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Attorneys for Plaintiff  
Orion Corporation

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

ORION CORPORATION,

Plaintiff,

v.

SUN PHARMACEUTICAL INDUSTRIES  
INC., and SUN PHARMACEUTICAL  
INDUSTRIES LIMITED,

Defendants.

CIVIL ACTION NO.

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, Orion Corporation (hereinafter "Orion"), brings this action for patent infringement against Sun Pharmaceutical Industries Inc. and Sun Pharmaceutical Industries Limited (hereinafter collectively "Defendants"). This action concerns a patent relating to the entacapone/ levodopa/ carbidopa 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 Pharmaceutical Industries Limited (hereinafter "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.
3. Upon information and belief, Sun Pharmaceutical Industries Inc. (hereinafter "Sun Inc.") is a Michigan corporation and is a wholly-owned subsidiary of Sun Ltd. The website for Sun Ltd. confirms that Sun Inc. conducts business in the State of New Jersey at its offices located at 270 Prospect Plains Road, Cranbury, New Jersey 08512.

### JURISDICTION AND VENUE

4. 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).
5. Upon information and belief, Sun Ltd. manufactures generic pharmaceuticals, which are marketed throughout the United States, including the State of New Jersey.
6. 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.
7. Personal jurisdiction over Sun Inc. is proper because Sun Inc. has purposely availed itself of the privilege of doing business in this State by registering to do business in New Jersey, and Sun Inc. maintains such continuous and systematic contacts with the state as to reasonably allow jurisdiction to be exercised over it.

**FACTUAL BACKGROUND**

8. United States Patent No. 6,500,867 (“the ‘867 patent”) for PHARMACEUTICAL COMPOSITION COMPRISING ENTACAPONE, LEVODOPA, AND CARBIDOPA was duly and legally issued to Orion Corporation by the United States Patent and Trademark Office on December 31, 2002. The ‘867 patent is presently owned by Orion. A copy of the ‘867 patent is attached hereto as Exhibit A.
9. 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.
10. 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.
11. Upon information and belief, Sun Ltd., through its agent, Sun Inc., 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 ‘867 patent.

12. Upon information and belief, Sun Ltd. also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging, *inter alia*, that the claims of the '867 patent is either invalid, unenforceable, or not infringed.
13. Counsel for Sun Ltd. sent a letter dated September 27, 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 October 1, 2007.
14. Upon information and belief, Sun Ltd.'s tablets will have the same indications and dosage instructions as those contained in the FDA-approved Stalevo<sup>®</sup> tablet product package insert.

### **COUNT I**

#### **PATENT INFRINGEMENT OF THE '867 PATENT**

15. Paragraphs 1-15 are incorporated herein by reference.
16. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed one or more claims of the '867 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '867 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 '867 patent.
17. Upon information and belief, Defendants will also induce or contribute to infringement of one or more claims of the '867 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 '867 patent by ultimate purchasers.

18. Orion will be substantially and irreparably damaged and harmed if Defendants' infringement is not enjoined. Orion does not have an adequate remedy at law.

## **COUNT II**

### **DECLARATORY JUDGMENT IN FAVOR OF THE '867 PATENT**

19. Paragraphs 1-18 are incorporated herein by reference.
20. Upon information and belief, Defendants have 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.
21. Upon further information and belief, Defendants further intend to commence sales of such carbidopa, levodopa and entacapone tablets immediately upon receiving approval from the FDA.
22. 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 '867 patent under 35 U.S.C. § 271 (a), (b), and/or (c).

23. Orion will be substantially and irreparably damaged and harmed if Defendants' threatened infringement is not enjoined. Orion does not have an adequate remedy at law.

**COUNT III**

**EXCEPTIONAL CASE**

24. Paragraphs 1-23 are incorporated herein by reference.

25. Defendants have proceeded with their unlawful activities despite knowledge of the '867 patent under 35 U.S.C. § 284.

26. This is an exceptional case warranting imposition of attorney fees against Defendants under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Orion respectfully request this Court to enter judgment against Defendants as follows:

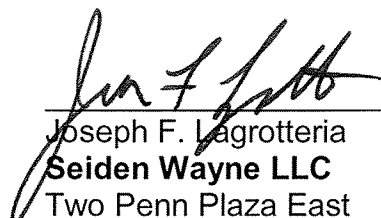
- (a) finding that Defendants have infringed one or more claims of the '867 patent by filing the aforesaid ANDA relating to Sun Ltd.'s carbidopa, levodopa and entacapone tablets;
- (b) prohibiting any approval by the FDA of Defendants' aforesaid carbidopa, levodopa and entacapone tablets on any effective date prior to the date of expiration of the '867 patent, or such later date as the Court may determine;
- (c) declaring that Defendants will infringe one or more claims of the '867 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 Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them or any of them, 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 '867 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: November 13, 2007

Respectfully submitted,

  
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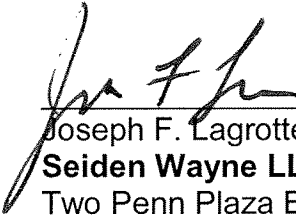
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Orion Corporation

**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

I hereby certify pursuant to Local Civil Rule 11.2 that this matter in controversy is not the subject of any other action pending in any court, arbitration or administrative proceeding.

Dated: November 13, 2007

  
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