

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ENDO PHARMACEUTICALS INC.,
Plaintiff,

v.

PAR PHARMACEUTICAL COMPANIES,
INC., and PAR PHARMACEUTICAL, INC.
Defendants.

C.A. No. 1:13-cv-3284

**DEFENDANTS PAR PHARMACEUTICAL COMPANIES, INC.’S
AND PAR PHARMACEUTICAL, INC.’S ANSWER, SEPARATE DEFENSES, AND
PAR PHARMACEUTICAL, INC.’S COUNTERCLAIMS**

Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (together, “Par”), by and through their attorneys, for their Answer to the Complaint of Plaintiff Endo Pharmaceuticals Inc. (“Endo”), hereby declare as follows:

PARTIES

1. Par is without knowledge and information sufficient to form a belief as to the location of organization and existence, principal place of business, nature of business, marketing profile, and product distribution information of Endo Pharmaceuticals Inc. Par thus denies the allegations of Paragraph 1.

2. Par admits that Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business located at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

3. Par avers that Par Pharmaceutical Companies, Inc. is a pharmaceutical company engaged in developing, manufacturing, and distributing, *inter alia*, generic pharmaceutical products throughout the United States, including in this judicial district. Par denies the remaining allegations of Paragraph 3.

4. Par admits that Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business located at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

5. Par avers that Par Pharmaceutical, Inc. is wholly owned by Sky Growth Holdings Corporation. Par denies the remaining allegations of Paragraph 5.

6. Par denies the allegations of Paragraph 6.

NATURE OF ACTION

7. Paragraph 7 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that the Complaint purports to be an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.* Par denies the remaining allegations of Paragraph 7.

JURISDICTION AND VENUE

8. Paragraph 8 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Endo purports to base subject matter jurisdiction on 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Paragraph 9 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Endo purports to base venue on 28 U.S.C. §§ 1391(b) and 1400(b).

10. Paragraph 10 states legal conclusions to which no response is required. To the extent a response is required, Par denies that it engaged in tortious conduct in the State of New York that has led to harm to Plaintiff. Par denies the remaining allegations of Paragraph 10.

11. Par admits that Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. are registered with the New York State Department of State as corporations. Par denies the remaining allegations of Paragraph 11.

12. Par denies the allegations of Paragraph 12.

13. Par states that Par Pharmaceutical Companies, Inc.'s website is self-evident with respect to its content.

14. Par admits that after Abbreviated New Drug Application ("ANDA") No. 20-0792's approval by the Food and Drug Administration ("FDA"), it may distribute and sell the product as described the ANDA (the "ANDA Product") in this judicial district. Par denies the remaining allegations of Paragraph 14.

15. Paragraph 15 states a legal conclusion to which no response is required.

16. Par states that its website is self-evident with respect to the products it has manufactured and sold. Par denies the remaining allegations of Paragraph 16.

17. Par admits that Par Pharmaceutical Companies, Inc. is registered with the New York State Department of State as an active corporation.

18. Par admits that Par Pharmaceutical, Inc. is registered as a Pharmacy Establishment in the State of New York, by the New York State Department of Education Office of the Professions, under Registration Nos. 027015, 029055, and 101405 through November 30, 2013, July 31, 2014, and October 31, 2015, respectively. Par denies the remaining allegations of Paragraph 18.

19. Paragraph 19 states a conclusion related to future events to which Par is unable to confirm.

20. Paragraph 20 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 20.

21. Paragraph 21 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 21.

FACTUAL BACKGROUND

Endo's OPANA[®] ER CRF NDA

22. Par admits that New Drug Application (“NDA”) No. 21-610 was approved on June 22, 2006 and lists Endo as the applicant. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 22 and thus denies the same.

23. Par admits that Supplemental New Drug Application (“sNDA”) No. 201655 was approved on December 9, 2011 and lists Endo as the applicant. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 23 and thus denies the same.

24. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 24 and thus denies the same.

25. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 25 and thus denies the same.

26. Par avers that OPANA[®] ER is indicated for relief of moderate to severe pain. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 26 and thus denies the same.

ENDO'S PATENTS

27. Par admits that US Patent No. 7,851,482 (the “482 patent”), on its face, is titled “Method for Making Analgesics,” and lists its date of issue as December 14, 2010. Par admits

that the '482 patent, on its face, identifies Jen-Sen Dung, Erno M. Keskeny, and James J. Mencil as its inventors, and Johnson Matthey Public Limited Company as its assignee. Par further admits that what appears to be a copy of the '482 patent is attached to the Complaint as Exhibit A. Par denies that the United States Patent and Trademark Office duly and legally issued the '482 patent and the remaining allegations of Paragraph 27.

28. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 28 and thus denies the same.

29. Par admits that US Patent No. 8,309,122 (the "'122 patent"), on its face, is titled "Oxymorphone Controlled Release Formulations," and lists its date of issue as November 13, 2012. Par admits that the '122 patent, on its face, identifies Huai-Hung Kao, Anand R. Baichwal, Troy McCall, and David Lee as its inventors, and Endo Pharmaceuticals, Inc. as its assignee. Par further admits that what appears to be a copy of the '122 patent is attached to the Complaint as Exhibit B. Par denies that the United States Patent and Trademark Office duly and legally issued the '122 patent and the remaining allegations of Paragraph 29.

30. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 30 and thus denies the same.

31. Par admits that US Patent No. 8,329,216 (the "'216 patent"), on its face, is titled "Oxymorphone Controlled Release Formulations," and lists its date of issue as December 11, 2012. Par admits that the '216 patent, on its face, identifies Huai-Hung Kao, Anand R. Baichwal, Troy McCall, and David Lee as its inventors, and Endo Pharmaceuticals Inc. as its assignee. Par further admits that what appears to be a copy of the '216 patent is attached to the Complaint as Exhibit C. Par denies that the United States Patent and Trademark Office duly and legally issued the '216 patent and the remaining allegations of Paragraph 31.

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