a) and (e), and for a declaratory judgment of infringement under 28 U.S.C. § 2201. This action relates to Abbreviated New Drug Application ("ANDA") No. 77-555 filed by Sun with the United States Food and Drug Administration ("FDA") for approval to market generic copies of Plaintiff's GABITRIL® pharmaceutical products that are sold in the United States.

Parties

1. Plaintiff Cephalon, Inc. is a Delaware corporation having its corporate offices and principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon, Inc. is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. On information and belief, Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") is a corporation operating and existing under the laws of India with its principal place of

business at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai 400059, Maharashtra, India.

3. On information and belief, Defendant Sun Pharmaceutical Industries Inc. ("Sun USA Inc.") is a wholly owned subsidiary of Sun Ltd. and is a corporation operating and existing under the laws of Michigan with its principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512.

Background

4. Cephalon is the holder of approved New Drug Application No. 20-646 for GABITRIL® tablets in 2 mg, 4 mg, 12 mg, and 16 mg dosage forms containing tiagabine hydrochloride.

5. GABITRIL® (tiagabine hydrochloride) is a prescription drug used as an anti-epilepsy agent.

6. Cephalon, among other things, manufactures, markets, and sells GABITRIL® tablets to treat epilepsy. Cephalon financially benefits from sales of GABITRIL® tablets in the United States, including sales in the State of Michigan.

7. On information and belief, Sun Ltd. and Sun USA Inc. filed with the FDA, in Rockville, Maryland, ANDA No. 77-555 under 21 U.S.C. § 355(j), to obtain FDA approval for the commercial manufacture, use, or sale of oral tiagabine hydrochloride tablets in the 2 mg and 4 mg dosage strengths, which are generic copies of Cephalon's GABITRIL® tablets in 2 mg and 4 mg dosage strengths, respectively.

8. By letter dated April 15, 2005, Sun Ltd. notified Cephalon that it had filed ANDA No. 77-555, seeking FDA approval to market tiagabine hydrochloride tablets in the 2 mg and 4 mg dosage strengths (hereinafter referred to as "Sun Tiagabine Hydrochloride Tablets"), and that

it was providing information to Cephalon pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c).

Jurisdiction and Venue

9. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

10. On information and belief, Sun Ltd. is in the business of manufacturing generic pharmaceutical products. On information and belief, Sun Ltd., directly or indirectly through Sun USA Inc., markets, distributes, and sells generic pharmaceutical products throughout the United States, including the State of Michigan.

11. Personal jurisdiction over Sun Ltd. is proper because it purposefully avails itself of the privilege of selling its generic products in the State of Michigan and can therefore reasonably expect to be subject to jurisdiction in courts in Michigan. Among other things, upon information and belief, Sun Ltd. places goods into the stream of commerce for distribution throughout the United States, including the State of Michigan. Upon information and belief, in this judicial district, Sun Ltd. through its subsidiaries (primarily Sun USA Inc.) leases and owns facilities, enters into contracts, distributes products, derives revenue, retains a registered agent, and avails itself of the forum in other matters.

12. Personal jurisdiction over Sun USA Inc. is proper because it is incorporated in the State of Michigan and has a place of business in the State of Michigan. Sun USA Inc. also owns facilities at 29714 Orion Ct., Farmington Hills, Michigan 48334 and 30600 Telegraph Rd., Bingham Farms, Michigan 48025.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

Count I

Infringement of United States Patent No. 5,958,951

14. Plaintiffs reallege and incorporate by reference paragraphs 1-13 of this Complaint as if fully set forth herein.

15. United States Patent No. 5,958,951 ("the '951 patent"), entitled "Modified Form Of The R(-)-N-(4,4-Di(3-Methylthien-2-yl)But-3-enyl)-Nipecotic Acid Hydrochloride," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on September 28, 1999. The '951 patent as issued was assigned to Novo Nordisk A/S. The '951 patent was subsequently assigned by Novo Nordisk A/S to Cephalon. This assignment was recorded in the PTO on September 14, 2011 on reel 026901, frame 0833. As a result, Cephalon is the current owner of the '951 patent and holds all relevant and substantial rights in the '951 patent, including the right to sue for infringement thereof. A true and correct copy of the '951 patent is attached as Exhibit A.

16. Cephalon listed the '951 patent with the FDA for publication in the "Orange Book" pursuant to 21 U.S.C. § 355(b)(1), and the FDA published that listing on the FDA's Internet Website.

17. On information and belief, Sun Ltd. and Sun USA Inc. filed ANDA No. 77-555 in order to obtain approval to market the Sun Tiagabine Hydrochloride Tablets in the United States before the expiration of the '951 patent.

18. On information and belief, Sun Ltd. and Sun USA Inc. included a certification in its ANDA alleging pursuant to 21 U.S.C. § 355 and 21 C.F.R. § 314.95 that the claims of the '951 patent are invalid and/or not infringed. Sun Ltd. sent Cephalon a letter dated April 15, 2005, purporting to be a Notice of Certification under Section 505(j)(2)(B)(ii) of the Federal

Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(ii). Although this letter alleged that claims 1-2, and 4-7 of the '951 patent are invalid, the letter did not allege any basis as to why the Sun Tiagabine Hydrochloride Tablets would not infringe these claims if they were valid.

19. On information and belief, the FDA has given tentative approval to Sun Ltd. and Sun USA Inc. for ANDA No. 77-555 to market, offer for sale, and sell the Sun Tiagabine Hydrochloride Tablets in the United States. Sun Ltd. and Sun USA Inc. have never asserted that U.S. Patent No. 5,010,090 ("the '090 patent"), another patent listed on the FDA's Orange Book for Gabitril, was invalid or not infringed by the Sun Tiagabine Hydrochloride Tablets. Thus, Sun Ltd. and Sun USA Inc. cannot market, offer to sell, or sell the Sun Tiagabine Hydrochloride Tablets in the United States until the expiration of the '090 patent on September 30, 2011. On information and belief, Sun Ltd. and Sun USA Inc. intend to market, offer for sale, and sell the Sun Tiagabine Hydrochloride Tablets in the United States after September 30, 2011 and before the expiration of the '951 patent on June 10, 2017.

20. Under 35 U.S.C. § 271(e)(2)(A), the submission by Sun Ltd. and Sun USA Inc, to the FDA of ANDA No. 77-555 to obtain approval for the commercial manufacture, use, or sale of the Sun Tiagabine Hydrochloride Tablets before the expiration date of the '951 patent constitutes infringement of one or more claims of the '951 patent, either literally or under the doctrine of equivalents.

21. Cephalon will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Cephalon has no adequate remedy at law.

Count II

Declaratory Judgment of Infringement of the ’951 patent

22. Cephalon realleges and incorporate by reference paragraphs 1-21 of this Complaint as if fully set forth herein.

23. On information and belief, in view of the FDA’s tentative approval of ANDA No. 77-555, Sun Ltd. and Sun USA Inc. plan to begin marketing, offering to sell, or selling Sun Tiagabine Hydrochloride Tablets in the United States immediately or soon after the expiration of the ’090 patent on September 30, 2011.

24. The manufacture, sale, offer for sale, and/or importation of Sun Tiagabine Hydrochloride Tablets will infringe one or more claims of the ’951 patent under 35 U.S.C. § 271(a) in violation of Cephalon’s patent rights.

25. There is a real, substantial, and continuing justiciable controversy between Cephalon and Sun Ltd. and Sun USA Inc. as to liability for the infringement of the ’951 patent claims. The actions of Sun Ltd. and Sun USA Inc. have created in Cephalon a reasonable apprehension of imminent harm and loss.

26. Cephalon will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Cephalon has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Cephalon respectfully requests that this Court enter judgment in its favor as follows:

(1) holding that the claims of the’951 patents are valid and enforceable;

(2) holding that the submission of ANDA No. 77-55 by Sun Ltd. and Sun USA Inc. infringes one or more claims of the ’951 patent;

(3) ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of the Sun Tiagabine Hydrochloride Tablets shall be no earlier than the expiration date of the ’951 patent;

(4) declaring that the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Sun Tiagabine Hydrochloride Tablets prior to the expiration of the ’951 patent would constitute infringement of the ’951 patent in violation of Cephalon’s patent rights;

(5) enjoining Sun Ltd. and Sun USA Inc. and all persons acting in concert with them, from commercially offering for sale or selling the Sun Tiagabine Hydrochloride Tablets within the United States prior to the expiration date of the ’951 patent;

(6) declaring this to be an exceptional case and awarding Cephalon its attorney fees under 35 U.S.C. § 285;

(7) awarding Cephalon its costs and expenses in this action; and

(8) awarding Cephalon any further and additional relief as this Court deems just and proper.

This 22nd day of September 2011.

Respectfully submitted,

/s/ Abraham Singer

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