IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	C.A. No. 14-1289-RGA
NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	C.A. No. 14-1494-RGA
NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	C.A. No. 15-0078-RGA

FINAL JUDGMENT

WHEREAS this matter came before the Court for trial on the merits of C.A. No. 14-1289-RGA ("the Par Zortress Litigation") to resolve the questions of (i) whether claims 1-3, 7 and 10 of U.S. Patent No. 5,665,772 ("'772 patent") are invalid by reason of obviousness or obviousness-type double patenting and (ii) whether claim 7 of U.S. Patent No. 6,455,518 ("'518

patent") is invalid by reason of obviousness or obviousness-type double patenting, and (iii) whether Par Pharmaceutical, Inc. ("Par") would induce infringement of claim 7 of the '518 patent by including within its proposed labeling for its 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: Liver transplant: Administer no earlier than 30 days post-transplant. Use in combination with tacrolimus (reduced doses) and corticosteroids", and

WHEREAS, pursuant to 35 U.S.C. § 271(e)(2)(A), the filing of Par's Abbreviated New Drug Application ("ANDA") No. 205775 with certifications according to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '772 patent and the '518 patent constituted an artificial act of infringement of the '772 patent and '518 patent, and

WHEREAS the Court has heard the testimony of the Plaintiffs Novartis Pharmaceuticals Corporation's and Novartis AG's ("Plaintiffs"), Defendants Breckenridge Pharmaceutical, Inc.'s, West-Ward Pharmaceuticals International Limited's, Par's, (collectively "the parties") witnesses 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 (C.A. No. 14-1289-RGA, D.I. 140; C.A. No. 14-1494-RGA; C.A. No. 15-0078-RGA) that Par's generic versions of Zortress® and Afinitor® everolimus products, if approved by the FDA, will 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 District of Delaware Civil Action No. 14-1289-RGA shall apply in District of Delaware Civil Actions Nos. 14-1494-RGA and 15-0078-RGA ("Par Afinitor I Litigations"); and

WHEREAS Plaintiffs at the Par Zortress Litigation trial indicated that they were no longer asserting infringement of claims 1-3 of the '772 patent against Par;

IT IS ORDERED AND ADJUDGED, for the reasons set forth in the Court's Amended Trial Opinion dated April 3, 2017 (C.A. No. 14-1289-RGA, D.I. 171), that Final Judgment is hereby entered in the Par Zortress Litigation and the Par Afinitor I Litigations in favor of Par and against Plaintiffs, that claims 1-3, 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 Par Zortress Litigation in favor of Plaintiffs and against Par that claim 7 of the '518 patent was 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 Par Zortress Litigation in favor of Plaintiffs and against Par that Par would induce infringement of claim 7 of the '518 patent by selling in the United States its ANDA products with proposed labeling containing 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"; and it is further

ORDERED, in view of the parties' aforementioned stipulation, that Final Judgment is hereby entered in the Par Zortress Litigation and Afinitor I Litigations in favor of Plaintiffs and against Par that Par'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 Par Pharmaceutical, Inc.'s ANDA No. 205775 shall be a date not earlier than the expiration of the pediatric exclusivity for the '518 patent, which is January 29, 2018, except to the extent subsequently (a) agreed between Plaintiffs and Par 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 1-3, 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

Richard G. Andrews

Honorable Richard G. Andrews
United States District Court Judge