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

DEPOMED, INC. and, GRÜNENTHAL GMBH, Plaintiffs and Counterclaim Defendants, v. ACTAVIS ELIZABETH LLC, ACTAVIS LLC, and ACTAVIS INC., Defendants and Counterclaim Plaintiffs,	C.A. No. 2:15-cv-06797-CCC-MF PUBLIC VERSION

ACTAVIS'S ANSWER TO COMPLAINT,
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants Actavis Elizabeth LLC, Actavis LLC, and Actavis Inc. (collectively, "Actavis"), by its attorneys, answer the Complaint (D.I. 1) of Plaintiffs Depomed, Inc. ("Depomed") and Grünenthal GmbH ("Grünenthal" and collectively with Depomed, "Plaintiffs") as follows.

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Actavis denies all allegations in Plaintiffs' Complaint except those expressly admitted below.

ALLEGATIONS REGARDING NATURE OF THE ACTION

1. This paragraph contains legal conclusions to which no response is required. To the extent any response is necessary, Actavis admits that Plaintiffs purport to bring this action under the patent laws of the United States, Title 35, United States Code, for infringement of U.S. Patent No. 8,536,130 ("the '130 patent") related to Actavis's Abbreviated New Drug

Application ("ANDA") for approval to manufacture and sell generic versions of NUCYNTA® ER. Actavis notes that Count I of this Complaint has already been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55). Actavis denies all other allegations in Paragraph 1.

ALLEGATIONS REGARDING THE PARTIES: PLAINTIFFS

2. On information and belief, Actavis admits Depomed's address. Actavis is without sufficient information or knowledge to admit or deny the remaining allegations contained in Paragraph 2 and, therefore, denies them on this basis.

3. On information and belief, Actavis admits Grünenthal's address. Actavis is without sufficient information or knowledge to admit or deny the remaining allegations contained in Paragraph 3 and, therefore, denies them on this basis.

4. On information and belief, Actavis admits the allegations in Paragraph 4.

5. On information and belief, Actavis admits the allegations in Paragraph 5.

6. On information and belief, Actavis admits that the label for NUCYNTA® ER has the following indications: (1) "pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate" and (2) "neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Actavis denies that the accuracy of the characterization of these indications as "Primary" or "Secondary." Actavis denies the remaining allegations in Paragraph 6.

ALLEGATIONS REGARDING THE PARTIES: DEFENDANTS

7. Actavis admits that Actavis Elizabeth LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of

business at 200 Elmora Avenue, Elizabeth, New Jersey. Actavis denies the remaining allegations in Paragraph 7.

8. Actavis LLC was dismissed from related action No. 2:13-cv-04507-CCC-MF by Order dated September 13, 2013 (D.I. 38) and for the same reasons should be dismissed from this action. To the extent a response is deemed required, Actavis admits that Actavis LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ. Actavis denies the remaining allegations in Paragraph 8.

9. Actavis, Inc. was dismissed from related action No. 2:13-cv-04507-CCC-MF by Order dated September 13, 2013 (D.I. 38) and for the same reasons should be dismissed from this action. To the extent a response is deemed required, Actavis admits it is a corporation organized and existing under the laws of the State of Nevada, with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ. Actavis denies the remaining allegations in Paragraph 9.

10. Actavis admits that Actavis Elizabeth LLC is wholly owned by Actavis, Inc. Actavis denies the remaining allegations in Paragraph 10.

ALLEGATIONS REGARDING PERSONAL JURISDICTION OVER ACTAVIS

11. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the purposes of this action only, Actavis does not contest that this Court has personal jurisdiction over Actavis Elizabeth LLC. Otherwise denied.

12. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the purposes of this action only, Actavis does not contest that this Court has personal jurisdiction over Actavis Elizabeth LLC. Otherwise denied.

13. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the purposes of this action only, Actavis does not contest that this Court has personal jurisdiction over Actavis Elizabeth LLC. Otherwise denied.

14. This paragraph contains legal conclusions to which no answer is required. Actavis LLC has been dismissed from related action No. 2:13-cv-04507-CCC-MF by Order dated September 13, 2013 (D.I. 38) and for the same reasons should be dismissed from this action. To the extent a response is deemed required, Actavis denies the allegations in Paragraph 14.

15. This paragraph contains legal conclusions to which no answer is required. Actavis LLC has been dismissed from related action No. 2:13-cv-04507-CCC-MF by Order dated September 13, 2013 (D.I. 38) and for the same reasons should be dismissed from this action. To the extent a response is deemed required, Actavis denies the allegations in Paragraph 15.

16. This paragraph contains legal conclusions to which no answer is required. Actavis LLC has been dismissed from related action No. 2:13-cv-04507-CCC-MF by Order dated September 13, 2013 (D.I. 38) and for the same reasons should be dismissed from this action this action. To the extent a response is deemed required, Actavis denies the allegations in Paragraph 16.

17. Actavis denies the allegations of Paragraph 17.

18. Actavis denies the allegations of Paragraph 18.

19. Actavis denies the allegations of Paragraph 19.

ALLEGATIONS REGARDING SUBJECT MATTER JURISDICTION

20. The Court has dismissed Plaintiffs' claims under 35 U.S.C. § 271(e)(2) as set forth in its Opinion dated January 8, 2016. (D.I. 55).

21. The Court has not dismissed Plaintiffs' count seeking declaratory judgment under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Actavis reserves its appellate rights with respect to the Court's decision in that respect.

ALLEGATIONS REGARDING VENUE

22. In light of the Court's Opinion dated January 8, 2016 (D.I. 55), and subject to the above-noted reservation of appellate rights, Actavis does not contest that venue in this Court is proper.

ALLEGATIONS REGARDING THE PATENT-IN-SUIT

23. Actavis admits that the '130 patent is entitled "USE OF 1 PHENYL-3-DIMETHYLAMINOPROPANE COMPOUNDS FOR TREATING NEUROPATHIC PAIN," that the patent states on its face an issue date of September 17, 2013, and that the patent lists, on its face, Thomas Christoph, Elmar Friderichs, Babette-Yvonne Koegel, and Murielle Meen as the inventors of the patent. Actavis admits that Exhibit 1 purports to be a copy of the '130 patent. Actavis denies that the '130 patent was duly and legally issued and the remaining allegations in Paragraph 23.

24. Actavis admits that claims 1, 2 and 4 of the '130 patent include the language "a method of treating polyneuropathic pain in a subject suffering therefrom." Actavis denies the remaining allegations of Paragraph 24.

25. Actavis admits that claims 3, 5 and 6 of the '130 patent include the language "wherein said polyneuropathic pain is diabetic polyneuropathic pain." Actavis denies the remaining allegations of Paragraph 25.

26. On information and belief, Actavis admits that the patent, on its face, indicates that Grünenthal is the assignee of the '130 patent. Actavis is without knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 26 and, therefore, denies them on this basis.

27. Actavis is without knowledge or information sufficient to admit or deny the allegations in Paragraph 27 and, therefore, denies them on this basis.

28. Actavis admits the allegations in Paragraph 28.

29. Actavis admits that the '130 patent is listed in the "Orange Book" in connection with NUCYNTA® ER. Actavis denies the remaining allegations in Paragraph 29.

ALLEGATIONS REGARDING ACTAVIS'S ANDA

30. Actavis admits that Actavis Elizabeth LLC submitted ANDA No. 204972. Actavis denies the remaining allegations in Paragraph 30.

31. Actavis admits that Actavis Elizabeth LLC submitted ANDA No. 204972. Actavis denies the remaining allegations in Paragraph 31.

32. Actavis LLC and Actavis, Inc. were dismissed from related action No. 2:13-cv-04507-CCC-MF by Order dated September 13, 2013 (D.I. 38) and for the same reasons should be dismissed from this action. To the extent a response is deemed required, Actavis denies the allegations of Paragraph 32.

33. Actavis admits the allegations in Paragraph 33.

34. [redacted]. Actavis denies the remaining allegations in Paragraph 34.

35. [redacted]. Actavis denies the remaining allegations in Paragraph 35.

36. Actavis denies the allegations of Paragraph 36.

37. Actavis denies the allegations of Paragraph 37.

38. Actavis denies the allegations of Paragraph 38.

ALLEGATIONS REGARDING COUNT I
PATENT INFRINGEMENT

39. Actavis incorporates its answers to Paragraphs 1-38 above as if fully set forth herein.

40. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

41. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

42. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

43. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

44. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

45. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

46. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

47. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

48. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

49. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

50. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

51. Count I of this Complaint has been dismissed by the Court in its Opinion dated January 8, 2016. (D.I. 55).

ALLEGATIONS REGARDING COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT

52. Actavis incorporates its answers to Paragraphs 1-51 above as if fully set forth herein.

53. Paragraph 53 contains legal conclusions for which no answer is required. To the extent an answer is required, Actavis admits that Actavis Elizabeth LLC submitted ANDA No. 204972. Actavis denies the remaining allegations in Paragraph 53.

54. Actavis denies the allegations in Paragraph 54.

55. Actavis denies the allegations in Paragraph 55.

56. Actavis denies the allegations in Paragraph 56.

57. Actavis denies the allegations in Paragraph 57.

58. Actavis denies the allegations in Paragraph 58.

59. Paragraph 59 contains legal conclusions for which no answer is required. To the extent an answer is required, Actavis admits that it has knowledge of the '130 patent. Actavis denies the remaining allegations of Paragraph 59.

60. Actavis denies the allegations in Paragraph 60.

61. Actavis denies the allegations in Paragraph 61.

62. Actavis denies the allegations in Paragraph 62.

RELIEF SOUGHT

Actavis denies that Plaintiffs are entitled to any of the relief sought or to any relief whatsoever.

ACTAVIS'S AFFIRMATIVE DEFENSES

Actavis asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Actavis does not assume the burden of proof on any such defenses, except as required by the applicable law with respect to the particular defense asserted. Actavis reserves the right to assert other defenses and/or to otherwise supplement or amend its Answer and Affirmative Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE
(No Direct Infringement ANDA No. 204972)

Actavis does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '130 patent, and if the products that are the subject of ANDA No.

204972 were marketed, Actavis would not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '130 patent.

SECOND DEFENSE
(No Indirect Infringement ANDA No. 204972)

Actavis has not induced or contributed to, and does not and will not induce or contribute to, the infringement, either literal or under the doctrine of equivalents, of any valid and enforceable claim of the '130 patent, and if the products that are the subject of ANDA No. 204972 were marketed, Actavis would not induce or contribute to the infringement, either literal or under the doctrine of equivalents, of any valid and enforceable claim of the '130 patent.

THIRD DEFENSE
(Invalidity)

The claims of the '130 patent are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112 and/or 251, or under other judicially-created bases for invalidation.

FOURTH DEFENSE
(No Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

FIFTH DEFENSE

Actavis reserves all defenses, at law or equity, that may now exist or in the future be available on discovery and further factual investigation in this case.

ACTAVIS ELIZABETH LLC'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Actavis Elizabeth LLC ("Actavis"), for its Counterclaims against Depomed, Inc. ("Depomed") and Grünenthal GmbH ("Grünenthal"), alleges as follows:

1. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Actavis's Answer and Affirmative Defenses to the Complaint.

2. These counterclaims are for (1) declaratory judgment of non-infringement, unenforceability, and/or invalidity of one or more claims of United States Patent No. 8,536,130 ("the '130 patent") under 28 U.S.C. §§ 2201 and 2202, 12 U.S.C. § 355(j) and 21 U.S.C. § 355(J)(5)(c), and (2) an order under 21 U.S.C. § 355(j)(5)(C)(ii) requiring Depomed to immediately correct the use code with the FDA for the '130 patent in the Orange Book listing for NDA No. 200533 for NUCYNTA® ER. A true and correct copy of the '130 patent is attached hereto as Exhibit A.

THE PARTIES

3. Actavis Elizabeth LLC is a single member limited liability company organized under the laws of the state of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, NJ, 07207.

4. On information and belief, Depomed is a California corporation, having its principal place of business at 7999 Gateway Blvd., Newark, California 94560.

5. On information and belief, Grünenthal is a corporation organized and existing under the laws of Germany, having an address at Zieglerstrasse 6, 52078 Aachen, Germany.

6. On information and belief, Depomed markets a tapentadol hydrochloride extended-release tablet under the trade name NUCYNTA® ER.

7. On information and belief, Depomed markets NUCYNTA® ER throughout the United States, including this district.

JURISDICTION

8. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 35 U.S.C. 271(e)(5), 28 U.S.C. §§ 1331, 1337(a), 1338,

2201, 2202; and/or 21 U.S.C. § 355(j), based on an actual controversy between Actavis and Depomed and Grünenthal arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

9. This Court has personal jurisdiction over Depomed and Grünenthal based, *inter alia*, on the filing by Depomed and Grünenthal of this lawsuit in this jurisdiction.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), and 21 U.S.C. § 355(j)(5)(c)(i)(II).

THE '130 PATENT

11. On information and belief, on September 17, 2013, the Patent and Trademark Office ("PTO") issued the '130 patent entitled, "Use of 1-Phenyl-3-Dimethylamino-Propane Compounds For Treating Neuropathic Pain." The '130 patent lists, on its face, Thomas Christoph, Elmar Friderichs, Babette-Yvonne Koegel, and Murielle Meen as the inventors of the patent. On information and belief, Grünenthal is the assignee of the '130 patent. According to the FDA publication entitled "*Approved Drug Products with Therapeutic Equivalence Evaluations*" (known as "the Orange Book"), the '130 patent will expire on September 22, 2028.

12. On information and belief, Depomed is a licensee of the '130 patent.

THE APPLICATIONS AT ISSUE

The NDA

13. On information and belief, Depomed is the current holder of NDA No. 200533 for extended-release tapentadol hydrochloride tablets, which Depomed markets under the trade name NUCYNTA® ER in the United States. NUCYNTA® ER is marketed in 50, 100, 150, 200 and 250 mg tablets and is indicated to treat (1) pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are

inadequate and (2) neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

14. On information and belief, the FDA approved NDA No. 200533 on August 25, 2011, which permitted Janssen Pharmaceuticals, Inc. ("Janssen") (from whom Depomed has purchased the rights to market NUCYNTA® ER in the United States) and now Depomed to market an extended-release tapentadol hydrochloride drug product.

15. The Federal Food, Drug and Cosmetic Act ("the Act") authorizes a pharmaceutical company to file an ANDA, which the FDA will approve if the pharmaceutical company shows that its product has the same active ingredient as, and is bioequivalent to, a product that the FDA has already approved. Typically, the ANDA applicant submits data showing that its product is bioequivalent to a product that has been the subject of an approved NDA.

16. The Act requires NDA holders to submit to the FDA the patent number and expiration date of any patent(s) for which the NDA holder believes "a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the manufacture, use or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA—with no substantive review of the patents—lists the patent number(s) and expiration date(s) in the Orange Book.

17. The FDA requires NDA holders to submit for Orange Book listing, a short statement describing the approved use claimed by the patent, known as the patent "use code." FDA regulations require the submission of certain patent information upon and after approval, including the following information for method-of-use patents:

> (P) Information on each method-of-use patent including the following:
>
> (1) Whether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use or indication and related patent claim of the patent being submitted;
>
> (2) Identification of the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted; and
>
> (3) The description of the patented method of use as required for publication;
>
> . . .

21 C.F.R. § 314.53(c)(2)(ii)(P).

18. FDA regulations state that the use code must properly describe, in sufficient detail, the scope of the patented method covering an approved use of the referenced drug. 21 C.F.R. § 314.53(c)(2)(ii).

19. If an ANDA applicant seeks approval to market its generic product before a patent listed in the Orange Book expires, the applicant must include in its ANDA a certification (a "paragraph IV certification") that its proposed product would not infringe that patent, and/or that the patent is invalid and/or unenforceable. The ANDA applicant must then send a notice letter to the NDA holder and patent owner(s), which includes a detailed statement of the factual and legal bases of the applicant's opinion that the patent is invalid, unenforceable and/or would not be infringed.

20. If the patent owner sues the ANDA applicant for infringement within 45 days of receiving the notice letter, the FDA cannot, on that basis alone, approve the ANDA for 30 months, or until the infringement action is over, absent a court order shortening the period.

21. As an alternative to a paragraph IV certification, an ANDA applicant may submit a statement pursuant to 21 U.S.C. § 505(j)(2)(A)(viii) ("Section viii Statement") stating that it is not seeking approval for the methods of use claimed in one or more Orange Book patent.

22. On information and belief, Janssen, as the previous NDA holder for NUCYNTA® ER (NDA No. 200533), filed a request with the FDA pursuant to 21 U.S.C. §355(b)(1) to list the '130 patent in the Orange Book for NUCYNTA® ER.

23. The maintenance of the '130 patent by Depomed in the Orange Book means that it believes the '130 patent "claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. §355(b)(1).

24. On information and belief, Janssen listed the '130 patent in the FDA's Orange Book for NDA No. 200533 with use code U-1276, which informed the FDA that each of claims 1–6 of the '130 patent claimed the use for the "[m]anagement of neuropathic pain associated with diabetic peripheral neuropathy."

25. On information and belief, at or about the time that Depomed and Grünenthal's Complaint was filed in September 2015, Depomed changed the use code associated with the '130 patent for NDA No. 200533 to use code U-1739 for the "[m]anagement of pain severe enough to require daily, around-the-clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy."

ANDA No. 204972

26. Actavis has filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to market a tapentadol hydrochloride extended-release drug product (the

"ANDA No. 204972 Product"). [redacted]

27. On September 11, 2015, Depomed and Grünenthal sued Actavis alleging infringement of the '130 patent initiating this action in the District of New Jersey. On October 8, 2015, Actavis filed a motion to dismiss Counts I and II of Depomed and Grünenthal's Complaint. On January 8, 2106, the Court granted Actavis's motion to dismiss as to Count I of Depomed and Grünenthal's Complaint alleging infringement under 35 U.S.C. § 271(e)(2).

28. Because Depomed listed the '130 patent in the Orange Book for NUCYNTA® ER and Depomed has maintained this listing, including the use code U-1739, Actavis suffers a direct legal injury from these actions.

29. Depomed's and Grünenthal's conduct impairs Actavis's ability to market its ANDA No. 204972 Product. Actavis thus seeks (1) a declaratory judgment that its ANDA No. 204972 Product does not infringe the claims of the '130 patent and/or that the claims of the '130 patent are invalid and/or unenforceable, and (2) an Order requiring Depomed to immediately request the FDA to correct the Orange Book use code for the '130 patent from U-1739 to U-1276.

30. Actavis suffers a direct legal injury from the Counterclaim Defendants' actions that requires judicial relief. *See* 21 U.S.C. §355(j)(5)(C).

THE PRESENCE OF A CASE OF ACTUAL CONTROVERSY

31. By maintaining the Orange Book listing of the '130 patent in connection with NUCYNTA® ER, Depomed continues to represent that the '130 patent could reasonably be asserted against anyone making, using or selling a generic extended-release tapentadol hydrochloride product without a license from Depomed and/or Grünenthal.

32. Depomed and Grünenthal's Complaint gives rise to an actual controversy with respect to the '130 patent, with respect to ANDA No. 204972.

33. To avoid legal uncertainty and to protect Actavis's substantial investment (and anticipated future investment) in its ANDA Products, Actavis seeks declaratory relief with respect to the '130 patent.

34. Actavis has not stipulated to or otherwise consented to the validity, infringement, or enforceability of the '130 patent.

35. Upon FDA approval of Actavis's ANDA, Actavis will be able to market and sell its ANDA Products in the United States.

36. A judgment declaring that the '130 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of Actavis's ANDA Products, will remove any independent barriers to competition that may exist by virtue of Depomed's maintenance of the listing of the '130 patent in the Orange Book in connection with NDA No. 200533.

37. The totality of circumstances support that a case or controversy exists with respect to the infringement, invalidity and/or unenforceability of the '130 patents.

FIRST COUNT

(Declaratory Judgment of Invalidity, '130 Patent)

38. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Actavis's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

39. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists

between Depomed and Grünenthal and Actavis concerning the invalidity of claims of the '130 patent.

40. The claims of the '130 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 120 and/or 251, and/or based on other judicially-created bases for invalidation.

41. Thus Actavis is entitled to a declaration that the claims of the '130 patent are invalid.

SECOND COUNT

(Declaratory Judgment of Non-Infringement, '130 Patent)

42. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Actavis's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

43. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Depomed and Grünenthal and Actavis concerning the infringement of the '130 patent.

44. Actavis's manufacture, use, offer for sale, sale and/or importation into the United States of its ANDA product pursuant to ANDA No. 204972 will not infringe any valid claim of the '130 patent.

45. Thus, Actavis is entitled to a declaration that the manufacture, use, offer for sale, sale and/or importation into the United States of Actavis's ANDA Products will not infringe any valid claim of the '130 patent.

THIRD COUNT

(Improper Use Code Listing for the '130 Patent in the Orange Book)

46. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Actavis's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

47. The FDA requires NDA holders to submit for Orange Book listing, a short statement describing the approved use claimed by the patent, known as the patent "use code." FDA regulations require the submission of certain patent information upon and after approval, including the following information for method-of-use patents:

> (P) Information on each method-of-use patent including the following:
>
> (1) Whether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use or indication and related patent claim of the patent being submitted;
>
> (2) Identification of the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted; and
>
> (3) The description of the patented method of use as required for publication;
>
> . . .

21 C.F.R. § 314.53(c)(2)(ii)(P).

48. Under 21 U.S.C. § 355(j)(5)(C)(ii), Actavis seeks an Order that requires Depomed to immediately request that the FDA correct the use code for the '130 patent in the Orange Book listing for NDA No. 200533 for NUCYNTA® ER from U-1739 ("[m]anagement of pain severe enough to require daily, around-the-clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy") to U-1276 ("[m]anagement of neuropathic pain associated with diabetic peripheral neuropathy), because the Patent

Information submitted by Depomed for NUCYNTA® ER does not comply with the applicable FDA regulations and instructions, since the U-1739 use code misrepresents the approved method of use covered by the claims of the '130 patent.

49. New use code U-1739 is vague on its face, because it does not provide, as the regulations require, "[t]he description of the patented method of use" in a manner that is both "accurate and detailed." 21 C.F.R. §314.53(c)(2)(ii)(P); 68 Fed. Reg. at 36682. On the contrary, the use code U-1739 fails to identify with any specificity whatsoever the methods claimed in the '130 patent and, read literally, suggests that the '130 patent covers any method of managing pain severe enough to require daily, around-the-clock, long-term opioid treatment.

50. Depomed, by the change in the use code narrative, is attempting to extend the life of an earlier patent (U.S. Patent No. RE39,593), which expires six years before the '130 patent.

51. 21 U.S.C. § 355(j)(5)(C)(ii)(I) states:

> In general. If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—
>
> (aa) the drug for which the application was approved; or
>
> (bb) an approved method of using the drug.

52. The legislative intent behind the 2003 amendments to the Hatch-Waxman Act that added the counterclaim provision, § 355(j)(5)(C)(ii), was to curb Orange Book abuses arising from misinformation regarding listed patents.

53. The '130 patent, which is listed in the Orange Book for NDA No. 200533 for NUCYNTA® ER, constitutes "patent information submitted by the holder under subsection (b)

or (c)" of section 505 of the Federal Food Drug and Cosmetic Act ("the Act"). On information and belief, the patent information originally submitted by Janssen under subsection (b) or (c) of section 505 of the Act represented that the '130 patent claims the use for the "[m]anagement of neuropathic pain associated with diabetic peripheral neuropathy." On information and belief, Depomed recently changed the patent information under subsection (b) or (c) of section 505 of the Act to represent that the '130 patent claims the use for "[m]anagement of pain severe enough to require daily, around-the-clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy."

54. The method claims of the '130 patent are limited to methods of using tapentadol for the treatment of polyneuropathic pain and/or diabetic polyneuropathic pain and do not claim methods for treating severe pain generally. Exhibit A; '130 patent at column 18, lines 1–21.

55. The use code in the Orange Book currently associated with the '130 patent does not meet the requirements of 21 U.S.C. § 355(b)(1), (b)(2), and the regulations thereunder, including, without limitation, 21 C.F.R. §§ 314.53(b), 314.53 (c)(2)(ii), and 314.3(b). It therefore was improper for Depomed to request the FDA to change the use code for the '130 patent in the Orange Book to describe any method of managing pain severe enough to require daily, around-the-clock, long-term opioid treatment.

56. Under 21 U.S.C. § 355(j)(5)(C)(ii)(I), Actavis is entitled to an Order that (1) finds that Depomed has improperly filed with the FDA for listing in the Orange Book the use code U-1739 narrative for the method of use of the '130 patent relating to NUCYNTA® ER, and (2) requires Depomed to immediately request that the FDA correct the use code to U-1276

("[m]anagement of neuropathic pain associated with diabetic peripheral neuropathy") for the '130 patent in the Orange Book for NDA No. 200533 for NUCYNTA® ER.

EXCEPTIONAL CASE

57. This case is an exceptional one, and Actavis is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYERS FOR RELIEF

WHEREFORE, Actavis prays that the Court enter judgment in its favor and against Depomed and Grünenthal as follows:

a. Declaring that the making, using, selling, offering for sale, marketing, or importation of its ANDA product described in Actavis's ANDA No. 204972 does not infringe any valid or enforceable claim of the '130 patent;

b. Declaring that the '130 patent and all of its claims are invalid;

c. Enjoining Depomed and Grünenthal, and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof, from threatening or initiating infringement litigation against Actavis or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Actavis, or charging them either orally or in writing with infringement of any patent asserted herein against Actavis;

d. Granting Actavis judgment in its favor on Depomed's and Grünenthal's claims;

e. Denying Depomed's and Grünenthal's request for injunctive relief;

f. Dismissing all of Depomed's and Grünenthal's claims with prejudice;

g. Ordering Depomed to immediately request that FDA correct the use code for the '130 patent to U-1276 for the "[m]anagement of neuropathic pain associated with diabetic peripheral neuropathy";

h. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Actavis its costs and reasonable attorneys' fees; and

i. Awarding any other such relief as is just and proper.

Dated: January 15, 2016

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