

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PROMETHEUS LABORATORIES INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	
AMNEAL PHARMACEUTICALS, LLC,)	C.A. No. _____
AMNEAL PHARMACEUTICALS OF)	
NEW YORK, LLC, and AMNEAL)	
PHARMACEUTICALS CO. INDIA)	
PVT. LTD.,)	
)	
Defendants.)	

COMPLAINT

Plaintiff Prometheus Laboratories Inc. ("Plaintiff" or "Prometheus"), as and for its Complaint against Defendants Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC, and Amneal Pharmaceuticals Co. India Pvt. Ltd. (collectively, "Defendants" or "Amneal"), alleges as follows:

THE PARTIES

1. Prometheus is a corporation organized and existing under the laws of the State of California, having a principal place of business at 9410 Carroll Park Drive, San Diego, California 92121. Prometheus is involved in the marketing of pharmaceutical products.

2. On information and belief, Defendant Amneal Pharmaceuticals, LLC ("Amneal Pharma") is a limited liability company organized and existing under the laws of the State of Delaware and has an agent for the service of process located at 1209 Orange Street, Wilmington, Delaware, 19801. Amneal Pharma has a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey, 08807. On information and belief, Amneal Pharma is in

the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this District.

3. On information and belief, Defendant Amneal Pharmaceuticals of New York, LLC ("Amneal NY") is a limited liability company organized and existing under the laws of the State of Delaware and has an agent for the service of process located at 1209 Orange Street, Wilmington, Delaware, 19801. Amneal NY has a principal place of business at 85 Adams Avenue, Hauppauge, New York, 11788, and is a wholly-owned subsidiary of Amneal Pharma. On information and belief, Amneal NY is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this District.

4. On information and belief, Defendant Amneal Pharmaceuticals Co. India Pvt. Ltd. ("Amneal India") is a corporation organized and existing under the laws of India, having a principal place of business at 882/1-871, Rajoda Village, Taluka, Near Hotel Kankavati, Bavla Taluka, Ahmedabab-382220, Gujarat, India, and is a wholly-owned subsidiary of Amneal Pharma. On information and belief, Amneal India is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this District.

5. On information and belief, Amneal Pharma, Amneal NY, and Amneal India operate and act in concert as an integrated, unitary business for purposes of manufacturing, marketing, selling, and distributing generic pharmaceutical products.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Amneal Pharma is subject to personal jurisdiction in this District because, *inter alia*, the company is organized and existing under the laws of the State of Delaware and has an agent for the service of process located at 1209 Orange Street, Wilmington, Delaware, 19801.

8. Amneal NY is subject to personal jurisdiction in this District because, *inter alia*, the company is organized and existing under the laws of the State of Delaware and has an agent for the service of process located at 1209 Orange Street, Wilmington, Delaware, 19801.

9. On information and belief, Amneal India has consented to personal jurisdiction in this District. *See, e.g., Forest Laboratories, Inc., et al. v. Amneal Pharmaceuticals, LLC, et al.*, Civil Action No. 13-01737-SLR (D. Del.). Amneal India is also subject to personal jurisdiction in this District, by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, its substantial and continuing contacts with the State, including but not limited to its sales of products in Delaware and derivation of substantial revenues therefrom.

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

11. On September 4, 2001, the United States Patent and Trademark Office ("PTO") duly and lawfully issued U.S. Patent No. 6,284,770 ("the '770 Patent"), entitled "Medicaments for the treatment of non-constipated female irritable bowel syndrome" to inventors Allen Wayne Mangel and Allison Ruth Northcutt. The '770 Patent was subsequently subject to reexamination proceedings before the PTO that resulted in the cancellation or amendment of all of the original claims of that patent. On October 19, 2010, the PTO duly and lawfully issued a reexamination certificate for the '770 Patent. A copy of the '770 Patent and its reexamination certificate are attached hereto as Exhibit A.

12. Prometheus holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), for alosetron hydrochloride tablets (NDA No. 21-107), which it sells under the trade name LOTRONEX[®]. The reexamined claims of the '770 Patent cover, *inter alia*, methods of use and administration of alosetron or a pharmaceutically acceptable derivative thereof. Prometheus owns the '770 Patent.

13. Following reexamination, the '770 Patent was properly listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") for LOTRONEX[®].

14. On information and belief, through the coordinated efforts of its staff worldwide, Defendants seek to constantly expand the range of generic products they sell.

15. On information and belief, Defendants collaborate in the manufacture, marketing and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to an approved abbreviated new drug application) within the United States generally and the State of Delaware specifically.

16. On information and belief, Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

17. On information and belief, Defendants reviewed the '770 Patent and certain commercial and economic information relating to LOTRONEX[®], including estimates of the revenues generated by the sale of LOTRONEX[®], and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market alosetron hydrochloride tablets.

18. On information and belief, Defendants collaborated in the research, development, preparation and filing of ANDA No. 206647 for alosetron hydrochloride tablets.

19. On information and belief, Amneal submitted to FDA ANDA No. 206647 seeking approval to engage in the commercial manufacture, use and sale of 0.5 mg and 1.0 mg alosetron hydrochloride tablets ("Amneal's Proposed Products"), prior to the expiration of the '770 Patent.

20. Prometheus received a letter from Amneal, dated June 11, 2014, notifying Prometheus that ANDA No. 206647 includes a certification under 21 U.S.C. 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Amneal's opinion, no valid, enforceable claim of the '770 Patent will be infringed by the commercial manufacture, use or sale of the alosetron hydrochloride tablet products described in ANDA No. 206647.

21. Amneal was aware of the '770 Patent when it filed its ANDA No. 206647 with a Paragraph IV certification.

22. Plaintiff commenced this action within 45 days of the date it received Amneal's notice of ANDA No. 206647 containing the Paragraph IV certification.

23. On information and belief, Amneal Pharma, Amneal NY, and Amneal India will continue to collaborate in seeking approval of ANDA No. 206647 from FDA and intend to collaborate in the commercial manufacture, marketing, and sale of alosetron hydrochloride tablets (including commercial marketing and sale of such products in the State of Delaware) in the event that FDA approves ANDA No. 206647.

24. On information and belief, Defendants will market and distribute Amneal's Proposed Products to resellers, pharmacies, healthcare professionals, and end-users of Amneal's Proposed Products in the event that FDA approves ANDA No. 206647. On information and belief, Defendants will also knowingly and intentionally issue a product label and product insert for Amneal's Proposed Products that will include instructions for administering Amneal's Proposed Products as claimed in the '770 Patent.

COUNT FOR INFRINGEMENT OF THE '770 PATENT

25. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 24 hereof, as if fully set forth herein.

26. By filing ANDA No. 206647 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and importation of alosetron hydrochloride tablet products described therein, prior to the expiration of the '770 Patent, Defendants have infringed the '770 Patent under 35 U.S.C. § 271(e)(2).

27. Unless enjoined by this Court, upon FDA approval of ANDA No. 206647, Defendants will infringe the '770 Patent under § 271(a) by making, using, offering to sell, importing, and/or selling Amneal's Proposed Products in the United States.

28. Unless enjoined by this Court, upon FDA approval of ANDA No. 206647, Defendants will induce infringement of the '770 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Amneal's Proposed Products in the United States. On information and belief, upon FDA approval of ANDA No. 206647, Defendants will intentionally encourage acts of direct infringement with knowledge of the '770 Patent and knowledge that its acts are encouraging infringement.

29. Unless enjoined by this Court, upon FDA approval of ANDA No. 206647, Defendants will contributorily infringe the '770 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Amneal's Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Amneal's Proposed Products are especially adapted for a use that infringes the '770 Patent and that there is no substantial noninfringing use for Amneal's Proposed Products.

30. Defendants were aware of the existence of the '770 Patent prior to filing ANDA No. 206647 but took such action knowing that it would constitute infringement of the '770 Patent.

31. Plaintiff has no adequate remedy at law for Defendants' infringement of the '770 Patent.

32. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285, which warrants reimbursement of Plaintiff's reasonable attorney's fees.

33. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing the '770 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

- A. An order adjudging and decreeing that Defendants have infringed the '770 Patent by submitting ANDA No. 206647;
- B. An order adjudging and decreeing that Defendants have infringed, and that Defendants' making, using, selling, offering to sell, or importing Amneal's Proposed Products will infringe one or more claims of the '770 Patent;
- C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 206647 be no earlier than the expiration date of the '770 Patent, including any extensions and/or exclusivities;
- D. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Defendants, 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 the alosetron hydrochloride tablet products

described in ANDA No. 206647 or any other ANDA not colorably different from ANDA No. 206647 until the expiration date of '770 Patent, including any extensions and/or exclusivities;

- E. A declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Amneal's Proposed Products will directly infringe, induce and/or contribute to infringement of the '770 Patent;
- F. To the extent that Defendants have committed any acts with respect to the methods claimed in the '770 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiff Prometheus be awarded damages for such acts;
- G. If Defendants engage in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Amneal's Proposed Products prior to the expiration of the '770 Patent, a Judgment awarding damages to Plaintiff Prometheus resulting from such infringement, together with interest;
- H. A declaration that this case is exceptional and an award of attorney's fees under 35 U.S.C. § 285 and costs and expenses in this action; and
- I. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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

Attorneys for Prometheus Laboratories Inc.

OF COUNSEL:

Eric J. Lobenfeld
Arlene L. Chow
HOGAN LOVELLS US LLP
875 Third Avenue
New York, New York 10022
(212) 918-3000

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