IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS SOLUTIONS INC., BAYER INTELLECTUAL PROPERTY GMBH, and BAYER PHARMA AG,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
PADDOCK LABORATORIES, LLC and PERRIGO COMPANY,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Endo Pharmaceuticals Solutions Inc., Bayer Intellectual Property GmbH, and Bayer Pharma AG bring this Complaint for patent infringement against Defendants Paddock Laboratories, LLC and Perrigo Company, and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and, more particularly, 35 U.S.C. §§ 271(b), 271(e)(2) and 281. This action relates to the Abbreviated New Drug Application ("ANDA") No. 207583, filed by Paddock, with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Endo's Aveed® drug product prior to the expiration of U.S. Patent Nos. 7,718,640 and 8,338,395.

PARTIES

2. Plaintiff Endo Pharmaceuticals Solutions Inc. ("Endo") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

3. Plaintiff Bayer Intellectual Property GmbH ("BIP") is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Alfred-Nobel-Straße 10, 40789 Monheim am Rhein, Germany.

4. Plaintiff Bayer Pharma AG ("Bayer Pharma"), is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstraße 178, 13353 Berlin, Germany.

5. On information and belief, Defendant Paddock Laboratories, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 3940 Quebec Avenue N, Minneapolis, Minnesota 55427.

6. On information and belief, Defendant Perrigo Company is a corporation organized and existing under the laws of the State of Michigan, with a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

7. On information and belief, Perrigo Company owns Paddock Laboratories, LLC.

8. On information and belief, Paddock Laboratories, LLC and Perrigo Company acted in concert to prepare and submit ANDA No. 207583 to the FDA.

9. On information and belief, Defendant Perrigo Company participated in, assisted, and cooperated with Defendant Paddock Laboratories, LLC in all of the acts complained of herein. Hereinafter, Defendants Perrigo Company and Paddock Laboratories, LLC are collectively referred to as "Defendants."

10. On information and belief, Paddock Laboratories, LLC and Perrigo Company will act in concert to distribute and sell Defendants' testosterone injection product under ANDA No. 207583 (Defendants' "ANDA Product") throughout the United States, including within Delaware. On information and belief, Paddock Laboratories, LLC and Perrigo Company know

and intend that Defendants' ANDA Product for ANDA No. 207583 will be distributed and sold in the United States, including within Delaware.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Defendant Paddock Laboratories, LLC due to its organization in the state of Delaware.

13. This Court has personal jurisdiction over Defendant Perrigo Company by virtue of, inter alia, the fact that it regularly transacts and solicits business in Delaware and has purposefully availed itself of this forum such that it should reasonably anticipate being haled into Court here.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND

15. Endo Pharmaceuticals Solutions Inc. is the holder of approved New Drug Application ("NDA") No. N022219, for Aveed®. Aveed® contains, as an active ingredient, testosterone undecanoate. Aveed® has been approved by the FDA to restore and maintain physiologically acceptable testosterone concentrations in patients suffering from hypogonadism.

16. Aveed® is sold in the United States by Endo as a series of 3-mL (750 mg) intramuscular injections given at initiation, at four weeks, and then every 10 weeks thereafter. Aveed® is an intramuscular injection comprising testosterone undecanoate in a vehicle of castor oil and a co-solvent.

17. On information and belief, Defendants submitted to the FDA ANDA No. 207583 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic version of Endo's Aveed®.

18. On information and belief, the method of administering the product that is the subject of Defendants' ANDA is as a series of 3-mL (750 mg) intramuscular injections given at initiation, at four weeks, and then every 10 weeks thereafter. On information and belief, the composition of the product that is the subject of Defendants' ANDA is for an intramuscular injection comprising testosterone undecanoate in a vehicle of castor oil and a co-solvent.

19. On information and belief, on or about October 8, 2014, Defendants sent a Notice Letter to Plaintiff BIP, and Endo Pharmaceuticals Inc., purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto. Endo Pharmaceuticals Inc. is the parent company of Endo Pharmaceuticals Solutions Inc.

20. The patents-in-suit are United States Patent Nos. 7,718,640 ("the '640 patent") (attached as Exhibit 1) and 8,338,395 ("the '395 patent") (attached as Exhibit 2). Inventors Doris Hubler, Sabine Fricke, Jan-Peter Ingwersen, and Wilhelm Kuhnz filed their application for the '640 patent on March 12, 2004 and for the '395 patent on February 24, 2009. The '640 patent was issued on May 18, 2010. The '395 patent was issued on December 25, 2012. BIP is the current owner of the '640 and '395 patents.

21. Bayer Pharma is the exclusive licensee of the '640 and '395 patents. Endo is the exclusive sublicensee of the '640 and '395 patents in the United States for the field of treatment of hypogonadism.

22. Endo markets Aveed® in the United States under Bayer Pharma's exclusive license.

CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES PATENT NO. 7,718,640

23. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

24. The '640 patent covers Endo's Aveed® intramuscular testosterone undecanoate injections and has been listed for the product in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

25. On information and belief, Defendants submitted their ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product before the expiration of the '640 patent.

26. On information and belief, Defendants made and included in their ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in their opinion, the '640 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product.

27. In its Notice Letter, Paddock Laboratories, LLC did not allege that Defendants' ANDA Product would not infringe claims 1-2, 4-9, or 11-14 of the '640 Patent.

28. On information and belief, Defendants' ANDA Product infringes one or more claims of the '640 patent.

29. By filing their ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product before the expiration of the '640 patent, Defendants have committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product will also infringe one or more claims of the '640 patent.

30. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Defendants' ANDA shall be a date which is not earlier than March 14, 2027, the current expiration date of the '640 patent, or any later date of exclusivity to which Plaintiffs become entitled.

31. On information and belief, when Defendants filed their ANDA, they were aware of the '640 patent and were aware that the filing of their ANDA with the request for its approval prior to the expiration of the '640 patent constituted an act of infringement of the '640 patent.

32. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES PATENT NO. 8,338,395

33. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

34. The '395 patent covers the FDA-approved method for administering Endo's Aveed® intramuscular testosterone undecanoate injections and has been listed for the product in the Orange Book.

35. On information and belief, Defendants submitted their ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product before the expiration of the '395 patent.

36. On information and belief, Defendants made and included in their ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in their opinion, the '395 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product.

37. On information and belief, Defendants' ANDA Product infringes one or more claims of the '395 patent.

38. In its Notice Letter, Paddock Laboratories, LLC did not allege that Defendants' ANDA Product would not infringe claims 1-4, 6, 7, and 10-22 of the '395 Patent, except by reference to an inapplicable defense that its allegedly good-faith invalidity defense absolves it of infringement liability under 35 U.S.C. § 271(b).

39. On information and belief, Defendants have notice of the '395 patent and know or should know that use of Defendants' ANDA Product will infringe one or more claims of the '395 patent. On further information and belief, Defendants will provide labeling for Defendants' ANDA Product that will instruct doctors and patients to utilize that Product in a way that will infringe one or more claims of the '395 patent, and in so labeling the Product intend to actively induce users to infringe one or more claims of the '395 patent.

40. By filing their ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product before the expiration of the '395 patent, Defendants have committed an act of infringement under 35 U.S.C. § 271(e)(2).

41. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Defendants' ANDA shall be a date which is not earlier than February 27, 2026, the current expiration date of the '395 patent, or any later date of exclusivity to which Plaintiffs become entitled.

42. On information and belief, when Defendants filed their ANDA, they were aware of the '395 patent and were aware that the filing of their ANDA with the request for its approval prior to the expiration of the '395 patent constituted an act of infringement of the '395 patent.

43. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed one or more claims of the '640 and '395 patents by filing their ANDA relating to Defendants' ANDA Product containing testosterone undecanoate;

B. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' ANDA Product prior to the expiration dates of the '640 and '395 patents or any later dates of exclusivity to which Plaintiffs become entitled;

C. An order that the effective date of any approval of Defendants' ANDA relating to Defendants' ANDA Product containing testosterone undecanoate be a date which is not earlier than the expiration dates of the '640 and '395 patents or any later dates of exclusivity to which Plaintiffs become entitled;

D. A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Defendants' ANDA Product, or any product that infringes the '640 patent or '395 patent, prior to the expiration date of the '640 patent or '395 patent or any later dates of exclusivity to which Plaintiffs become entitled, will infringe and actively induce infringement by others of the '640 patent or '395 patent;

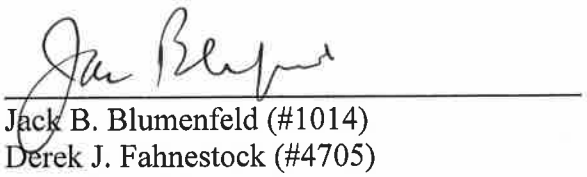
E. Damages from Defendants for any commercial activity constituting infringement of the '640 and '395 patents;

F. A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;

G. An award of Plaintiffs' costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



Jack B. Blumenfeld (#1014)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mant.com
dfahnestock@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Adam K. Mortara
J. Scott McBride
Nevin Gewertz
Faye E. Paul
BARTLIT BECK HERMAN PALENCHAR
& SCOTT LLP
54 West Hubbard Street
Suite 300
Chicago, IL 60654
(312) 494-4400

November 20, 2014