IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, and MITSUI SUGAR CO., LTD.,

Plaintiffs,

v.

EZRA VENTURES, LLC,

Defendant.

C.A. No. 15-0150-LPS

LPS

~~[PROPOSED]~~ FINAL JUDGMENT

This patent infringement action was brought by Novartis Pharmaceuticals Corporation ("NPC"), Novartis AG ("NAG"), Mitsubishi Tanabe Pharma Corporation ("Mitsubishi") and Mitsui Sugar Co., Ltd. ("Mitsui"), alleging Ezra Ventures LLC's ("Ezra") Abbreviated New Drug Application ("ANDA") No. 20-7945 infringed U.S. Patent No. 5,604,229 ("the '229 patent"). NAG has been dismissed for lack of standing. On February 27, 2017, Ezra stipulated that ANDA No. 20-7945 infringes claims 9, 10, 35, 36, 46 and 48 of the '229 patent if said claims are not invalid, expired or unenforceable. (D.I. 208).

With Ezra having withdrawn its defenses under 35 U.S.C. § 112 in order to proceed to final judgment and appeal on defenses already decided, there remain no further disputes between the parties. As discussed at the pre-trial conference of April 18, 2017, the standing ruling of March 17, 2017 by this Court necessitates a final judgment that the patent term extension of the '229 patent is not invalid because this Court has ruled that NPC has an exclusive license to the '229 patent.

On May 31, 2017, having considered the parties' filings related to the final judgment to be entered (Actavis D.I. 291 and 296), the Court ordered Actavis and the Plaintiffs to submit a final judgment order consisting of all of Actavis' proposed final judgment (Actavis D.I. 291, Ex. 1) except not Actavis' proposed paragraphs 9-10, and further consisting of paragraphs 10 and 11 of Plaintiffs' proposed final judgment (Actavis D.I. 297, Ex. B). The Court similarly ordered (D.I. 224) Ezra and Plaintiffs to submit a final judgment order consistent with its order in the Actavis case, where applicable.

The Court hereby enters an appealable final judgment as set forth below. **IT IS ORDERED AND ADJUDGED** that:

1. Under Japanese law, Novartis Pharmaceuticals AG ("NPAG") obtained exclusive rights in the '229 patent from Yoshitomi Pharmaceutical Industries, Ltd. and Taito Co., Ltd., predecessors of Plaintiffs Mitsubishi and Mitsui, respectively. Thus, NPAG had exclusionary rights that could be conveyed to NPC and NAG.

2. NPC has an implied exclusive license to the '229 patent from NPAG. Thus, NPC has standing to assert the '229 patent.

3. Plaintiffs failed to show that NAG has exclusive rights in the '229 patent. Thus, NAG lacks standing to assert the '229 patent.

4. The Court's finding that NPC is the exclusive licensee of the '229 patent necessitates a finding that the patent term extension is not invalid on the grounds asserted by Defendants. NPC correctly represented NPC as the exclusive licensee of the '229 patent to the United States Patent and Trademark Office.

5. This Court on September 22, 2016 denied Ezra's motion under Fed. R. Civ. Pro. 12(c) that the patent term extension is invalid under theories of violation of the "one patent per

period" rule of 35 U.S.C. § 156 and the policy that expired patents are dedicated to the public. This Court further did not preclude that possible facts could be presented at a later date on the same issues. Ezra elected not to present further evidence at trial in support of its double patenting theory, and thus the Court's ruling is ready for judgment.

6. Judgment is entered in favor of NPC, Mitsubishi, and Mitsui against Ezra that the patent term extension for the '229 patent is valid and that the '229 patent is not expired or unenforceable.

7. Judgment is entered in favor of NPC, Mitsubishi, and Mitsui against Ezra that the commercial manufacture, use, offer for sale, sale in the United States and/or importation into the United States of the fingolimod product that is the subject of Ezra's ANDA 20-7945 would infringe claims 9, 10, 35, 36, 46, and 48 of the '229 patent.

8. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of Ezra's ANDA No. 20-7945 shall be a date not earlier than February 18, 2019, the date of expiration of the '229 patent, together with any period of pediatric exclusivity that may be awarded to NPC under 21 U.S.C. § 355a.

9. Pursuant to 35 U.S.C. § 271(e)(4)(B), Ezra and its officers, agents, employees and attorneys, and those who are in active concert or participation with those who receive actual notice of this Consent Judgment by personal service or otherwise, are hereby enjoined from engaging in the commercial manufacture, use, offer for sale, sale in the United States and/or importation into the United States of the fingolimod product that is the subject of Ezra's ANDA No. 20-7945 until February 18, 2019, the expiration date of the '229 patent.

10. All issues in this case, with the exception of costs and fees to the extent not stipulated by the parties, have been resolved.

11. The deadlines for moving for costs and attorneys' fees are reset. Any such motion shall now be due 60 days after the latter of:

(a) the deadline for filing a notice of appeal expires;

(b) the Federal Circuit dismisses the appeal;

(c) in the event this Court's judgment ultimately is affirmed without intervening remand to this Court, the date the mandate issues to this Court; or

(d) in the event this Court's judgment is remanded to this Court, the date this Court enters final judgment.

12. Consistent with the Court's order of May 31, 2017 (D.I. 224), the pending motions regarding entry of final judgment are **DENIED IN PART AND GRANTED IN PART**, as reflected in this final judgment. To the extent any additional pending motions may exist that are not addressed in this final judgment, they are **DENIED AS MOOT**.

13. This Final Judgment constitutes a final, appealable, dispositive ruling denying all arguments Ezra raised in its Rule 12(c) motion for judgment on the pleadings that all or part of the patent term extension of the '229 patent is invalid under theories of violation of the "one patent per period" rule of 35 U.S.C. § 156, the policy that expired patents are dedicated to the public, and/or double patenting.

SO ORDERED this 8th of June, 2017

Chief United States District Judge

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