IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC., ASTRAZENECA AB, and ASTRAZENECA UK LIMITED, Plaintiffs, v. LANNETT HOLDINGS, INC., and LANNETT COMPANY, INC., Defendants.	C.A. No. 14-984 (RGA) (Consolidated)

FINAL JUDGMENT AND INJUNCTION

WHEREAS, this matter having come before the Court for trial on the merits of all remaining issues in the above-captioned case, namely, to resolve the questions whether Defendants Lannett Holdings, Inc. and Lannett Company, Inc. (collectively "Defendants") infringe any of claims 4, 11, 12, or 14 of U.S. Patent No. 6,750,237 ("the '237 patent"), or claims 6, 14, or 15 of U.S. Patent No. 7,220,767 ("the '767 patent"), based on the filing of Abbreviated New Drug Application ("ANDA") No. 206350 describing a generic product with a target pH of 5; whether those claims are invalid; and whether Plaintiffs Impax Laboratories, Inc., AstraZeneca AB, and AstraZeneca UK Limited (collectively, "Plaintiffs") have standing to bring suit;

WHEREAS, after having been informed by Defendants that Defendants were amending ANDA No. 206350 so that the pH range of the generic product would lie outside the range of 5 +/- 0.04, the Court indicated during a telephonic hearing on September 1, 2016 that it would proceed to conduct the trial based on the generic product described in the non-amended ANDA and having a target pH of 5, but would retain jurisdiction post-trial to consider any amendments

to the ANDA setting the pH outside the range of 5 +/- 0.04 (D.I. 131 in C.A. No. 14-984);

WHEREAS, at trial, Plaintiffs asserted claims 4, 11, 12, and 14 of the '237 patent and claims 6, 14, and 15 of the '767 patent against Defendants based on the filing of ANDA No. 206350 describing a generic product with a target pH of 5; Defendants asserted counterclaims of invalidity and lack of standing against Plaintiffs; the Court heard testimony of the expert witnesses and considered the evidence submitted by the parties; and the Court reviewed the post-trial briefs of the parties; and

WHEREAS, subsequent to trial, the parties stipulated that Defendants' generic product as described in ANDA No. 206350 with a target pH of 5, if approved by the FDA, will infringe each of claims 4, 11, 12, and 14 of the '237 patent and claims 6, 14, and 15 of the '767 patent, to the extent each such claim is finally judged to be valid (D.I. 137 in C.A. No. 14-984), with Defendants reserving their rights to contest at all appropriate times and in all appropriate forums the Court's rulings which impact claim construction, including D.I. 64 and D.I. 116 in C.A. No. 14-984, and to seek reconsideration of the issue of infringement in the event of any change in the rulings on claim construction by this Court or upon appeal, and with Defendants further reserving their rights to have the Court fully consider the issue of infringement by any amended version of ANDA No. 206350 directed to a generic product with an approved pH range that would exclude pHs of 5 +/- 0.04; now therefore,

IT IS ORDERED AND ADJUDGED as follows:

1. In view of the Court's findings that claims 4, 11, 12, and 14 of the '237 patent, and claims 6, 14, and 15 of the '767 patent, were not shown at trial to be invalid, and consistent with the Stipulation and Order Regarding Infringement (D.I. 137 in C.A. No. 14-984), final judgment is hereby entered, in favor of Plaintiffs and against Defendants, that Defendants'

generic product that is the subject of ANDA No. 206350 and having a target pH of 5 infringes each of claims 4, 11, 12, and 14 of the '237 patent and claims 6, 14, and 15 of the '767 patent.

2. For the reasons set forth in the Court's Trial Opinion dated March 29, 2017 (D.I. 169 in C.A. No. 14-984), final judgment is hereby entered, in favor of Plaintiffs and against Defendants, that each of claims 4, 11, 12, and 14 of the '237 patent and claims 6, 14, and 15 of the '767 patent has not been shown to be invalid.

3. For the reasons set forth in the Court's Trial Opinion dated March 29, 2017 (D.I. 169 in C.A. No. 14-984), final judgment is hereby entered in favor of Plaintiffs and against Defendants, that Plaintiff Impax Laboratories, Inc., Plaintiff AstraZeneca AB, and Plaintiff AstraZeneca UK Limited, collectively, have standing to bring suit.

4. Pursuant to 35 U.S.C. § 271(e)(4)(a), the Food and Drug Administration ("FDA") shall not make the effective date of any final approval of ANDA No. 206350 earlier than: (i) May 29, 2021, which is the first day after the date on which Plaintiffs' pediatric exclusivity period ends with respect to the '237 and '767 patents, or (ii) the entry of a final judgment that claims 4, 11, 12, and 14 of the '237 patent, and claims 6, 14, and 15 of the '767 patent, are invalid; or (iii) the entry of a final judgment that claims 11, 12, and 14 of the '237 patent, and claims 6, 14, and 15 of the '767 patent, are invalid ***and*** ANDA No. 206350 being tentatively approved with a pH range that does not include 5 +/- 0.04.

5. Pursuant to 35 U.S.C. § 271(e)(4)(b), Defendants and their subsidiaries, affiliates, officers, directors, agents, servants, employees, attorneys, and assigns, and those in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby enjoined from the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the drug product that is the

subject of ANDA No. 206350 until the earlier of: (i) the expiration date of the '237 patent or the '767 patent, whichever occurs later; or (ii) the entry of a final judgment that claims 4, 11, 12, and 14 of the '237 patent, and claims 6, 14, and 15 of the '767 patent, are invalid; or (iii) the entry of a final judgment that claims 11, 12, and 14 of the '237 patent, and claims 6, 14, and 15 of the '767 patent, are invalid ***and*** ANDA No. 206350 being tentatively approved with a pH range that does not include 5 +/- 0.04.

6. The Court will retain jurisdiction to consider the effect on and possible modification of paragraphs 4 and 5 hereof of any amendments to ANDA No. 206350 setting the pH of the generic product outside the range of 5 +/- 0.04.

Dated this 17 day of April, 2017.

Richard G. Andrews
UNITED STATES DISTRICT JUDGE