IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED, Defendant.	C.A. No. 14-1196-RGA
NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED, Defendant.	C.A. No. 14-1508-RGA
NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED, Defendant.	C.A. No. 15-0128-RGA

FINAL JUDGMENT

WHEREAS this matter came before the Court for trial on the merits of C.A. No. 14-1196-RGA (the "West-Ward Zortress Litigation") to resolve the questions of: (i) whether claims

7 and 10 of U.S. Patent No. 5,665,772 ("'772 patent") are invalid by reason of obviousness or obviousness-type double patenting; (ii) whether claim 7 of U.S. Patent No. 6,239,124 ("'124 patent") and claim 7 of U.S. Patent No. 6,455,518 ("'518 patent") are invalid by reason of obviousness or obviousness-type double patenting; and (iii) whether Defendant West-Ward Pharmaceuticals International Limited ("West-Ward") would induce infringement of claim 7 of the '124 patent by including within its proposed labeling for the 0.25 mg, 0.5 mg, and 0.75 mg dosage strength everolimus tablets ("ANDA products") the indication "prophylaxis of organ rejection in adult patients: Kidney Transplant: at low-moderate immunologic risk. Use in combination with basiliximab, cyclosporine (reduced doses) and corticosteroids" ("the kidney transplant indication") and claim 7 of the '518 patent by including within its proposed labeling for its ANDA products the kidney transplant indication and the indication "prophylaxis of organ rejection in adult patients: . . . Liver transplant: Administer no earlier than 30 days post-transplant. Use in combination with tacrolimus (reduced doses) and corticosteroids" ("the liver transplant indication"), and

WHEREAS the Court has heard the witness testimony of the Plaintiffs Novartis Pharmaceuticals Corporation and Novartis AG ("Plaintiffs"), Defendants Breckenridge Pharmaceutical, Inc., Defendant Par Pharmaceutical, Inc., and West-Ward, (collectively "the parties") and has considered the evidence submitted by the parties, and the Court has reviewed the post-trial submissions of the parties, and

WHEREAS the parties stipulated and the Court ordered in advance of trial in the West-Ward Zortress Litigation, as well as in C.A. Nos. 14-1508-RGA and 15-0128-RGA ("West-Ward Afinitor I Litigations"), that West-Ward's generic versions of Zortress® and Afinitor® everolimus products, if approved by the FDA, would infringe claims 1-3, 7 and 10 of the '772

patent, and that the Court's decision regarding the validity of the '772 patent in the West-Ward Zortress Litigation shall apply in the West-Ward Afinitor I Litigations ("'772 Patent Stipulation"), and

WHEREAS Plaintiffs at the West-Ward Zortress Litigation trial informed the Court that they were no longer asserting infringement of claims 1-3 of the '772 patent against West-Ward, and

WHEREAS, pursuant to 35 U.S.C. § 271(e)(2)(A), the filing of West-Ward's Abbreviated New Drug Application ("ANDA") with certifications according to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '772 patent, the '518 patent, and the '124 patent constituted an artificial act of infringement of the '772 patent, the '518 patent, and the '124 patent, and

WHEREAS, as of May 2, 2017, the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") entry for Zortress indicates that the term of the '124 patent expires on August 11, 2017, and that the pediatric exclusivity associated with the '124 patent expires on February 11, 2018, and

WHEREAS, on July 19, 2016, Plaintiffs filed a terminal disclaimer of the '124 patent in view of the '518 patent ("the Terminal Disclaimer"), such that, notwithstanding any contrary information in the Orange Book, the term of the '124 patent expires on July 29, 2017, the same expiration date as the '518 patent, and the pediatric exclusivity associated with the '124 patent and the '518 patent expires on January 29, 2018;

IT IS ORDERED AND ADJUDGED, for the reasons set forth in the Court's Amended Trial Opinion dated April 3, 2017 (C.A. No. 14-1196-RGA, D.I. 195), that Final Judgment is hereby entered in the West-Ward Zortress Litigation and Afinitor I Litigations in favor of West-

Ward and against Plaintiffs that claims 7 and 10 of the '772 patent are invalid for obviousness-type double patenting; and it is further

ORDERED AND ADJUDGED, for the reasons set forth in the Court's April 3, 2017 Amended Trial Opinion, that Final Judgment is hereby entered in the West-Ward Zortress Litigation in favor of Plaintiffs and against West-Ward that claim 7 of the '124 patent and claim 7 of the '518 patent were not proven to be invalid by reason of obviousness or obviousness-type double patenting; and it is further

ORDERED AND ADJUDGED, for the reasons set forth in the Court's April 3, 2017 Amended Trial Opinion, that Final Judgment is hereby entered in the West-Ward Zortress Litigation in favor of Plaintiffs and against West-Ward that West-Ward would induce infringement of claim 7 of the '124 patent by selling its ANDA products in the United States with proposed labeling containing the kidney transplant indication; and it is further

ORDERED AND ADJUDGED, for the reasons set forth in the Court's April 3, 2017 Amended Trial Opinion, that Final Judgment is hereby entered in the West-Ward Zortress Litigation in favor of Plaintiffs and against West-Ward that West-Ward would induce infringement of claim 7 of the '518 patent by selling its ANDA products in the United States with proposed labeling containing the kidney transplant indication or the liver transplant indication; and it is further

ORDERED, in view of the parties' aforementioned '772 Patent Stipulation, that Final Judgment is hereby entered in the West-Ward Zortress Litigation and Afinitor I Litigations in favor of Plaintiffs and against West-Ward that West-Ward's generic versions of Zortress® and Afinitor® everolimus products, if approved by the FDA, would infringe claims 7 and 10 of the '772 patent; and it is further

ORDERED, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) of any final approval by the United States Food and Drug Administration of West-Ward's ANDA No. 206133 shall be a date not earlier than the expiration of the pediatric exclusivity for the '518 patent and '124 patent, which for both patents is January 29, 2018, except to the extent subsequently (a) agreed between Plaintiffs and West-Ward or (b) ordered or otherwise permitted by this Court or other tribunal; and it is further

ORDERED, Plaintiffs are not entitled to any injunction under 35 U.S.C. § 271(e)(4)(B); and it is further

ORDERED, in the event that a party appeals this Final Judgment, that 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 it is further

ORDERED, in the event that no party appeals this Final Judgment, that 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; and it is further

ORDERED, in the event that Plaintiffs appeal the Final Judgment that claims 7 and 10 of the '772 patent are invalid for obviousness-type double patenting, there shall not be three separate appeals with respect to that issue, but one appeal, because the Court's April 3, 2017 Amended Trial Opinion concerning that issue is based on one set of stipulated facts.

Dated this 16 day of May, 2017

Honorable Richard G. Andrews
United States District Court Judge