IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	C.A. No. 14-1043-RGA
NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	C.A. No. 16-0431-RGA
NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	C.A. No. 17-00420-RGA

FINAL JUDGMENT

WHEREAS this matter came before the Court for trial on the merits of Civil Action No. 14-1043-RGA 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; (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 Breckenridge Pharmaceutical, Inc. ("Breckenridge") would induce infringement of claim 7 of the '124 patent on account of its kidney transplant indication for its 0.25 mg, 0.5 mg, and 0.75 mg dosage strength everolimus tablets ("ANDA products"), and claim 7 of the '518 patent on account of its kidney transplant and liver transplant indications for its ANDA products (the "Breckenridge Zortress Litigation"); and

WHEREAS, pursuant to 35 U.S.C. § 271(e)(2)(A), the filing of Breckenridge's Abbreviated New Drug Application ("ANDA") No. 205432 with certifications according to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '772, '518 and '124 patents constituted an artificial act of infringement of the '772, '518, and '124 patents; and

WHEREAS the Court has heard the witness testimony of the Plaintiffs Novartis Pharmaceuticals Corporation and Novartis AG ("Plaintiffs"), Defendant West-Ward Pharmaceuticals International Limited, Defendant Par Pharmaceutical, Inc., and Defendant Breckenridge, (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 (C.A. No. 14-1043-RGA, D.I. 152) that Breckenridge'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 Civil Action No. 14-1043-RGA shall apply in Civil Action No. 16-0431-RGA, (C.A. No. 14-1043-RGA, D.I. 152); and

WHEREAS the parties hereby stipulate that the Court's decision regarding the validity of the '772 patent in Civil Action No. 14-1043-RGA shall apply in District of Delaware Civil Action No. 17-00420-RGA; and

WHEREAS the parties hereby stipulate that the Court's order regarding the infringement of claims 1-3, 7 and 10 of the '772 patent in Civil Action Nos. 14-1043-RGA and 16-0431-RGA shall apply in District of Delaware Civil Action No. 17-00420-RGA; and

WHEREAS Plaintiffs at the Breckenridge Zortress Litigation trial informed the Court that they were no longer asserting infringement of claims 1-3 of the '772 patent against Breckenridge; 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, that Final Judgment is hereby entered in District of Delaware Civil Action No. 14-1043-RGA in favor of Breckenridge 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 pursuant to Rule 54(b) of the Federal Rules of Civil Procedure, this Court now makes (a) "an express determination that there is no just reason for delay;" and (b) "an express direction for the entry of judgment" in favor of Breckenridge against Plaintiffs that claims 1-3, 7 and 10 of the '772 patent are invalid for obviousness-type double patenting in Civil Action Nos. 16-0431-RGA, and 17-00420-RGA. The Court is entering this Rule 54(b) judgment for the purpose of rendering a final judgment appealable to the Federal Circuit, which the Court believes will promote efficient judicial administration and will not result in any unfair prejudice to the parties. This Rule 54(b) judgment does not include: Plaintiffs' allegations of infringement of U.S. Patent No. 8,410,131 and U.S. Patent No. 8,778,962, which claims shall remain pending and proceed on the schedule ordered by the Court following entry of this Rule 54(b) judgment; 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 Civil Action No. 14-1043-RGA in favor of Plaintiffs and against Breckenridge that claim 7 of the '124 patent and claim 7 of the '518 patent are not 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 District of Delaware Civil Action No. 14-1043-RGA in favor of Plaintiffs and against Breckenridge that Breckenridge would induce infringement of claim 7 of the '124 patent by the sale in the United States of an ANDA product approved by the FDA with proposed labeling containing 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 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 District of Delaware Civil Action No. 14-1043-RGA in favor of Plaintiffs and against Breckenridge that Breckenridge would induce infringement of claim 7 of the '518 patent by the sale in the United States of an ANDA product approved by the FDA with proposed labeling containing 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 it is further

ORDERED, in view of the parties' aforementioned stipulation concerning infringement of the asserted claims of the '772 patent, that Final Judgment is hereby entered in Civil Actions Nos. 14-1043-RGA, 16-0431-RGA, and 17-00420-RGA in favor of Plaintiffs and against Breckenridge that Breckenridge'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 that claims 1-3 of the '772 patent are withdrawn from assertion by Plaintiffs; 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 Breckenridge 's ANDA No. 205432, shall be a date not earlier than the expiration of the pediatric exclusivity for the '124 and '518 patents, which for both is January 29, 2018, except to the extent subsequently (a) agreed between

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