

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

ORION CORPORATION,

Plaintiff,

v.

WOCKHARDT USA, INC. a/k/a
WOCKHARDT USA LLC and
WOCKHARDT LIMITED,

Defendants.

CIVIL ACTION NO.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Orion Corporation (hereinafter “Orion”), brings this action for patent infringement against Wockhardt USA, Inc. a/k/a Wockhardt USA LLC and Wockhardt Limited (hereinafter collectively “Defendants”). This action concerns three patents relating to the carbidopa/ levodopa/ entacapone pharmaceutical, Stalevo[®], a prescription drug used in the treatment of Parkinson’s disease.

JURISDICTION AND PARTIES

1. Plaintiff Orion is a Finnish company 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.

2. Upon information and belief, Wockhardt Limited (hereinafter “Wockhardt”) is an Indian company and maintains an office at Bandra (East), Mumbai, Maharashtra 400 051, India.
3. Upon information and belief, Wockhardt USA, Inc. a/k/a Wockhardt USA LLC (hereinafter “Wockhardt USA”) is a Delaware corporation and is a wholly-owned subsidiary of Wockhardt EU Operations (Swiss) AG, which, in turn, is a wholly-owned subsidiary of Wockhardt. The website for Wockhardt USA lists an office at 135 Route 202/206, Bedminster, New Jersey 07921.
4. Wockhardt is Defendant and Counterclaim Plaintiff in Civil Action No. 07-550-GMS-LPS and is Defendant in Civil Action No. 08-917-UNA in this Court with Plaintiff Orion regarding an entacapone product.
5. Wockhardt USA is Defendant and Counterclaim Plaintiff in Civil Action No. 07-550-GMS-LPS and is Defendant in Civil Action No. 08-917-UNA in this Court with Plaintiff Orion regarding an entacapone product.
6. Personal jurisdiction over Wockhardt is proper because Wockhardt has consented to personal jurisdiction for the purpose of this litigation in this Court.
7. Personal jurisdiction over Wockhardt USA is proper because Wockhardt USA has consented to personal jurisdiction for the purpose of this litigation in this Court.
8. 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 because both Wockhardt and Wockhardt USA have agreed to venue in this Court for the purpose of this litigation.

FACTUAL BACKGROUND

9. United States Patent No. 5,446,194 (“the ‘194 patent”) for 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 A.

10. United States Patent No. 5,135,950 (“the ‘950 patent”) for STABLE POLYMORPHIC FORM OF (E)-N,N-DIETHYL-2-CYANO-3-(3,4-DIHYDROXY-5-NITROPHENYL)ACRYLAMIDE AND THE PROCESS FOR ITS PREPARATION was duly and legally issued to Orion-yhtymä Oy by the United States Patent and Trademark Office on August 4, 1992. The ‘950 patent is presently owned by Orion. A copy of the ‘950 patent is attached hereto as Exhibit B.

11. 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 C.

12. Orion is the holder of a New Drug Application approved by the United States Food and Drug Administration (“FDA”) for the use of carbidopa, levodopa, and entacapone tablets in the treatment of Parkinson’s disease.
13. Orion, through its partner Novartis, sells Stalevo[®] in the United States. Stalevo[®] is a combination of carbidopa, levodopa, and entacapone approved by the FDA for the treatment of Parkinson’s disease.
14. Upon information and belief, Wockhardt, through its agent, Wockhardt USA, 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, Wockhardt filed the ANDA, assigned ANDA number 90-833, to obtain approval to market a generic version of carbidopa, levodopa and entacapone before the expiration of the ‘194, the ‘950, or the ‘867 patent.
15. Upon information and belief, Wockhardt also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), certifications alleging, *inter alia*, that the claims of the ‘950, ‘194, and ‘867 patents are either invalid, unenforceable, or not infringed.
16. Counsel for Wockhardt sent a letter dated December 8, 2008, to Orion to notify Orion that Wockhardt had filed an ANDA for carbidopa, levodopa and entacapone tablets and was providing Orion with information pursuant to 355(j)(2)(B)(ii). Orion received the letter on or about December 10, 2008.

17. Upon information and belief, Wockhardt'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

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

19. Under 35 U.S.C. § 271(e)(2)(A), Defendants 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.

20. Upon information and belief, Defendants 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.

21. 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

PATENT INFRINGEMENT OF THE '950 PATENT

22. Paragraphs 1-21 are incorporated herein by reference.

23. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed one or more claims of the '950 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '950 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 '950 patent.

24. Upon information and belief, Defendants will also induce or contribute to infringement of one or more claims of the '950 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 '950 patent by ultimate purchasers.

25. 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 III

PATENT INFRINGEMENT OF THE '867 PATENT

26. Paragraphs 1-25 are incorporated herein by reference.

27. 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.

28. 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.

29. 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 IV

DECLARATORY JUDGMENT IN FAVOR OF THE '194 PATENT

30. Paragraphs 1-29 are incorporated herein by reference.

31. 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[®] product sold by Orion.

32. 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.

33. The manufacture, importation, use, 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).

34. 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 V

DECLARATORY JUDGMENT IN FAVOR OF THE '950 PATENT

35. Paragraphs 1-34 are incorporated herein by reference.

36. 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[®] product sold by Orion.

37. 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.

38. The manufacture, importation, use, 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 '950 patent under 35 U.S.C. § 271 (a), (b), and/or (c).

39. 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 VI

DECLARATORY JUDGMENT IN FAVOR OF THE '867 PATENT

40. Paragraphs 1-39 are incorporated herein by reference.

41. 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[®] product sold by Orion.

42. 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.

43. The manufacture, importation, use, 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).

44. 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 VII
EXCEPTIONAL CASE

45. Paragraphs 1-44 are incorporated herein by reference.

46. Defendants have proceeded with their unlawful activities despite knowledge of the '194, '950, and '867 patents under 35 U.S.C. § 284.

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

PRAYER FOR RELIEF

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

- (a) finding that Defendants have infringed one or more claims of the '194, '950, and '867 patents by filing the aforesaid ANDA relating to Wockhardt'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 latest to expire of the '194, the '950, or the '867 patent, or such later date as the Court may determine;
- (c) declaring that Defendants will infringe one or more claims of the '194, '950, and '867 patents if Defendants' 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 '194, '950, and '867 patents;
- (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: January 15, 2009

/s/ Richard K. Herrmann
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