IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs Impax Laboratories, Inc. and AstraZeneca AB (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. 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.

5. 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.

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

7. 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

8. 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

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

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

11. 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.

12. 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.

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

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

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

FACTUAL BACKGROUND

A. Zomig®

23. 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

24. 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 is the owner by assignment of the '237 patent and has 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.

25. Impax Laboratories, Inc. holds an exclusive license under the '237 patent.

C. The '767 Patent

26. 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 is the owner by assignment of the '767 patent and has the right to sue for infringement thereof. AstraZeneca lists the '767 patent in the Orange Book for NDA No. 021450. A true and correct copy of the '767 patent is attached as Exhibit B.

27. Impax Laboratories, Inc. holds an exclusive license under the '767 patent.

D. Lannett's ANDA No. 206350

28. On information and belief, Lannett filed or caused to be filed with the FDA ANDA No. 206350 under 21 U.S.C. § 355(j)(2)(B), seeking FDA approval to market generic zolmitriptan nasal spray, 5 mg/spray ("Lannett's Generic Product"), in the United States. Lannett's Generic Product is a generic copy of Zomig® Nasal Spray.

29. ANDA No. 206350 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), alleging that the claims of the '237 and '767 patents are invalid.

30. On or about June 16, 2014, AstraZeneca received a letter sent on behalf of Lannett, dated June 13, 2014, purporting to be a "Notification of Certification" for ANDA No. 206350 ("Lannett's Notice Letter") pursuant to section 505(j)(2)(b)(iv) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Lannett's Notice Letter notified AstraZeneca that Lannett had filed ANDA No. 206350, seeking approval to market Lannett's Generic Product before the expiration of the '237 and '767 patents. The Notice Letter does not identify any alleged grounds of non-infringement of the '237 or '767 patents.

31. Plaintiffs commenced this action within 45 days of receiving Lannett's Notice Letter.

COUNT I
(INFRINGEMENT OF U.S. PATENT NO. 6,750,237 B1)

32. Paragraphs 1–31 are incorporated herein by reference.

33. On information and belief, Lannett, through Lannett Holdings, Inc., filed ANDA No. 206350 to obtain approval to manufacture, use, and market Lannett's Generic Product in the United States before the expiration of the '237 patent. On information and belief, ANDA No. 206350 identifies Lannett as the manufacturer of the generic zolmitriptan nasal spray,

5 mg/spray. On information and belief, Lannett filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '237 patent are invalid.

34. On information and belief, in its ANDA No. 206350, Lannett has represented to the FDA that Lannett's Generic Product is pharmaceutically and therapeutically equivalent to Zomig® Nasal Spray.

35. Under 35 U.S.C. § 271(e)(2)(A), Lannett's submission to the FDA of ANDA No. 206350, seeking approval for the commercial manufacture, use, or sale of Lannett's Generic Product before the expiration of the '237 patent, constitutes infringement of at least one claim of the '237 patent, either literally or under the doctrine of equivalents.

36. The filing of the ANDA by Lannett through Lannett Holdings, Inc. constituted direct infringement of the '237 patent under 35 U.S.C. § 271(e).

37. Under 35 U.S.C. § 271(e)(2)(A), Lannett Company, Inc. induced the infringement of the '237 patent by actively and knowingly causing ANDA No. 206350 to be submitted, and/or assisting with, participating in, contributing to, and/or directing the submission of the ANDA, knowing that the submission would constitute direct infringement of the '237 patent.

38. Upon FDA approval of ANDA No. 206350, Lannett will infringe one or more claims of the '237 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(a), by making, using, offering to sell, selling, and/or importing Lannett's Generic Product, unless this Court orders that the effective date of any FDA approval of ANDA No. 206350 shall be no earlier than the expiration of the '237 patent and any additional periods of exclusivity.

39. Plaintiffs will be irreparably harmed if Lannett is not enjoined from infringing or actively inducing infringement of the '237 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are

entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT II
(INFRINGEMENT OF U.S. PATENT NO. 7,220,767 B2)

40. Paragraphs 1–39 are incorporated herein by reference.

41. On information and belief, Lannett, through Lannett Holdings, Inc., filed ANDA No. 206350 to obtain approval to manufacture, use, and market Lannett's Generic Product in the United States before the expiration of the '767 patent. On information and belief, ANDA No. 206350 identifies Lannett as the manufacturer of the generic zolmitriptan nasal spray, 5 mg/spray. On information and belief, Lannett filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '767 patent are invalid.

42. On information and belief, in its ANDA No. 206350, Lannett has represented to the FDA that Lannett's Generic Product is pharmaceutically and therapeutically equivalent to Zomig® Nasal Spray.

43. Under 35 U.S.C. § 271(e)(2)(A), Lannett's submission to the FDA of ANDA No. 206350 seeking approval for the commercial manufacture, use, or sale of Lannett's Generic Product before the expiration of the '767 patent, constitutes infringement of at least one claim of the '767 patent, either literally or under the doctrine of equivalents.

44. The filing of the ANDA by Defendants through Lannett Holdings, Inc. constituted direct infringement of the '767 patent under 35 U.S.C. § 271(e).

45. Under 35 U.S.C. § 271(e)(2)(A), Lannett Company, Inc. induced the infringement of the '767 patent by actively and knowingly causing ANDA No. 206350 to be submitted, and/or

assisting with, participating in, contributing to, and/or directing the submission of the ANDA to the FDA, knowing that the submission would constitute direct infringement of the '767 patent.

46. Upon FDA approval of ANDA No. 206350, Lannett will infringe one or more claims of the '767 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(a), by making, using, offering to sell, selling, and/or importing Lannett's Generic Product, unless this Court orders that the effective date of any FDA approval of ANDA No. 206350 shall be no earlier than the expiration of the '767 patent and any additional periods of exclusivity.

47. Plaintiffs will be irreparably harmed if Lannett is not enjoined from infringing or actively inducing infringement of the '767 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. the entry of judgment that the claims of the '237 and '767 patents are valid;

B. the entry of judgment that Lannett's submission of ANDA 206350 was an act of infringement, and that its making, using, offering to sell, selling or importing Lannett's Generic Product before the expiration of the '237 and '767 patents will infringe those patents;

C. the entry of judgment that Lannett Company, Inc.'s knowing and purposeful conduct in causing ANDA 206350 to be submitted, and/or assisting with, participating in, contributing to, and/or directing its filing,

knowing that its submission would constitute direct infringement, induced infringement of the ’237 and ’767 patents;

D. the entry of an order that the effective date of any FDA approval of Lannett’s Generic Product shall be no earlier than the expiration of the ’237 and ’767 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

E. the entry of a permanent injunction, enjoining Lannett, and all persons acting in concert with Lannett, from commercially manufacturing, using, offering for sale, or selling Lannett’s Generic Product within the United States, or importing Lannett’s Generic Product into the United States, until the expiration of the ’237 and ’767 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. an award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. an award to Plaintiffs of any further and additional relief that the Court deems just and proper.

ASHBY & GEDDES

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July 25, 2014