

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACORDA THERAPEUTICS, INC., et al.)

Plaintiffs,)

v.)

ROXANE LABORATORIES INC., et al.)

Defendants.)

C.A. No. 14-882 (LPS)
(CONSOLIDATED)

PROPOSED FINAL JUDGMENT

This action, having been tried before the Court on September 19, 20, 21 and 23, 2016, Honorable Leonard P. Stark, Chief District Judge presiding, the evidence and testimony of witnesses of each side having been heard and a decision having been rendered:

IT IS HEREBY ORDERED AND ADJUDGED this 24th day of April, 2017, for the reasons set forth in the Memorandum Opinion dated March 31, 2017 (D.I. 284) that:

1. Judgment is entered in favor of plaintiffs Acorda Therapeutics, Inc. ("Acorda") and Alkermes Pharma Ireland Limited (collectively, "Plaintiffs") and against defendants Mylan Pharmaceuticals Inc. ("Mylan"), Roxane Laboratories, Inc. ("Roxane"), and Teva Pharmaceuticals USA Inc. ("Teva") (collectively, "Defendants") that claims 3 and 8 of U.S. Patent No. 5,540,938 (the "'938 Patent") would be infringed by the use of the products that are the subjects of ANDA Nos. 206858, 206646 and 206854, filed with the Food and Drug Administration ("FDA") by defendants Mylan, Roxane and Teva, respectively, and that claims 3 and 8 of the '938 patent are valid and enforceable.

2. Judgment is entered in favor of Defendants and against Plaintiffs that the following patent claims asserted by Plaintiffs are invalid for obviousness: claims 1, 7, 38 and 39 of U.S. Patent No. 8,007,826 (the "'826 Patent"); claims 3 and 5 of U.S. Patent No. 8,663,685

(the “’685 Patent”); claims 1, 2, 5, 22, 32, 36 and 37 of U.S. Patent No. 8,354,437 (the “’437 Patent”); and claims 36, 38 and 45 of U.S. Patent No. 8,440,703 (the “’703 Patent”).

3. On September 1, 2016, Plaintiffs and Defendants stipulated that claims 1, 7, 38 and 39 of the ’826 Patent, claims 3 and 5 of the ’685 Patent, claims 1, 2, 5, 22, 32, 36 and 37 of the ’437 Patent, and claims 36, 38 and 45 of the ’703 Patent would be infringed by the use in the United States of the products that are the subjects of ANDA Nos. 206858, 206646 and 206854, filed with the FDA by defendants Mylan, Roxane and Teva, respectively, if those claims were not invalid for obviousness. (D.I. 254.)

4. Pursuant to 35 U.S.C. § 271(e)(4)(A), it is hereby ordered that the effective date of any final approval by the FDA of the product that is the subject of Mylan’s ANDA No. 206858 shall not be a date earlier than the date of the expiration of the ’938 Patent, inclusive of the patent term extension granted under 35 U.S.C. § 156 (July 30, 2018) (“the ’938 Patent Term”).

5. Pursuant to 35 U.S.C. § 271(e)(4)(B), and subject to 35 U.S.C. § 271(i), Mylan and its officers, agents, servants, employees, and those persons in active concert or participation with any of them, are enjoined from selling or offering for sale in the United States Mylan’s proposed generic dalfampridine product that is the subject of Mylan’s ANDA No. 206858 prior to the expiration of the ’938 Patent Term.

6. Pursuant to 35 U.S.C. § 271(e)(4)(A), it is hereby ordered that the effective date of any final approval by the FDA of the product that is the subject of Roxane’s ANDA No. 206646 shall not be a date earlier than the date of the expiration of the ’938 Patent, inclusive of the patent term extension granted under 35 U.S.C. § 156 (July 30, 2018).

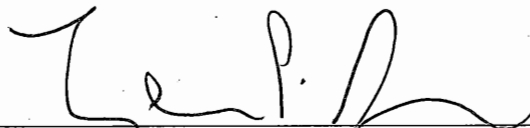
7. Pursuant to 35 U.S.C. § 271(e)(4)(B), and subject to 35 U.S.C. § 271(i), Roxane and its officers, agents, servants, employees, and those persons in active concert or participation with any of them, are enjoined from selling or offering for sale in the United States Roxane's proposed generic dalfampridine product that is the subject of Roxane's ANDA No. 206646 prior to the expiration of the '938 Patent Term.

8. Pursuant to 35 U.S.C. § 271(e)(4)(A), it is hereby ordered that the effective date of any final approval by the FDA of the product that is the subject of Teva's ANDA No. 206854 shall not be a date earlier than the date of the expiration of the '938 Patent, inclusive of the patent term extension granted under 35 U.S.C. § 156 (July 30, 2018).

9. Pursuant to 35 U.S.C. § 271(e)(4)(B), and subject to 35 U.S.C. § 271(i), Teva and its officers, agents, servants, employees, and those persons in active concert or participation with any of them, are enjoined from selling or offering for sale in the United States Teva's proposed generic dalfampridine product that is the subject of Teva's ANDA No. 206854 prior to the expiration of the '938 Patent Term.

April 24, 2017

DATED



CHIEF UNITED STATES DISTRICT JUDGE

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