

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC.,)
ASTRAZENECA AB, and)
ASTRAZENECA UK LIMITED,)
)
Plaintiffs,) C.A. No. _____
)
v.)
)
LANNETT HOLDINGS, INC. and)
LANNETT COMPANY, INC.,)
)
Defendants.)

COMPLAINT

Plaintiffs Impax Laboratories, Inc., AstraZeneca AB, and AstraZeneca UK Limited (collectively “Plaintiffs”), by way of their Complaint against Defendants Lannett Holdings, Inc. and Lannett Company, Inc. (collectively, “Lannett”), allege as follows:

THE PARTIES

1. Impax Laboratories, Inc. is a Delaware corporation with its headquarters at 30831 Huntwood Avenue, Hayward, CA 94544.
2. Impax Pharmaceuticals, the branded products division of Impax Laboratories, Inc., is a neurology-focused specialty pharmaceutical company dedicated to developing products for unmet needs in the treatment of central nervous system disorders.
3. AstraZeneca AB is a Swedish corporation having its principal place of business at Karlebyhus, Astraallén, Södertälje, SE-151 85, Sweden.
4. AstraZeneca UK Limited is an English corporation having its headquarters at 2 Kingdom Street, Paddington, London, W2 6BD, England.

5. On information and belief, Defendant Lannett Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 103 Foulk Road, Suite 202, Wilmington, DE 19803.

6. On information and belief, Defendant Lannett Company, Inc. is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 13200 Townsend Road, Philadelphia, PA 19154.

7. On information and belief, Lannett Company, Inc. is the parent company of Lannett Holdings, Inc.

8. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. manufacture and sell various generic drug products and conduct business throughout the United States, including in the State of Delaware.

NATURE OF THE ACTION

9. This is a civil action for infringement of U.S. Patent Nos. 6,750,237 (“the ’237 patent”) and 7,220,767 (“the ’767 patent”) arising under the United States Patent Laws, Title 35, United States Code, § 100, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application (“ANDA”) No. 206350, which Lannett filed or caused to be filed under 21 U.S.C. § 355(j) with the U.S. Food and Drug Administration (“FDA”), for approval to market a generic copy of Plaintiffs’ Zomig[®] Nasal Spray product, which is sold in the United States.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. On information and belief, this Court has personal jurisdiction over Lannett Holdings, Inc. and Lannett Company, Inc.

12. On information and belief, Lannett Holdings, Inc. is a Delaware corporation. On information and belief, Lannett Holdings, Inc. has a registered agent in Delaware (located at The CSC Entity Services, LLC, 2711 Centerville Road Suite 400, Wilmington, DE 19808) for the receipt of service of process.

13. On information and belief, Lannett Company, Inc. is a Delaware corporation. On information and belief, Lannett Company, Inc. has a registered agent in Delaware (located at The Office Service Company 203 NE Front St, Ste 101, Milford, DE 19963) for the receipt of service of process.

14. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. operate as an integrated business.

15. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. share common officers and directors and are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in Delaware.

16. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. together formulate, develop, market, and sell active pharmaceutical ingredients (APIs), solid dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such APIs or pharmaceutical formulations (collectively “Lannett’s products”) that they distribute in Delaware and throughout the United States.

17. On information and belief, Lannett Holdings, Inc., and Lannett Company, Inc. together routinely file, and/or aid, abet, contribute to, and/or participate in the filing of, ANDAs to seek FDA approval to market their products in the United States, including in Delaware.

18. On information and belief, Lannett Holdings, Inc. is a wholly owned subsidiary of Lannett Company, Inc. On information and belief, Lannett Company, Inc., acting either alone or in concert with Lannett Holdings, Inc., either directly or through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes pharmaceutical products in Delaware.

19. On information and belief, Lannett Company, Inc. holds current and valid “Distributor/Manufacturer CSR” (DM-0009166) and “Pharmacy-Wholesale” (A-4-0001963) licenses in Delaware.

20. On information and belief, Lannett Company, Inc. directs, authorizes, cooperates, participates, and/or assists Lannett Holdings, Inc. with the marketing, selling, and/or distributing pharmaceutical products in Delaware. On information and belief, the acts of Lannett Holdings, Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Lannett Company, Inc.

21. On information and belief, this judicial district is a likely destination of products that will be manufactured and sold as a result of FDA approval of Lannett’s ANDA No. 206350, which is the subject of this lawsuit.

22. On information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. have committed, or aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs including Impax Laboratories, Inc., a Delaware corporation.

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

FACTUAL BACKGROUND

A. Zomig[®]

24. AstraZeneca Pharmaceuticals LP is the holder of approved New Drug Application (“NDA”) No. 021450 for the manufacture and sale of zolmitriptan nasal spray, 5 mg/spray, used for the acute treatment of migraine with or without aura in adults, which Impax Laboratories, Inc., through its branded products division Impax Pharmaceuticals, distributes under the trademark Zomig[®] Nasal Spray.

B. The '237 Patent

25. The '237 patent, which claims pharmaceutical formulations containing zolmitriptan, was duly and legally issued by the U.S. Patent and Trademark Office (“PTO”) on June 15, 2004. AstraZeneca AB and AstraZeneca UK Limited own all rights, title, and interest in the '237 patent and have the right to sue for infringement thereof. AstraZeneca lists the '237 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) for NDA No. 021450. A true and correct copy of the '237 patent is attached as Exhibit A.

26. Impax Laboratories, Inc. holds an exclusive license under the '237 patent and also has rights to commercialize zolmitriptan in the United States under a Distribution, License, Development and Supply Agreement with AstraZeneca UK Limited. Impax Laboratories, Inc. has the right to sue for infringement of the '237 patent.

C. The '767 Patent

27. The '767 patent, which claims pharmaceutical formulations containing zolmitriptan, was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on May 22, 2007. AstraZeneca AB and AstraZeneca UK Limited own all rights, title,

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