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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUMITOMO DAINIPPON PHARMA CO., LTD. and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. (collectively, "Sunovion" or "Plaintiffs"), for their Complaint against Defendants Teva Pharmaceutical Industries, Ltd. (hereinafter "Teva Ltd.") and Teva Pharmaceuticals USA, Inc. (hereinafter "Teva USA") (together with Teva Ltd., "Teva" or "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Sumitomo Dainippon Pharma Co., Ltd. is a Japanese corporation, having its primary place of business at 6-8, Doshomachi 2-chome, Chuo-ku, Osaka, Osaka 541-0045, Japan.

2. Plaintiff Sunovion Pharmaceuticals Inc. is a corporation having its principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

3. Upon information and belief, Defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

4. Upon information and belief, Teva USA has appointed Corporate Creations Network Inc., 811 Church Road Suite 105, Cherry Hill, New Jersey, 08002, as its agent in New Jersey authorized to accept service of process for this actions filed in this Judicial District.

5. Upon information and belief, Teva USA has at least three places of business in the State of New Jersey, including, but not limited to, the following business addresses: (1) 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677-7604; (2) 208 Passaic Avenue, Suite 1, Fairfield, New Jersey 07004-3515; and (3) 8 Gloria Lane, Fairfield, New Jersey 07004-3306.

6. Upon information and belief, Defendant Teva USA is a wholly-owned subsidiary and agent of Defendant Teva Ltd.

7. Upon information and belief, Defendant Teva Ltd. is an Israeli corporation having a place of business at 5 Basel Street, P.O. Box 3190, Petah Tikva 49131, Israel.

8. Upon information and belief, Teva Ltd., by itself or through its wholly-owned subsidiary Teva USA, develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District. Upon information and belief, Teva Ltd., by itself or through its wholly-owned subsidiary and agent Teva USA, markets, distributes, and/or sells generic pharmaceutical versions of branded products throughout the United States, including in the State of New Jersey.

JURISDICTION AND VENUE

9. This is a civil action for infringement of United States Patent No. 5,532,372 ("the '372 patent"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

12. This Court has personal jurisdiction over both Teva USA and Teva Ltd. because, *inter alia*, both Teva USA and Teva Ltd. have availed themselves of the legal protections of the State of New Jersey and consented to personal jurisdiction in this Judicial District. *See, e.g.*, *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 15-471 (CCC)(MF) (D.N.J. Jan. 22, 2015); *Teva Pharmaceuticals USA,*

Inc., et al. v. Synthon Pharmaceuticals Inc., et al., Civil Action No. 15-472 (CCC)(MF) (D.N.J. Jan. 22, 2015); *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 14-5672 (MAS)(TJB) (D.N.J. Sept. 11, 2014).

13. This Court also has personal jurisdiction over Defendants because, *inter alia*, Defendants have committed, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey. Defendants sent a Paragraph IV Certification Notice Letter to Sunovion, dated July 13, 2015 ("Notice Letter").

14. Teva's Notice Letter states that Defendants filed Abbreviated New Drug Application ("ANDA") No. 208060 seeking approval from the United States Food and Drug Administration ("FDA") to commercially manufacture, use, market, or sell generic lurasidone hydrochloride tablets 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the '372 patent.

15. This Court also has personal jurisdiction over Defendants because, upon information and belief, *inter alia*: (1) Defendants have affiliations with the State of New Jersey that are pervasive, continuous, and systematic, including the direct marketing, distribution, or sale of generic pharmaceutical drugs within the State of New Jersey and to residents of the State of New Jersey by Defendants; (2) Teva USA is registered to do business in the State of New Jersey under entity ID # 0100250184; (3) Teva USA has at least three places of business in New Jersey; (4) Teva USA is licensed by the State of New Jersey as a "wholesaler" and "manufacturer and wholesaler" of generic pharmaceutical products in New Jersey with License

Nos. 5003436 and 5000583, respectively; (5) Teva Ltd. holds Drug Master File ("DMF") No. 28178 for the active pharmaceutical ingredient in Teva's infringing ANDA products (as defined in Paragraph 22, *infra*), lurasidone hydrochloride; (6) Teva Ltd. controls Teva USA; (7) Teva Ltd. makes its generic drug products available in this State through Teva USA; (8) Defendants maintain a broad distributorship network within this State; (9) Defendants intend to market, sell, and/or distribute Teva's infringing ANDA products; and (10) Defendants enjoy substantial income from sales of its generic pharmaceutical products in this State.

16. Defendants have previously consented and submitted to the jurisdiction of this Court. *See, e.g., Boehringer Ingelheim Pharma GmbH & co. KG, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 14-7811 (MLC)(TJB) (D.N.J. Dec. 15, 2014); *Helsinn Healthcare, S.A., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 14-6341 (MLC)(DEA) (D.N.J. Oct. 13, 2014); *United Therapeutics Corp. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 14-5498 (PGS)(LHG) (D.N.J. Sept. 2, 2014); *Novo Nordisk Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 14-4248 (MAS)(DEA) (D.N.J. July 3, 2014); *Amarin Pharma, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 14-3558 (MLC)(TJB) (D.N.J. Jun. 4, 2014); *Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 11-3962 (MLC)(DEA) (D.N.J. Jul. 8, 2011); *Teva Pharmaceutical Industries ,Ltd., et al. v. Glenmark Generics, Inc. USA, et al.*, Civil Action No. 08-4355 (GEB)(DEA) (D.N.J. Aug. 29, 2008).

17. Alternatively, to the extent the above facts are not found to establish personal jurisdiction over Teva Ltd., this Court may exercise jurisdiction over Teva Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (1) Sunovion's claims arise under federal law; (2) Teva Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts

of any state; and (3) Teva Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

THE PATENT-IN-SUIT

18. Plaintiff Sunovion Pharmaceuticals Inc. holds approved New Drug Application ("NDA") No. 200603, under which the FDA granted approval for 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg lurasidone HCl tablets marketed in the United States under the trade name LATUDA®.

19. The LATUDA® (lurasidone HCl) tablets approved in NDA No. 200603 are indicated for the treatment of (1) depressive episodes associated with Bipolar I Disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate; and (2) the treatment of schizophrenia.

20. Plaintiff Sumitomo Dainippon Pharma Co., Ltd. owns the '372 patent titled "Imide derivatives, and their production and use." The '372 patent was duly and legally issued on July 2, 1996. A copy of the '372 patent is attached as Exhibit A.

21. The '372 patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for LATUDA®.

DEFENDANTS' ANDA AND NOTICE LETTER

22. Upon information and belief, Defendants submitted ANDA No. 208060 ("Teva's ANDA") to the FDA, including a certification with respect to the '372 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use,

sale, or offer for sale within the United States, or importation into the United States, of generic lurasidone hydrochloride tablets 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg (collectively, "ANDA Products") prior to expiration of the '372 patent.

23. Upon information and belief, on or about July 13, 2015, Teva sent its Notice Letter to Plaintiffs. In the Notice Letter, Teva represented that ANDA No. 208060 for the ANDA Products was filed, including a Paragraph IV Certification with respect to the '372 patent, and that Teva sought approval of ANDA No. 208060 prior to the expiration of the '372 patent. Plaintiffs first received Teva's Notice Letter on or about July 14, 2015.

24. Plaintiffs commenced this action within 45 days of the date of receipt of Teva's Notice Letter.

DEFENDANTS' INFRINGEMENT OF THE '372 PATENT

25. Plaintiffs repeat and re-allege paragraphs 1-24 as if fully set forth herein.

26. By seeking approval of its ANDA No. 208060 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Products prior to the expiration of the '372 patent, Defendants have infringed that patent under 35 U.S.C. § 271(e)(2)(A).

27. Defendants are jointly and severally liable for infringement of the '372 patent under 35 U.S.C. § 271(e)(2)(A). This is because, upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of Defendants' ANDA seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA products prior to the expiration of the '372 patent.

28. If Defendants manufacture, use, offer to sell, or sell within the United States, or import into the United States, the ANDA Products prior to the expiration of the '372 patent, Defendants will infringe one or more claims of this patent under 35 U.S.C. § 271(a), (b), or (c).

29. Sunovion is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Defendants' ANDA be a date that is not earlier than the expiration date of the '372 patent, or any later expiration of any patent term extension or exclusivity for the '372 patent to which Sunovion is or becomes entitled.

30. Sunovion is entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell the ANDA Products within the United States, import the ANDA Products into the United States, or induce or contribute to such conduct, Defendants will infringe the '372 patent under 35 U.S.C. § 271(a), (b), or (c).

31. Sunovion will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Sunovion does not have an adequate remedy at law.

PRAYER FOR RELIEF

Sunovion requests that the Court grant the following relief:

A. An Order adjudging and decreeing that Defendants have infringed the '372 patent by submitting Defendants' ANDA to the FDA;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with them, from infringing the

'372 patent by the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product claimed in the '372 patent;

C. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of Defendants' ANDA be a date that is not earlier than the expiration date of the '372 patent, or any later expiration of any patent term extension or exclusivity for the '372 patent to which Sunovion is or becomes entitled;

D. That Sunovion be awarded monetary relief to the extent Defendants commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the '372 patent within the United States prior to the expiration of the '372 patent, including any later expiration of any patent term extension or exclusivity for the patent to which Sunovion is or becomes entitled, and that any such monetary relief be awarded to Sunovion with prejudgment interest;

E. An Order be entered that this case is exceptional, and that Sunovion is entitled to reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

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

Dated: August 24, 2015

Respectfully submitted,

By: s/ Charles M. Lizza

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