LITE DEPALMA GREENBERG, LLC
Allyn Z. Lite
Michael E. Patunas
Mayra V. Tarantino
Two Gateway Center, Suite 1201
Newark, New Jersey 07102
Tel: (973) 623-3000
alite@litedepalma.com
mpatunas@litedepalma.com
mtarantino@litedepalma.com

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
Richard B. Racine
Jill K. MacAlpine
901 New York Ave., N.W.
Washington, D.C. 20001
Tel: (202) 408-4000

Charles E. Lipsey
Two Freedom Square
11955 Freedom Drive
Reston, Virginia 20190
Tel: (571) 203-2700

Mukta Jhalani
3300 Hillview Avenue
Palo Alto, California 94304
Tel: (650) 849-6600

Attorneys for Plaintiff Cephalon, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CEPHALON, INC., Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES LTD. and CARACO PHARMACEUTICAL LABORATORIES LTD., Defendants.	Civil Action No.: 11-5474 (FLW)(DEA) **JURY TRIAL DEMANDED**

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL

Plaintiff, Cephalon, Inc., for its Complaint against Defendants Sun Pharmaceutical Industries, Ltd. and Caraco Pharmaceutical Laboratories Ltd., (collectively, "Defendants"), 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), for a declaratory judgment of infringement under 28 U.S.C. § 2201, and for willful infringement. This action relates to Abbreviated New Drug Application ("ANDA") No. 77-555 filed by Sun Ltd. 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.

THE 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 Caraco Pharmaceutical Laboratories Ltd. ("Caraco") is a subsidiary of Sun Ltd. and is a corporation operating and existing under the laws of Michigan with its principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202.

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 antiepilepsy 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 New Jersey.

7. On information and belief, Sun Ltd., citing Caraco as its agent, filed with the FDA, 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).

9. On information and belief, the FDA has given final approval to Sun Ltd. for ANDA No. 77-555 to market, offer for sale, and sell the Sun Tiagabine Hydrochloride Tablets in the United States.

10. On information and belief, on October 19, 2012, Sun Ltd. and Caraco began marketing, offering to sell, and selling Sun Tiagabine Hydrochloride Tablets in the United States.

JURISDICTION AND VENUE

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

12. 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 Caraco, markets, distributes, and sells generic pharmaceutical products throughout the United States, including New Jersey.

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

14. Personal jurisdiction over Caraco is proper because it purposefully avails itself of the privilege of selling its generic products in the state of New Jersey and can therefore reasonably expect to be subject to jurisdiction in courts in New Jersey. Among other things, upon information and belief, Caraco places goods into the stream of commerce for distribution throughout the United States, including in the state of New Jersey. Upon information and belief, in this judicial district, Caraco enters into contracts, distributes products, derives revenues, and avails itself of the forum in other matters.

15. 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

16. Cephalon realleges and incorporates by reference paragraphs 1-15 of this Complaint as if fully set forth herein.

17. 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.

18. 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.

19. On information and belief, Sun Ltd. citing Caraco as its agent, 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.

20. On information and belief, Sun Ltd. 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 (known as "Paragraph IV Certification"). Sun Ltd. sent Cephalon a letter dated April 15, 2005 ("Notice Letter"), 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.

21. On information and belief, the FDA has given final approval to Sun Ltd. for ANDA No. 77-555 to market, offer for sale, and sell the Sun Tiagabine Hydrochloride Tablets in the United States. Sun Ltd. and Caraco 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 Caraco could not 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 Caraco intended to, and did, 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.

22. Under 35 U.S.C. § 271(e)(2)(A), the submission by Sun Ltd. 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.

23. Without license or authorization, Sun Ltd. and Caraco have been making, using, selling, offering for sale and/or importing into the United States the Sun Tiagabine Hydrochloride Tablets that embody the inventions claimed in the '951 patent, thus infringing one or more claims of the '951 patent. Such acts constitute infringement under at least 35 U.S.C. § 271(a).

24. Sun Ltd. and Caraco were aware of the existence of the ’951 patent, as demonstrated by their reference to that patent in their Notice of Certification, and were aware that the filing of their Paragraph IV Certification with respect to the ’951 patent would constitute infringement of the patent.

25. 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

26. Cephalon realleges and incorporates by reference paragraphs 1-25 of this Complaint as if fully set forth herein.

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

28. On information and belief, on October 19, 2012, Sun Ltd. and Caraco began marketing, offering to sell, and selling Sun Tiagabine Hydrochloride Tablets.

29. 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.

30. There is a real, substantial, and continuing justiciable controversy between Cephalon and Sun Ltd. and Caraco as to liability for the infringement of the ’951 patent claims. The actions of

Sun Ltd. and Caraco have created in Cephalon a reasonable apprehension of imminent harm and loss.

31. 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 III

Willful Infringement of the '951 Patent

32. Cephalon realleges and incorporates by reference paragraphs 1-31 of this Complaint as if fully set forth herein.

33. The actions of Defendants, as alleged herein, resulting in their launch of generic Sun Tiagabine Hydrochloride Tablets in October 2012, prior to the June 10, 2017 expiration of the '951 patent, constitute willful infringement of that patent and make this an exceptional case under the Patent Statutes.

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 Caraco 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 Caraco 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) ordering an accounting to determine the damages to be awarded to Cephalon as a result of Defendants’ infringement;

(7) awarding damages to Cephalon as a result of Defendants’ infringing sales prior to the expiration of the ’951 patent;

(8) finding Defendants’ infringement willful and entering an award of enhanced damages up to three times the amount of actual damages pursuant to 35 U.S.C. § 284.

(9) assessing pre-judgment and post-judgment interest and costs against Defendants, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

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

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

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

JURY DEMAND

Pursuant to Fed. R. Civ. P. Rule 38, Cephalon demands a trial by jury on all claims, counterclaims, and issues so triable.

Dated: February 20, 2013

Respectfully submitted,
LITE DEPALMA GREENBERG, LLC

/s/ Michael E. Patunas
Allyn Z. Lite
Michael E. Patunas
Mayra V. Tarantino
Two Gateway Center, Suite 1201
Newark, New Jersey 07102
Telephone: (973) 623-3000
Facsimile: (973) 877-3872
alite@litedepalma.com
mpatunas@litedepalma.com
mtarantino@litedepalma.com

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
Richard B. Racine
Jill K. MacAlpine
901 New York Avenue, N.W.
Washington, D.C. 20001
Telephone: (202) 408-4000
Facsimile: (202) 408-4400

Charles E. Lipsey
Two Freedom Square
11955 Freedom Drive
Reston, Virginia 20190
Telephone: (571) 203-2700
Facsimile: (202) 408-4400

Mukta Jhalani
3300 Hillview Avenue,
Palo Alto, CA 94304
Telephone: (650) 849-6600
Facsimile: (650) 849-6666

Attorneys for Plaintiff Cephalon Inc.

CERTIFICATE OF SERVICE

I, Michael E. Patunas, hereby certify that on February 20, 2013, I caused a copy of Plaintiff Cephalon, Inc. Second Amended Complaint for Patent Infringement and Demand for Jury Trial to be served on counsel for Defendants through the Court's ECF system and by email.

By: *s/ Michael E. Patunas*
Michael E. Patunas