

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ORION CORPORATION,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C.A. No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, Orion Corporation (hereinafter “Orion”), brings this action for patent infringement against Mylan Pharmaceuticals Inc. (hereinafter “Mylan”). This action concerns a patent relating to the pharmaceutical entacapone, Comtan<sup>®</sup>, a prescription drug used in the treatment of Parkinson’s disease as an adjunct to levodopa/carbidopa therapy.

**THE PARTIES**

1. Plaintiff Orion is a Finnish company having an office and principal place of business at Orionintie 1A, 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 in the United States and the State of Delaware.

2. Upon information and belief, Mylan is a wholly-owned subsidiary of Mylan Inc., and has a principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505.

3. Upon information and belief, Mylan is in the business of, among other things, manufacturing, marketing, distributing, and selling generic pharmaceutical products throughout the United States, including in the State of Delaware.

**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 judicial district under 28 U.S.C. §§ 1391(b), (c), and (d), and § 1400(b).

5. This Court has personal jurisdiction over Mylan because it purposefully avails itself of the privilege of selling its generic pharmaceutical products in the State of Delaware and can therefore reasonably expect to be subject to jurisdiction in the Delaware Courts. Among other things, upon information and belief, Mylan has expressly consented to jurisdiction by registering to do business in the State of Delaware and appointing an agent in Delaware for service of process (Exhibit A), and Mylan has marketing and sales activities in the State of Delaware, including but not limited to the distribution, marketing, and/or sales of generic pharmaceutical products to Delaware residents that are continuous and systematic. Moreover, upon information and belief, Mylan has invoked the benefits and protections afforded by the State of Delaware by bringing at least two lawsuits in this Court.

**BACKGROUND**

6. United States Patent No. 5,446,194 (“the ’194 patent”), entitled PHARMACOLOGICALLY ACTIVE CATECHOL DERIVATIVES, was duly and legally issued to Orion-yhtymä Oy 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 B.

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 in the treatment of Parkinson’s disease as an adjunct to levodopa/carbidopa therapy.

8. Orion, through its partner Novartis, sells Comtan<sup>®</sup>, an entacapone-based product approved by the FDA for use in the treatment of Parkinson’s disease, in the United States.

9. Upon information and belief, Mylan has filed with the FDA 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 entacapone 200 mg tablets for the treatment of Parkinson’s disease. Upon information and belief, Mylan filed the ANDA, assigned ANDA No. 202394, to obtain approval to market a generic version of entacapone before the expiration of the ’194 patent.

10. Upon information and belief, Mylan 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 ’194 patent are invalid, unenforceable, and/or will not be infringed.

11. Counsel for Mylan sent a letter (“the Notice Letter”), dated December 13, 2010, to Orion to notify Orion that Mylan had filed an ANDA for entacapone 200 mg 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 14, 2010.

12. The Notice Letter contained no allegation of non-infringement for one or more claims of the ’194 patent.

13. Upon information and belief, Mylan's package insert will have the same indications and dosage instructions as those contained in the FDA-approved Comtan<sup>®</sup> tablet product package insert.

**COUNT I**

**INFRINGEMENT OF THE '194 PATENT**

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

15. Under 35 U.S.C. § 271(e)(2)(A), Mylan 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 entacapone 200 mg tablets, a product the manufacture, importation, use, or sale of which would infringe one or more claims of the '194 patent.

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

**COUNT II**

**DECLARATORY JUDGMENT ON THE '194 PATENT**

17. Paragraphs 1-16 are incorporated herein by reference.

18. Upon information and belief, Mylan has made substantial preparations to sell entacapone 200 mg tablets labeled for the same indications and the same dosage and method of use as the Comtan<sup>®</sup> product sold by Orion.

19. Upon further information and belief, Mylan further intends to commence sales of such entacapone 200 mg tablets immediately upon receiving approval from the FDA.

20. The manufacture, importation, sale, and offer for sale of entacapone 200 mg tablets so labeled, if 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 Mylan'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. Mylan has proceeded with its unlawful activities with knowledge of the '194 patent.

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

#### **PRAYER FOR RELIEF**

WHEREFORE, Orion respectfully requests this Court to enter judgment against Mylan as follows:

(a) finding that Mylan has infringed one or more claims of the '194 patent by filing the aforesaid ANDA relating to Mylan's entacapone 200 mg tablets;

(b) ordering that any approval by the FDA of Mylan's aforesaid entacapone 200 mg tablets be not earlier than the date of expiration of the '194 patent;

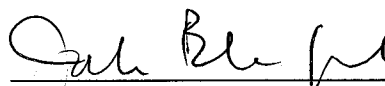
(c) declaring that Mylan will infringe one or more claims of the '194 patent if Mylan's aforesaid ANDA relating to entacapone 200 mg tablets is approved and the approved product is sold and used in the United States;

(d) enjoining Mylan, its 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 an entacapone 200 mg 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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Jack B. Blumenfeld (#1014)  
Maryellen Noreika (#3208)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200  
jblumenfeld@mnat.com  
mnoreika@mnat.com

*Attorneys for Plaintiff*

OF COUNSEL:

Charles E. Lipsey  
FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, LLP.  
Two Freedom Square  
11955 Freedom Drive  
Reston, Virginia 20190-5675  
(571) 203-2700

Susan Haberman Griffen  
Bryan C. Diner  
FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, LLP.  
901 New York Avenue, N.W.  
Washington, D.C. 20001-4413  
(202) 408-4000

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