

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

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IMPAX LABORATORIES, INC.,))	
ASTRAZENECA AB, and))	
ASTRAZENECA UK LIMITED,))	
))	
Plaintiffs,))	
v.))	C.A. No. 1:14-cv-999 (RGA)
))	
LANNETT HOLDINGS, INC., and))	
LANNETT COMPANY, INC.,))	
))	
Defendants.))	
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**LANNETT HOLDINGS, INC. AND LANNETT COMPANY, INC.’S
ANSWER, DEFENSES AND COUNTERCLAIMS**

Defendants Lannett Holdings, Inc. and Lannett Company, Inc. (collectively “Lannett”), answers the Complaint filed by Impax Laboratories, Inc., AstraZeneca AB and AstraZeneca UK Limited (collectively “Plaintiffs”), and sets forth its defenses and counterclaims, as follows:

THE PARTIES

1. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1, and therefore denies these allegations.
2. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2, and therefore denies these allegations.
3. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3, and therefore denies these allegations.
4. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4, and therefore denies these allegations.

ACTIVE 27527082v2 09/24/2014

5. Lannett admits that Lannett Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware. Any remaining allegations in paragraph 5 are conclusions of law for which no response is required. To the extent a response is required, Lannett denies any and all other allegations in paragraph 5.

6. Lannett admits that Lannett Company, Inc. is a corporation organized and existing under the laws of the State of Delaware. Any remaining allegations in paragraph 6 are conclusions of law for which no response is required. To the extent a response is required, Lannett denies any and all other allegations in paragraph 6.

7. Lannett admits that Lannett Holdings, Inc. is wholly owned subsidiary of Lannett Company, Inc. Any remaining allegations in paragraph 7 are conclusions of law for which no response is required. To the extent a response is required, Lannett denies any and all other allegations in paragraph 7.

8. Lannett admits that Lannett Company, Inc. is involved in the manufacture and/or sale of various pharmaceutical products, with business activities in several states, including in the State of Delaware. Any and all remaining allegations in paragraph 8 are denied.

NATURE OF THE ACTION

9. Lannett admits that this purports to be an action alleging infringement of U.S. Patent Nos. 6,750,237 (“the ’237 patent”) and 7,220,767 (“the ’767 patent”). Lannett further admits that Lannett Holdings, Inc. submitted Abbreviated New Drug Application No. 206350 seeking approval to market Lannett’s Zolmitriptan Nasal Spray, 5mg/spray (“the Lannett product”) prior to the expiration of the ’237 and ’767 patents. Lannett denies the remaining allegations of paragraph 9.

JURISDICTION AND VENUE

10. Lannett admits that paragraph 10 of the complaint invokes the subject matter jurisdiction of this Court based on 28 U.S.C. §§ 1331 - 1338(a), 2201 and 2202. Lannett lacks knowledge or information sufficient to form a belief as to whether the Court has subject matter jurisdiction and therefore denies the allegations in paragraph 10.

11. Lannett admits that this Court has personal jurisdiction for purposes of this action only.

12. Admitted.

13. Admitted.

14. The allegations in paragraph 14 are conclusions of law for which no response is required. To the extent a response is required, Lannett denies any and all other allegations in paragraph 14.

15. Lannett admits that Lannett Holdings, Inc. and Lannett Company, Inc. have certain individuals who are officers in both Lannett Holdings, Inc. and Lannett Company, Inc. To the extent the remaining allegations in paragraph 15 are understood, they are denied and/or are conclusions of law for which no response is required.

16. Denied.

17. Denied.

18. Lannett admits that Lannett Holdings, Inc. is a wholly owned subsidiary of Lannett Company, Inc. Lannett admits that Lannett Company, Inc. markets, sells, and/or distributes pharmaceutical products in Delaware. Any and all remaining allegations in paragraph 18 are denied.

19. Admitted.

20. The allegations in paragraph 20 are conclusions of law for which no response is required. To the extent a response is required, Lannett denies any and all other allegations in paragraph 20.

21. Lannett admits that if and when products are manufactured and sold as a result of FDA approval of Lannett's ANDA, it is possible that Delaware might be a destination for such products. Any and all remaining allegations in paragraph 21 are denied.

22. The allegations in paragraph 22 are conclusions of law for which no response is required. To the extent a response is required, Lannett denies any and all other allegations in paragraph 22.

23. Lannett admits that venue is proper in this District for purposes of this action only.

FACTUAL BACKGROUND

A. Zomig

24. Lannett admits that New Drug Application ("NDA") No. 021450 is for the manufacture and sale of zolmitriptan nasal spray, 5 mg/spray and that such spray has been used for the acute treatment of migraine with or without aura in adults. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 24, and therefore denies these allegations.

B. The '237 Patent

25. Lannett admits that the '237 patent contains claims directed to a pharmaceutical formulation containing zolmitriptan. Lannett admits that a copy purporting to be the '237 patent was attached to the Complaint as Exhibit A. Lannett admits that the "Orange Book: Approved

Drug Products With Therapeutic Equivalence Evaluations” published by the FDA (the “Orange Book”) stated that NDA No. 021450 applicant was “AstraZeneca AB.” Lannett denies that the ‘237 patent was duly and legally issued. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 25, and therefore denies these allegations.

26. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26, and therefore denies these allegations.

C. The ’767 Patent

27. Lannett admits that the ‘767 patent contains claims directed to a pharmaceutical formulation containing zolmitriptan. Lannett admits that a copy purporting to be the ‘767 patent was attached to the Complaint as Exhibit B. Lannett admits that the “Orange Book: Approved Drug Products With Therapeutic Equivalence Evaluations” published by the FDA (the “Orange Book”) stated that NDA No. 021450 applicant was “AstraZeneca AB.” Lannett denies that the ‘767 patent was duly and legally issued. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 27, and therefore denies these allegations.

28. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 28, and therefore denies these allegations.

D. Lannett’s ANDA No. 206350

29. Lannett admits that Lannett Holdings, Inc. submitted Abbreviated New Drug Application No. 206350 seeking approval to market Lannett’s Zolmitriptan Nasal Spray, 5mg/spray (“the Lannett product”). Any and all remaining allegations in paragraph 29 are denied.

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