

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC., UCB BIOPHARMA SPRL,
RESEARCH CORPORATION
TECHNOLOGIES, INC. AND HARRIS
FRC CORPORATION,

Plaintiffs,

v.

ACCORD HEALTHCARE, INC.. et al.,

Defendants.

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) C.A. No 13-1206-LPS
) CONSOLIDATED
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PROPOSED FINAL JUDGMENT

This action, having been tried before the Court from November 9 through November 13, 2015, 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 1st day of September 2016, for the reasons set forth in the Opinion dated August 12, 2016 (D.I. 313) that:

Accord Defendants

1. Judgment is entered in favor of Plaintiffs UCB, Inc., UCB BioPharma SPRL, Research Corporation Technologies, Inc. and Harris FRC Corporation (collectively, "Plaintiffs") and against defendants Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd. (collectively, "Accord") on Plaintiffs' claim that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic lacosamide product that is the subject of Accord's Abbreviated New Drug Application ("ANDA") No. 205011 would infringe claims 9, 10, and 13 of U.S. Reissued Patent No. RE 38,551 (the "'551 Patent").

2. Judgment is entered in favor of Plaintiffs and against Accord on Accord's counterclaim for invalidity of claims 9, 10, and 13 of the '551 Patent.

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), it is hereby ordered that the effective date of any final approval by the Food and Drug Administration (“FDA”) of Accord’s ANDA No. 205011 is to be a date not earlier than the date of expiration of the ’551 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 (March 17, 2022).

4. Pursuant to 35 U.S.C. § 271(e)(4)(B), Accord and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Accord’s proposed generic lacosamide product that is the subject of Accord’s ANDA No. 205011 during the term of the ’551 Patent.

Alembic

5. Judgment is entered in favor of Plaintiffs and against defendant Alembic Pharmaceuticals Ltd. (“Alembic”) on Plaintiffs’ claim that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic lacosamide product that is the subject of Alembic’s ANDA No. 204974 would infringe claims 9, 10, and 13 of the ’551 Patent.

6. Pursuant to 35 U.S.C. § 271(e)(4)(A), the FDA is ordered to reset the effective date of the approval of Alembic’s ANDA No. 204974 to be a date that is not earlier than the date of expiration of the ’551 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 (March 17, 2022).

7. Pursuant to 35 U.S.C. § 271(e)(4)(B), Alembic and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby

enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Alembic's proposed generic lacosamide product that is the subject of Alembic's ANDA No. 204974 during the term of the '551 Patent.

Amneal Defendants

8. Judgment is entered in favor of Plaintiffs and against defendants Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal") on Plaintiffs' claim that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic lacosamide products that are the subject of Amneal's ANDAs Nos. 204839 and 204857 would infringe claims 9, 10, and 13 of the '551 Patent.

9. Judgment is entered in favor of Plaintiffs and against Amneal on Amneal's counterclaim for invalidity of claims 9, 10, and 13 of the '551 Patent.

10. Pursuant to 35 U.S.C. § 271(e)(4)(A), the FDA is ordered to reset the effective date of the approval of Amneal's ANDAs Nos. 204839 and 204857 to be a date that is not earlier than the date of expiration of the '551 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 (March 17, 2022). It is further ordered that the effective date of any final approval by the FDA of Amneal's ANDAs Nos. 204839 and 204857 is to be a date not earlier than the date of expiration of the '551 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 (March 17, 2022).

11. Pursuant to 35 U.S.C. § 271(e)(4)(B), Amneal and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or

importing into the United States, Amneal's proposed generic lacosamide products that are the subjects of Amneal's ANDAs Nos. 204839 and 204857 during the term of the '551 Patent.

Apotex Defendants

12. Judgment is entered in favor of Plaintiffs and against defendants Apotex Corp. and Apotex, Inc. (collectively, "Apotex") on Plaintiffs' claims that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic lacosamide products that are the subjects of Apotex's ANDAs Nos. 204986 and 206355 would infringe claims 9, 10, and 13 of the '551 Patent.

13. Judgment is entered in favor of Plaintiffs and against Apotex on Apotex's counterclaims for invalidity of claims 9, 10, and 13 of the '551 Patent.

14. 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 Apotex's ANDAs Nos. 204986 and 206355 is to be a date not earlier than the date of expiration of the '551 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 (March 17, 2022).

15. Pursuant to 35 U.S.C. § 271(e)(4)(B), Apotex and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Apotex's proposed generic lacosamide products that are the subjects of Apotex's ANDAs Nos. 204986 and 206355 during the term of the '551 Patent.

Aurobindo Defendants

16. Judgment is entered in favor of Plaintiffs and against defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo") on Plaintiffs' claim

that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic lacosamide product that is the subject of Aurobindo's ANDA No. 204994 would infringe claims 9, 10, and 13 of the '551 Patent.

17. Judgment is entered in favor of Plaintiffs and against Aurobindo on Aurobindo's counterclaim for invalidity of claims 9, 10, and 13 of the '551 Patent.

18. Pursuant to 35 U.S.C. § 271(e)(4)(A), the FDA is ordered to reset the effective date of the approval of Aurobindo's ANDA No. 204994 to be a date that is not earlier than the date of expiration of the '551 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 (March 17, 2022).

19. Pursuant to 35 U.S.C. § 271(e)(4)(B), Aurobindo and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Aurobindo's proposed generic lacosamide product that is the subject of Aurobindo's ANDA No. 204994 during the term of the '551 Patent.

Breckenridge Defendants

20. Judgment is entered in favor of Plaintiffs and against defendants Breckenridge Pharmaceutical, Inc. and MSN Laboratories Pvt. Ltd. (collectively, "Breckenridge") on Plaintiffs' claim that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic lacosamide product that is the subject of Breckenridge's ANDA No. 204921 would infringe claims 9, 10, and 13 of the '551 Patent.

21. Judgment is entered in favor of Plaintiffs and against Breckenridge on Breckenridge's counterclaim for invalidity of claims 9, 10, and 13 of the '551 Patent.

22. Pursuant to 35 U.S.C. § 271(e)(4)(A), the FDA is ordered to reset the effective date of the approval of Breckenridge's ANDA No. 204921 to be a date that is not earlier than the date of expiration of the '551 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 (March 17, 2022).

23. Pursuant to 35 U.S.C. § 271(e)(4)(B), Breckenridge and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Breckenridge's proposed generic lacosamide product that is the subject of Breckenridge's ANDA No. 204921 during the term of the '551 Patent.

Mylan Defendants

24. Judgment is entered in favor of Plaintiffs and against defendants Mylan Pharmaceuticals Inc. and Mylan, Inc. (collectively, "Mylan") on Plaintiffs' claim that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic lacosamide product that is the subject of Mylan's ANDA No. 205026 would infringe claims 9, 10, and 13 of the '551 Patent.

25. Judgment is entered in favor of Plaintiffs and against Mylan on Mylan's counterclaim for invalidity of claims 9, 10, and 13 of the '551 Patent.

26. Pursuant to 35 U.S.C. § 271(e)(4)(A), the FDA is ordered to reset the effective date of approval of Mylan's ANDA No. 205026 to a date that is not earlier than the date of expiration of the '551 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 (March 17, 2022).

27. Pursuant to 35 U.S.C. § 271(e)(4)(B), Mylan and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Mylan's proposed generic lacosamide product that is the subject of Mylan's ANDA No. 205026 during the term of the '551 Patent.

Sun Defendants

28. Judgment is entered in favor of Plaintiffs and against defendants Sun Pharma Global FZE and Sun Pharmaceutical Industries, Ltd. (collectively, "Sun") on Plaintiffs' claim that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic lacosamide product that is the subject of Sun's ANDA No. 205031 would infringe claims 9, 10, and 13 of the '551 Patent.

29. Judgment is entered in favor of Plaintiffs and against Sun on Sun's counterclaim for invalidity of claims 9, 10, and 13 of the '551 Patent.

30. Pursuant to 35 U.S.C. § 271(e)(4)(A), the FDA is ordered to reset the effective date of the approval of Sun's ANDA No. 205031 to be a date that is not earlier than the date of expiration of the '551 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 (March 17, 2022).

31. Pursuant to 35 U.S.C. § 271(e)(4)(B), Sun and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or

importing into the United States, Sun's proposed generic lacosamide product that is the subject of Sun's ANDA No. 205031 during the term of the '551 Patent.

Actavis Defendants

32. Judgment is entered in favor of Plaintiffs and against defendants Watson Laboratories, Inc. – Florida (n/k/a Actavis Laboratories FL, Inc.), Watson Pharma, Inc. (n/k/a Actavis Pharma, Inc.), and Actavis, Inc. (collectively, "Actavis") on Plaintiffs' claim that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic lacosamide product that is the subject of Actavis's ANDA No. 204855 would infringe claims 9, 10, and 13 of the '551 Patent.

33. Judgment is entered in favor of Plaintiffs and against Actavis on Actavis's counterclaim for invalidity of claims 9, 10, and 13 of the '551 Patent.

34. Pursuant to 35 U.S.C. § 271(e)(4)(A), the FDA is ordered to reset the effective date of the approval of Actavis's ANDA No. 204855 to be a date that is not earlier than the date of expiration of the '551 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 (March 17, 2022).

35. Pursuant to 35 U.S.C. § 271(e)(4)(B), Actavis and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Actavis's proposed generic lacosamide product that is the subject of Actavis's ANDA No. 204855 during the term of the '551 Patent.

Zydus Defendants

36. Judgment is entered in favor of Plaintiffs and against defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (collectively, “Zydus”) on Plaintiffs’ claim that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic lacosamide product that is the subject of Zydus’s ANDA No. 204947 would infringe claims 9, 10, and 13 of the ’551 Patent.

37. Judgment is entered in favor of Plaintiffs and against Zydus on Zydus’s counterclaim for invalidity of claims 9, 10, and 13 of the ’551 Patent.

38. Pursuant to 35 U.S.C. § 271(e)(4)(A), it is hereby ordered that the effective date of any final approval of Zydus’s ANDA No. 204947 is to be a date that is not earlier than the date of expiration of the ’551 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 (March 17, 2022).

39. Pursuant to 35 U.S.C. § 271(e)(4)(B), Zydus and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Zydus’s proposed generic lacosamide product that is the subject of Zydus’s ANDA No. 204947 during the term of the ’551 Patent.

September 1, 2016
DATED



UNITED STATES DISTRICT JUDGE