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. 15-474-RGA

[PROPOSED] FINAL JUDGMENT

WHEREAS this matter came before the Court for trial on the merits of C.A. No. 15-474-RGA to resolve the questions of: (i) whether claims 1-3 of U.S. Patent No. 8,410,131 ("the '131 patent") are invalid by reason of obviousness, and (ii) whether claim 1 of U.S. Patent No. 9,006,224 ("the '224 patent") is invalid by reason of obviousness; and

WHEREAS the Court has heard the witness testimony of the Plaintiffs Novartis Pharmaceuticals Corporation and Novartis AG ("Plaintiffs") and Defendant West-Ward Pharmaceuticals International Limited ("Defendant"), has considered the evidence submitted by the parties, and has reviewed the post-trial submissions of the parties; and

WHEREAS Defendant filed Abbreviated New Drug Application ("ANDA") No. 207486 for everolimus 2.5, 5.0, 7.5, and 10 mg tablet products ("Defendant's ANDA Products") for the treatment of advanced renal cell carcinoma ("RCC") after failure of treatment with sunitinib or sorafenib ("Everolimus RCC Indication"), and the treatment of adult patients with progressive neuroendocrine tumors of pancreatic origins ("PNET") with unresectable, locally advanced or metastatic disease ("Everolimus PNET Indication"); and

WHEREAS the parties stipulated and the Court ordered in advance of trial that Novartis, having had a full and fair opportunity to assert that West-Ward infringes the claims of the '131 patent, would not assert that West-Ward induces, or contributes to, infringement of claims 5-9 of the '131 patent at trial and that because West-Ward had no counterclaims, the validity of claims 5-9 of the '131 patent would not be tried at trial (D.I. 67, ¶ 1); and

WHEREAS the parties stipulated and the Court ordered in advance of trial that the use of Defendant's ANDA Products in accordance with the Everolimus RCC Indication will constitute direct infringement of claims 1-3 of the '131 patent under 35 U.S.C. § 271(a) and that Defendant will induce such infringement under 35 U.S.C. § 271(b) (D.I. 67, ¶ 3); and

WHEREAS the parties stipulated and the Court ordered in advance of trial that Novartis, having had a full and fair opportunity to assert that West-Ward infringes the claims of the '224 patent, would not assert that West-Ward induces, or contributes to, infringement of claim 2 of the '224 patent at trial and that because West-Ward had no counterclaims, the validity of claim 2 of the '224 patent would not be tried at trial (D.I. 67, ¶ 2); and

WHEREAS the parties stipulated and the Court ordered in advance of trial that the use of Defendant's ANDA Products in accordance with the Everolimus PNET Indication will constitute direct infringement of claim 1 of the '224 patent under 35 U.S.C. § 271(a) and that Defendant will induce such infringement under 35 U.S.C. § 271(b) (D.I. 67, ¶ 4); and

WHEREAS the parties stipulated and the Court ordered in advance of trial that pursuant to 35 U.S.C. § 271(e)(2)(A), the filing and/or amending of Defendant's ANDA No. 207486 constituted an artificial act of infringement of claims 1-3 of the '131 patent (D.I. 67, ¶ 5); and

WHEREAS the parties stipulated and the Court ordered in advance of trial that pursuant to 35 U.S.C. § 271(e)(2)(A), the filing and/or amending of Defendant's ANDA No. 207486 constituted an artificial act of infringement of claim 1 of the '224 patent (D.I. 67, ¶ 6).

IT IS ORDERED AND ADJUDGED, for the reasons set forth in the Court's Trial Opinion dated December 14, 2017 (C.A. No. 15-474-RGA, D.I. 100), that Final Judgment is hereby entered in C.A. No. 15-474-RGA in favor of Plaintiffs and against Defendant that claims 1-3 of the '131 patent were not proven invalid by reason of obviousness; and it is further

ORDERED AND ADJUDGED, for the reasons set forth in the Court's December 14, 2017 Trial Opinion, that Final Judgment is hereby entered in C.A. No. 15-474-RGA in favor of Plaintiffs and against Defendant that claim 1 of the '224 patent was not proven invalid by reason of obviousness; and it is further

ORDERED in view of the parties' aforementioned stipulation (D.I. 67), that Final Judgment is hereby entered in C.A. No. 15-474-RGA in favor of Plaintiffs and against Defendant that the use of Defendant's ANDA Products in accordance with the Everolimus RCC Indication will constitute direct infringement of claims 1-3 of the '131 patent under 35 U.S.C. § 271(a) and that Defendant will induce such infringement under 35 U.S.C. § 271(b); and it is further

ORDERED in view of the parties' aforementioned stipulation (D.I. 67), that Final Judgment is hereby entered in C.A. No. 15-474-RGA in favor of Plaintiffs and against Defendant that the use of Defendant's ANDA Products in accordance with the Everolimus PNET indication will constitute direct infringement of claim 1 of the '224 patent under 35 U.S.C. § 271(a) and that Defendant will induce such infringement under 35 U.S.C. § 271(b); 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 Defendant's ANDA No. 207486 for the Everolimus RCC Indication shall be a date not earlier than the expiration of the pediatric exclusivity for the '131 patent, which is May 1, 2026; except to the extent subsequently (a) agreed between Plaintiffs and Defendant or (b) ordered or otherwise permitted by this Court or other tribunal; 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 Defendant's ANDA No. 207486 for the Everolimus PNET Indication shall be a date not earlier than the expiration of the '224 patent, which is July 1, 2028; except to the extent subsequently (a) agreed between Plaintiffs and Defendant or (b) ordered or otherwise permitted by this Court or other tribunal; 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.

Dated this 21 day of December, 2017

Richard G. Andrews

Honorable Richard G. Andrews
United States District Court Judge