IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DEPOMED, INC. and GRÜNENTHAL GMBH, Plaintiffs/Counterclaim Defendants, v. ACTAVIS ELIZABETH LLC and ALKEM LABORATORIES LIMITED, Defendants/Counterclaim Plaintiffs.	Civil Action No. 2:13-cv-04507-CCC-MF
AND CONSOLIDATED CASES	Civil Action No. 2:13-cv-07803-CCC-MF Civil Action No. 2:13-cv-06929-CCC-MF Civil Action No. 2:14-cv-03941-CCC-MF Civil Action No. 2:14-cv-04617-CCC-MF Civil Action No. 2:15-cv-06797-CCC-MF

FINAL JUDGMENT AND INJUNCTION[1]

THIS MATTER, having come before the Court on the patent infringement claims of plaintiffs Depomed, Inc. ("Depomed") and Grünenthal GmbH ("Grünenthal") (collectively, "Plaintiffs"), and the counterclaims and defenses of defendants Actavis Elizabeth LLC, Actavis UT, Actavis LLC, Actavis, Inc. (collectively, "Actavis"), Roxane Laboratories, Inc. ("Roxane"), and Alkem Laboratories Ltd. ("Alkem") (all together, "Defendants"), a bench trial having been held by this Court, and the Court having issued its Opinion in this matter on September 30, 2016 (Dkt. 536, Case No. 13-04507),

[1] This serves as Final Judgment as to all claims and counterclaims asserted in each of the above-referenced actions with the following exception: pursuant to the Court's November 19, 2015 Order (Dkt. 287, Case No. 13-04507), all proceedings related to U.S. Patent No. 8,309,060 are stayed.

IT IS on this 11 day of April, 2017, hereby

ORDERED, ADJUDGED, and DECREED as follows:

1. This Court has jurisdiction over the subject matter of the above consolidated actions and has personal jurisdiction over the parties for purposes of the above consolidated actions.

I. U.S. Patent No. RE39,593

A. Infringement

2. Judgment is hereby entered in favor of Plaintiffs, and against Defendants, on Plaintiffs' claim of infringement of U.S. Patent No. RE39,593 (the "'593 Patent").

3. Judgment is hereby entered against Defendants on their respective counterclaims for a declaratory judgment of non-infringement of the '593 Patent.

4. Claims 8, 61, 117, and 147 of the '593 Patent are infringed under 35 U.S.C. § 271(e)(2)(A) by the following Abbreviated New Drug Applications ("ANDAs") (collectively, "Defendants' ANDAs"):

A. Actavis's ANDA Nos. 204971, 206657, and 204972;

B. Roxane's ANDA Nos. 205057 and 206418; and

C. Alkem's ANDA Nos. 205015 and 205016.

5. Submission of Defendants' ANDAs to the U.S. Food & Drug Administration ("FDA") constitutes acts of infringement of the '593 Patent under 35 U.S.C. § 271(e)(2)(A).

6. Each of Defendants, their affiliates and subsidiaries, and all of their officers, agents, servants, employees, and attorneys, and all persons and entities in active concert or participation or privity with any of them, and their successors and assigns, are hereby enjoined from engaging in the commercial manufacture, use, or sale within the United States of the products described in Defendants' ANDAs (the "ANDA Products") or the active pharmaceutical

ingredient (tapentadol hydrochloride) thereof, from offering to sell the ANDA Products or the active pharmaceutical ingredient (tapentadol hydrochloride) thereof within the United States, or from importing the ANDA Products or the active pharmaceutical ingredient (tapentadol hydrochloride) thereof into the United States before the expiration of the '593 Patent on August 5, 2022. This paragraph does not restrict Defendants' activities that fall within the scope of 35 U.S.C. § 271(e)(1), including, for example, the sale, manufacture, importation, or use of tapentadol hydrochloride solely for uses reasonably related to the development and/or submission of information to FDA.

7. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval by FDA of Defendants' ANDAs shall be a date which is not earlier than August 5, 2022 or, to the extent FDA determines that pediatric exclusivity is available, the date any such exclusivity ends. Depomed will provide written notice to Defendants of such grant of pediatric exclusivity within five (5) business days of receiving such an award of exclusivity from FDA.

B. Validity and/or Enforceability

8. Judgment is hereby entered against Defendants on their respective counterclaims for a declaratory judgment of invalidity and/or unenforceability of the '593 Patent.

9. The Court finds that claims 8, 61, 117, and 147 of the '593 Patent are not invalid under 35 U.S.C. § 1 *et seq.*

II. U.S. Patent No. 7,994,364

A. Infringement

10. Judgment is hereby entered in favor of Plaintiffs, and against Defendants, on Plaintiffs' claim of infringement of U.S. Patent No. 7,994,364 (the "'364 Patent").

11. Judgment is hereby entered against Defendants on their respective counterclaims for a declaratory judgment of non-infringement of the '364 Patent.

12. Claims 1, 2, 3, and 25 of the '364 Patent are infringed by Defendants' ANDAs

under 35 U.S.C. § 271(e)(2)(A).

13. Submission of Defendants' ANDAs to FDA constitutes acts of infringement of the '364 Patent under 35 U.S.C. § 271(e)(2)(A).

14. Each of Defendants, their affiliates and subsidiaries, and all of their officers, agents, servants, employees, and attorneys, and all persons and entities in active concert or participation or privity with any of them, and their successors and assigns, are hereby enjoined from engaging in the commercial manufacture, use, or sale within the United States of the ANDA Products or the active pharmaceutical ingredient (tapentadol hydrochloride Form A) thereof, from offering to sell the ANDA Products or the active pharmaceutical ingredient (tapentadol hydrochloride Form A) thereof within the United States, or from importing the ANDA Products or the active pharmaceutical ingredient (tapentadol hydrochloride Form A) thereof into the United States before the expiration of the '364 Patent on June 27, 2025. This paragraph does not restrict Defendants' activities that fall within the scope of 35 U.S.C. § 271(e)(1), including, for example, the sale, manufacture, importation, or use of tapentadol hydrochloride Form A solely for uses reasonably related to the development and/or submission of information to FDA.

15. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval by FDA of Defendants' ANDAs shall be a date which is not earlier than June 27, 2025 or, to the extent FDA determines that pediatric exclusivity is available, the date any such exclusivity ends. Depomed will provide written notice to Defendants of such grant of pediatric exclusivity within five (5) business days of receiving such an award of exclusivity from FDA.

B. Validity and/or Enforceability

16. Judgment is hereby entered against Defendants on their respective counterclaims for a declaratory judgment of invalidity and/or unenforceability of the '364 Patent.

17. The Court finds that claims 1, 2, 3, and 25 of the '364 Patent are not invalid under 35 U.S.C. § 1 *et seq*.

18. The Court finds that the '364 Patent is not unenforceable under the doctrine of unclean hands.

III. U.S. Patent No. 8,536,130

A. Infringement

1. *Alkem*

19. Judgment is hereby entered in favor of Plaintiffs and against Alkem on Plaintiffs' claim of infringement of U.S. Patent No. 8,536,130 (the "'130 Patent").

20. Judgment is hereby entered for Plaintiffs, and against Alkem, on Alkem's counterclaim for a declaratory judgment of non-infringement of the '130 Patent.

21. Claims 1, 2, 3, and 6 of the '130 Patent are infringed under 35 U.S.C. § 271(e)(2)(A) by Alkem's ANDA No. 205016.

22. Submission of Alkem's ANDA No. 205016 to FDA constitutes an act of infringement of the '130 Patent under 35 U.S.C. § 271(e)(2)(A).

23. Alkem, its affiliates and subsidiaries, and all of its officers, agents, servants, employees, and attorneys, and all persons and entities in active concert or participation or privity with any of them, and their successors and assigns, are hereby enjoined from engaging in the commercial manufacture, use, or sale within the United States of the products described in Alkem's ANDA No. 205016 (the "ANDA No. 205016 products") or the active pharmaceutical ingredient (tapentadol hydrochloride) thereof for use in treating polyneuropathic pain, from offering to sell the ANDA No. 205016 Products or the active pharmaceutical ingredient (tapentadol hydrochloride) thereof for use in treating polyneuropathic pain within the United States, or from importing the ANDA No. 205016 Products for use in treating polyneuropathic pain or the active pharmaceutical ingredient (tapentadol hydrochloride) with knowledge that it will be used for treating polyneuropathic pain into the United States before the expiration of the '130 Patent on September 22, 2028. This paragraph does not restrict Defendants' activities that fall

within the scope of 35 U.S.C. § 271(e)(1), including, for example, the sale, manufacture, importation, or use of tapentadol hydrochloride for treatment of polyneuropathic pain, solely in connection with uses reasonably related to the development and/or submission of information to FDA.

24. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval by FDA of Alkem's ANDA No. 205016 shall be a date which is not earlier than September 22, 2028 or, to the extent FDA determines that pediatric exclusivity is available, the date any such exclusivity ends. Depomed will provide written notice to Defendants of such grant of pediatric exclusivity within five (5) business days of receiving such an award of exclusivity from FDA.

2. Actavis and Roxane

25. Judgment is hereby entered against Plaintiffs on their claim of infringement of the '130 Patent.

26. Judgment is hereby entered for Actavis and Roxane, and against Plaintiffs, on their respective counterclaims for a declaratory judgment of non-infringement of the '130 Patent.

27. Claims 1 and 2 of the '130 Patent are not infringed under 35 U.S.C. § 271(e)(2)(A) by Actavis's ANDA No. 204972 or Roxane's ANDA No. 206418.

28. Submission of Actavis's ANDA No. 204972 and Roxane's ANDA No. 206418 to FDA does not constitute acts of infringement of the '130 Patent under 35 U.S.C. § 271(e)(2)(A).

B. Validity and/or Enforceability (as to All Defendants)

29. Judgment is hereby entered against Defendants on their respective counterclaims for a declaratory judgment of invalidity and/or unenforceability of the '130 Patent.

30. The Court finds that claims 1, 2, 3, and 6 of the '130 Patent are not invalid under 35 U.S.C. § 1 *et seq.*

* * * * *

31. Consistent with the Court's November 19, 2015 Order (Dkt. 287, Case No. 13-04507), all proceedings relating to U.S. Patent No. 8,309,060 (the "'060 patent") (Plaintiffs' Count V at Dkt. 12 and 146, Case No. 13-04507 and Actavis's Fifth and Sixth Counts at Dkt. 39, Case No. 13-04507 and Actavis's Fifth, Sixth and Seventh Counts at Dkt. 132, 133, and 150, Case No. 13-04507) are stayed pending resolution of the Federal Circuit appeal from *Endo Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, No. 12-cv-8115 et al. (S.D.N.Y.).

32. Pursuant to Federal Rule of Civil Procedure 54(b), the Court determines that there is no just reason for delay in entering final judgment as to all claims adjudged in this Final Judgment, because doing so would prejudice the parties. This Final Judgment, and any appeal therefrom, will have no impact on the pending and stayed '060 patent proceedings. Likewise, the '060 patent proceedings (including the Court's previous Order staying those proceedings) and the resolution of the appeal in *Endo* will have no impact on this Final Judgment (or any appeal therefrom).

33. Pursuant to Fed. R. Civ. P. 58(a), this is the FINAL JUDGMENT of the Court. *See supra* n. 1.

34. Pursuant to Fed. R. Civ. P. 54, Plaintiffs are the Prevailing Party entitled to costs. Plaintiffs shall serve and file their Bill of Costs and Disbursements in accordance with Local Rule 54.1.

Claire C. Cecchi
U.S. District Judge