

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and)
MALLINCKRODT LLC,)
)
Plaintiffs,)
)
v.) C.A. No. 14-1382 (RGA)
)
AMNEAL PHARMACEUTICALS, LLC)
and AMNEAL PHARMACEUTICALS OF)
NEW YORK, LLC,)
)
Defendants.)

FINAL JUDGMENT

Pursuant to Rule 58 of the Federal Rules of Civil Procedure, and for the reasons stated in the Court's October 7, 2016 Trial Opinion (D.I. 155) and the Stipulation and Order of Infringement of U.S. Patent No. 8,871,779 ("the '779 patent") (D.I. 110), the Court enters judgment as follows:

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

1. Final judgment is entered in favor of Plaintiffs and against Defendants that claims 1-6 of U.S. Patent No. 8,871,779 patent are not invalid;
2. Final judgment is entered in favor of Plaintiffs and against Defendants (as stipulated in D.I. 110) that Defendants' filing of ANDA No. 20-4294 to obtain approval for the commercial manufacture, use, and sale of the proposed oxymorphone hydrochloride extended-release products that are the subject of that ANDA ("Defendants' ANDA products") is an act of patent infringement of asserted claims 1-6 of the '779 patent under 35 U.S.C. § 271(e)(2)(A);

3. Final judgment is entered in favor of Plaintiffs and against Defendants that the making, use, offer for sale, sale, and/or importation of Defendants' ANDA products as they are currently described in ANDA No. 20-4294 in/into the United States before the expiration of the '779 patent would directly infringe asserted claims 1-6 of the '779 patent under 35 U.S.C. § 271(a);

4. The partial judgment entered by the Court on February 5, 2016, relating to U.S. Patent No. 8,808,737 ("the '737 patent") patent (D.I. 108) is hereby rendered final, and final judgment is entered in favor of Defendants and against Plaintiff Endo Pharmaceuticals Inc. ("Endo") that: (i) the claims of the '737 patent are invalid under 35 U.S.C. § 101; and (ii) Endo's claims against Defendants for infringement of the '737 patent (Counts I and II of the Complaint) are dismissed;

5. Defendants' counterclaim regarding non-infringement of the '737 patent (Counterclaim I of the Answer (DI 12)) is dismissed without prejudice as moot;

6. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of Defendants' ANDA No. 20-4294 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date not earlier than the date of expiration of the '779 patent, including any applicable periods of regulatory exclusivity; and

7. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, Defendants and their affiliates, subsidiaries, officers, agents, employees, and attorneys, and those acting in privity or concert therewith are hereby enjoined prior to the expiration of the '779 patent from the commercial manufacture, use, marketing, sale, offer for sale within the United States or importation into the United States of Defendants' proposed oxymorphone hydrochloride

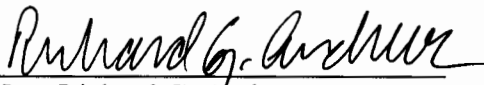
extended-release products that are the subject of ANDA No. 20-4294, said injunctive relief shall not cover any activities that are protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

IT IS HEREBY FURTHER ORDERED, ADJUDGED AND DECREED that:

8. In the event any party appeals this Final Judgment, any motion for attorneys’ fees and/or costs under Fed. R. Civ. P. 54(d) and/or Local Rules 54.1 and/or 54.3, including any motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and served within thirty (30) days after final disposition of any such appeal; and

9. In the event no party appeals this Final Judgment, any motion for attorneys’ fees and/or costs under Fed. R. Civ. P. 54(d) and/or Local Rules 54.1 and/or 54.3, including any motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and served within thirty (30) days after the expiration of the time for filing a notice of appeal under Fed. R. App. P. 3 and 4.

Dated this 21 day of October, 2016



Hon. Richard G. Andrews
United States District Judge