

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

RHODES PHARMACEUTICALS L.P.,

Plaintiff,

v.

ASCENT PHARMACEUTICALS INC.,

Defendant.

Case No. 2:17-cv-02755

COMPLAINT

Plaintiff Rhodes Pharmaceuticals L.P. (“Rhodes” or “Plaintiff”) for its Complaint against Defendant Ascent Pharmaceuticals Inc. (“Ascent” or “Defendant”) hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 et seq. This action relates to Abbreviated New Drug Application (“ANDA”) No. 210176 filed by or for the benefit of Defendant with the United States Food and Drug Administration (“FDA”) for approval to market generic versions of Plaintiff’s Dilaudid® pharmaceutical products that are sold in the United States.

THE PARTIES

2. Rhodes is a limited partnership organized and existing under the laws of the State of Delaware, having a principal place of business at 498 Washington Street, Coventry, RI 02816. Rhodes is the registered holder of approved New Drug Application (“NDA”) No. 19-891, which covers the manufacture and sale of Dilaudid® (hydromorphone hydrochloride) oral solution (“Dilaudid®”), which is sold throughout the United States.

3. Upon information and belief, Ascent is a New York corporation, having its principal place of business at 500 S. Research Place, Central Islip, New York 11722-4415. Ascent is registered to do business in New York under DOS ID #: 4136894. Upon information and belief, Ascent is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval of, and marketing generic copies of branded pharmaceutical products throughout the United States, including within this Judicial District.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Ascent, by virtue of, *inter alia*, its systematic and continuous contacts with the State of New York. Upon information and belief, Ascent maintains its principal place of business in New York, is registered to do business in New York, and either directly or indirectly, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this Judicial District.

6. Because Defendant is headquartered and/or registered to do business in New York, it is subject to general personal jurisdiction in this Judicial District.

7. Upon information and belief, upon approval of ANDA No. 210176, the Defendant and/or its subsidiaries, affiliates or agents will market, sell and/or distribute the generic pharmaceutical products that are the subject of that ANDA throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

8. Upon information and belief, venue is proper in this Judicial District under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

FACTUAL BACKGROUND

9. United States Patent No. 6,589,960 (“the ’960 Patent”), entitled “Hydromorphone And Hydrocodone Compositions And Methods For Their Synthesis,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on July 8, 2003. Rhodes is the owner of the entire right, title, and interest in the ’960 Patent by assignment, including the right to sue for infringement of the ’960 Patent. A true and correct copy of the ’960 Patent is attached as Exhibit A.

10. Rhodes is the owner and holder of approved New Drug Application (“NDA”) No. 19-891, which covers the manufacture and sale of Dilaudid® (hydromorphone hydrochloride) oral solution (“Dilaudid®”), which is sold throughout the United States.

11. The ’960 Patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”) as covering Dilaudid®.

12. Upon information and belief, Ascent submitted ANDA No. 210176 to the FDA under § 505(j)(2) of the Federal Food, Drug, and Cosmetic Act to obtain approval to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of a generic hydromorphone hydrochloride oral solution product containing 5 mg/5 mL hydromorphone hydrochloride (“the Ascent Products”) before the expiration of the ’960 Patent.

13. Upon information and belief, Ascent’s ANDA No. 210176 contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) alleging that the ’960 Patent, which is listed in the Orange Book as covering Rhodes’ Dilaudid® products, is invalid and/or would not be infringed by the manufacture, use, or sale of the Ascent Products.

14. Ascent sent a letter dated March 22, 2017 (“the Ascent Paragraph IV Notice Letter”) signed by a representative of Ascent, purporting to be notice in compliance with 21

U.S.C. § 355(j)(2)(B) of Ascent's filing of ANDA No. 210176, and stating that said ANDA contains a Paragraph IV Certification regarding the '960 Patent.

15. The Ascent Paragraph IV Notice Letter states Ascent's intention to seek approval to market the Ascent Products prior to the expiration of the '960 Patent.

COUNT I: Infringement of the '960 Patent under 35 U.S.C. § 271

16. The allegations of the preceding paragraphs 1-15 are repeated, realleged, and incorporated herein by reference.

17. Under 35 U.S.C. § 271(e)(2)(A), Ascent's submission to the FDA of ANDA No. 210176 to obtain approval for the commercial manufacture, importation, use, and/or sale throughout the United States, including New York, of the Ascent Products, before the expiration of the '960 Patent constitutes infringement of the '960 Patent.

18. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Ascent Products prior to patent expiration will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '960 Patent. Upon information and belief, Ascent has been aware of the existence of the '960 Patent and has no reasonable basis for believing that the manufacture, use, offer for sale, sale, and/or importation of the Ascent Products will not infringe, contribute to the infringement of, and/or induce the infringement of the '960 Patent, thus rendering the case "exceptional" as that term is used in 35 U.S.C. § 285.

19. The acts of infringement by Ascent set forth above will cause Plaintiff irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

PRAYER FOR RELIEF

Plaintiff respectfully prays for the following relief:

A. Adjudging that Ascent has infringed the '960 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210176 to the FDA to obtain approval for the commercial manufacture, importation, use, offer for sale, and/or sale of the Ascent Products, and that the commercial manufacture, importation, use, offer for sale, and/or sale of the Ascent Products would infringe, contribute to the infringement of, and/or induce the infringement of the '960 Patent;

B. Adjudging that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Ascent's ANDA No. 210176, under § 505(b) of the Federal Food, Drug and Cosmetic Act, to be a date not earlier than the date of expiration of the '960 Patent plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Ascent, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of any drug product that infringes the '960 Patent;

D. Declaring this an exceptional case and awarding Plaintiff its attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285;

E. Awarding Plaintiff costs and expenses; and

F. Awarding Plaintiff such other and further relief as this Court may deem just and proper.

Dated: May 5, 2017

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Respectfully submitted,

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