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Orion Corporation

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

ORION CORPORATION,

Plaintiff,

v.

SUN PHARMACEUTICAL INDUSTRIES  
LIMITED,

Defendant.

CIVIL ACTION NO.

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, Orion Corporation (hereinafter "Orion"), brings this action for patent infringement against Sun Pharmaceutical Industries Limited (hereinafter "Sun Ltd."). This action concerns a patent relating to the carbidopa/ levodopa / entacapone pharmaceutical, Stalevo<sup>®</sup>, a prescription drug used in the treatment of Parkinson's Disease.

### **THE PARTIES**

1. Plaintiff Orion is a corporation organized and existing under the laws of Finland, having an office and principal place of business at Orionintie 1, FI-02200 Espoo, Finland. Orion is engaged in the business of research, development, and sale of pharmaceutical products. These products are sold throughout the world, including the United States and the State of New Jersey.
2. Upon information and belief, Sun Ltd. is a public limited liability company incorporated and existing under the laws of India and having a principal place of business located at Acme Plaza, Andheri- Kurla Road, Andheri (East), Mumbai 400059, Maharashtra, India.

### **JURISDICTION AND VENUE**

3. This action for patent infringement arises under the United States Patent Laws, Title 35, United States Code, including 35 U.S.C. §§ 271 (a), (b), (c), and (e), and §§ 281-285. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), (c), and (d), and §1400(b).

4. Upon information and belief, Sun Ltd. manufactures generic pharmaceuticals, which are marketed throughout the United States, including the State of New Jersey.
5. Personal jurisdiction over Sun Ltd. is proper because it maintains such minimum contacts with the State of New Jersey as would cause it to reasonably expect to be haled into Court 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 New Jersey, and conducts business at its Cranbury, New Jersey manufacturing facility, which, upon information and belief, is owned by Sun Ltd.

#### **FACTUAL BACKGROUND**

6. United States Patent No. 5,446,194 (“the ‘194 patent”) for PHARMACOLOGICALLY ACTIVE CATECHOL DERIVATIVES was duly and legally issued to Orion-yhtymä Oy, Espoo, Finland, by the United States Patent and Trademark Office on August 29, 1995. The ‘194 patent is presently owned by Orion. A copy of the ‘194 patent is attached hereto as Exhibit A.
7. Orion is the holder of a New Drug Application approved by the United States Food and Drug Administration (“FDA”) for the use of entacapone, levodopa, and carbidopa in the treatment of Parkinson’s Disease.
8. Orion, through its partner Novartis, sells Stalevo<sup>®</sup> in the United States. Stalevo<sup>®</sup> is a combination of carbidopa, levodopa, and entacapone approved by the FDA for the treatment of Parkinson’s disease.

9. Upon information and belief, Sun Ltd., through its U.S. agent, has filed with the FDA, in Rockville, Maryland, an Abbreviated New Drug Application (“ANDA”) under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, importation, and sale of carbidopa, levodopa and entacapone tablets for the treatment of Parkinson’s disease. Upon information and belief, Sun Ltd. filed the ANDA, assigned ANDA number 79-085, to obtain approval to market a generic version of carbidopa, levodopa, and entacapone before the expiration of the ‘194 patent.
10. Upon information and belief, Sun Ltd. has submitted an amendment to the FDA, on December 26, 2007, to include in the aforesaid ANDA a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging, *inter alia*, that the claims of the ‘194 patent are either invalid or will not be infringed.
11. Counsel for Sun Ltd. sent a letter dated December 26, 2007, to Orion to notify Orion that Sun Ltd. had filed an ANDA for carbidopa, levodopa and entacapone tablets and was providing Orion with information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Orion received the letter on or about December 28, 2007.
12. Upon information and belief, Sun Ltd.’s tablets will have the same indications and dosage instructions as those contained in the FDA-approved Stalevo® tablet product package insert.

**COUNT I**

**PATENT INFRINGEMENT OF THE ‘194 PATENT**

13. Paragraphs 1-12 are incorporated herein by reference.

14. Under 35 U.S.C. § 271(e)(2)(A), Sun Ltd. infringed one or more claims of the '194 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '194 patent, of carbidopa, levodopa and entacapone tablets, a product the manufacture, importation, use, or sale of which would infringe one or more claims of the '194 patent.
15. Upon information and belief, Sun Ltd. will also induce or contribute to infringement of one or more claims of the '194 patent by actively aiding, abetting, encouraging, and inducing, upon FDA approval, the sale of such a carbidopa, levodopa and entacapone tablet product together with instructions and labeling which will result in direct infringement of one or more claims of the '194 patent by ultimate purchasers.
16. Orion will be substantially and irreparably damaged and harmed if Sun Ltd.'s infringement is not enjoined. Orion does not have an adequate remedy at law.

**COUNT II**

**DECLARATORY JUDGMENT IN FAVOR OF THE '194 PATENT**

17. Paragraphs 1-16 are incorporated herein by reference.
18. Upon information and belief, Sun Ltd. has made substantial preparations to sell carbidopa, levodopa and entacapone tablets labeled for the same indications and the same dosage and method of use as the Stalevo<sup>®</sup> product sold by Orion.

19. Upon further information and belief, Sun Ltd. further intends to commence sales of such carbidopa, levodopa and entacapone tablets immediately upon receiving approval from the FDA.
20. The manufacture, importation, sale, and offer for sale of carbidopa, levodopa and entacapone tablets so labeled, once approved by the FDA, will directly infringe, induce and/or contribute to infringement of one or more claims of the '194 patent under 35 U.S.C. § 271 (a), (b), and/or (c).
21. Orion will be substantially and irreparably damaged and harmed if Sun Ltd.'s threatened infringement is not enjoined. Orion does not have an adequate remedy at law.

**COUNT III**

**EXCEPTIONAL CASE**

22. Paragraphs 1-21 are incorporated herein by reference.
23. Sun Ltd. has proceeded with its unlawful activities despite knowledge of the '194 patent under 35 U.S.C. § 284.
24. This is an exceptional case warranting imposition of attorney fees against Sun Ltd. under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

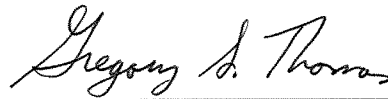
WHEREFORE, Orion respectfully requests this Court to enter judgment against Sun Ltd. as follows:

- (a) finding that Sun Ltd. has infringed one or more claims of the '194 patent by filing the aforesaid ANDA relating to Sun Ltd.'s carbidopa, levodopa and entacapone tablets;
- (b) prohibiting any approval by the FDA of Sun Ltd.'s aforesaid carbidopa, levodopa and entacapone tablets on any effective date prior to the date of expiration of the '194 patent, or such later date as the Court may determine;
- (c) declaring that Sun Ltd. will infringe one or more claims of the '194 patent if Sun Ltd.'s aforesaid ANDA relating to carbidopa, levodopa and entacapone tablets is approved and the approved product is sold and used in the United States;
- (d) enjoining Sun Ltd., its officers, agents, attorneys, and employees, and those acting in privity or concert with it, from the commercial manufacture, use, importation, or sale of a carbidopa, levodopa and entacapone tablet product labeled for use in treating Parkinson's disease until the expiration of the '194 patent;
- (e) finding that this is an exceptional case and granting Orion reasonable attorney fees pursuant to 35 U.S.C. § 285; and

(f) awarding Orion any further and additional relief as this Court deems just and proper.

Dated: February 7, 2008

Respectfully submitted,



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