UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	Civil Action No. 11-3962 (MLC) (DEA) (Consolidated) Hon. Mary L. Cooper, U.S.D.J. Hon. Douglas E. Arpert, U.S.M.J.

FINAL JUDGMENT

WHEREAS, Plaintiffs Helsinn Healthcare S.A. and Roche Palo Alto LLC (collectively, "Plaintiffs") asserted that the submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 090713 by Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva") for its generic palonosetron hydrochloride intravenous solution products (0.25 mg / 5 mL and 0.075 mg / 1.5 mL) ("Teva's ANDA Products") infringed U.S. Patent Nos. 7,947,724 ("the '724 patent"), 7,947,725 ("the '725 patent"), 7,960,424 ("the '424 patent"), and 8,598,219 ("the '219 patent");

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WHEREAS, Plaintiffs further asserted that the commercial manufacture, use, offer to sell, sale, or importation of Teva's ANDA Products, if approved by the FDA prior to the expiration of the '724, '725, '424, and '219 patents, including any pediatric exclusivity, would infringe the '724, '725, '424, and '219 patents;

WHEREAS, Plaintiffs asserted claims 2 and 9 of the '724 patent, claim 2 of the '725 patent, claim 6 of the '424 patent, and claims 1, 2, and 6 of the '219 patent ("the asserted claims") against Teva.

WHEREAS, this action was tried before the Court on June 2-5, 8-12, 15-16, 2015, and August 12, 2015;

NOW THEREFORE, IT IS ORDERED AND ADJUDGED that for the reasons set forth in the November 13, 2015 Memorandum Opinion, and any further opinion that the Court will issue:

1. Judgment is entered as follows:

a. The asserted claims of the '724, '725, and '424 patents are valid and are infringed by both of Teva's proposed 0.25 mg / 5 mL and 0.075 mg / 1.5 mL generic products.

b. The asserted claims of the '219 patent are valid and are infringed by Teva's proposed 0.25 mg / 5 mL generic product.

c. The asserted claims of the '219 patent are valid and are not infringed by Teva's proposed 0.075 / 1.5 mL mg generic product.

2. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval of ANDA No. 090713 by the FDA shall be no earlier than July 30, 2024, the expiration of the '724, '725, '424, and '219 patents, including pediatric exclusivity. If Plaintiffs become entitled to any other exclusivities that are not referenced herein, Plaintiffs may apply to the Court for further relief as may be appropriate.

3. Pursuant to 35 U.S.C. § 271(e)(4)(B), Teva and its officers, agents, servants, employees, and attorneys, and other persons who are in active concert or participation with Teva, its officers, agents, servants, employees, and attorneys, are hereby enjoined until the expiration of the '724, '725, '424, and '219 patents, including any applicable exclusivity, from the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any palonosetron hydrochloride intravenous solution product that is the subject of ANDA No. 090713.

SO ORDERED this 16th day of NOVEMBER, 2015.

Mary L. Cooper

The Honorable Mary L. Cooper
United States District Judge