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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DEPOMED, INC. and GRÜNENTHAL GMBH, Plaintiffs, v. ACTAVIS ELIZABETH LLC, ACTAVIS LLC, and ACTAVIS INC., Defendants.	Civil Action No._____

COMPLAINT

In this patent infringement action, Plaintiffs Depomed, Inc. ("Depomed") and Grünenthal GmbH ("Grünenthal") (together, "Plaintiffs"), for their complaint against Defendants Actavis Elizabeth LLC, Actavis LLC, and Actavis Inc. (collectively, "Actavis"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and in response to the submission of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of NUCYNTA® ER prior to the expiration of U.S. Patent No. 8,536,130 ("the '130 Patent").

THE PARTIES: PLAINTIFFS

2. Plaintiff Depomed is a California corporation, having its principal place of business at 7999 Gateway Blvd., Newark, California 94560. As discussed below, Depomed is an exclusive licensee of the '130 Patent.

3. Plaintiff Grünenthal is a corporation organized and existing under the laws of Germany, having an address at Zieglerstrasse 6, 52078 Aachen, Germany. Grünenthal owns the '130 Patent.

4. Depomed holds FDA-approved New Drug Application ("NDA") No. 200533 for an extended release opioid pain medication whose active ingredient is tapentadol hydrochloride.

5. Depomed, through its manufacturers, makes and markets tapentadol hydrochloride in the United States. The drug is marketed under the registered trade name NUCYNTA ER®. NUCYNTA ER® is available in 50, 100, 150, 200 and 250 mg tablets.

6. NUCYNTA ER® is approved by the FDA for two indications: (1) the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (the "Primary Indication"); and (2) the management of 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 (the "Secondary Indication"). The drug is labeled "ER" because it has extended-release properties.

THE PARTIES: DEFENDANTS

7. On information and belief, Defendant Actavis Elizabeth LLC ("Actavis Elizabeth") is a single-member limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 200 Elmora Avenue, Elizabeth, New Jersey.

8. On information and belief, Defendant Actavis LLC is a limited liability company organized and existing under the laws of the State of Delaware, having places of business at 60 Columbia Road, Building B, Morristown, New Jersey and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

9. On information and belief, Defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having its headquarters and principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

10. On information and belief, Actavis Elizabeth is wholly owned by Actavis LLC. On information and belief, Actavis LLC is wholly owned by Actavis US Holding LLC. On information and belief, Actavis US Holding LLC is wholly owned by Actavis, Inc. Thus, on information and belief, Actavis, Inc. owns Actavis Elizabeth and Actavis LLC through its ownership of other entities.

PERSONAL JURISDICTION OVER ACTAVIS

11. This Court has personal jurisdiction over Actavis Elizabeth. On information and belief, Actavis Elizabeth regularly conducts and/or solicits business in the State of New Jersey, engages in other persistent courses of conduct in the State of New Jersey, and/or derives substantial revenue from services or things used or consumed in the State of New Jersey, purposefully availing itself of the jurisdiction of the State of New Jersey. On information and belief, Actavis Elizabeth

is registered with the New Jersey Department of Treasury under the business entity identification number 0600272818. On information and belief, Actavis Elizabeth, formerly as Actavis Inc., a Delaware corporation, maintains a corporate agent for service of process at 80 Main Street, 5th Floor, West Orange, New Jersey.

12. On information and belief, Actavis Elizabeth has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Actavis Elizabeth engages in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey and to the residents of the State of New Jersey. On information and belief, Actavis Elizabeth is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Actavis Elizabeth directly or through its subsidiaries, affiliates and agents develops, formulates, manufactures, markets, imports and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in this Judicial District. On information and belief, Actavis, Inc. as the parent company and Actavis Elizabeth as the trade name holds an active wholesale drug license for the State of New Jersey under License No. 5003329.

13. On information and belief, Actavis Elizabeth has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in the matters of *Janssen Pharmaceuticals, Inc. et al. v. Actavis Elizabeth LLC. et al.*, Civil Action No. 2:13-cv-04507 (CCC)(MF), D.I. 150 at 10, 23-38 (D.N.J. Sep. 3, 2014); *Shire LLC et al. v. Actavis Elizabeth LLC. et al.,* Civil Action No. 2:11-cv-03781 (SRC)(CLW), D.I. 231 at 5, 40-47 (D.N.J. Jan. 17, 2013);

and *Depomed, Inc. v. Actavis Elizabeth LLC. et al.*, Civil Action No. 3:12-cv-01358 (JAP)(TJB), D.I. 40 at 3, 23-27 (D.N.J. Apr. 13, 2012).

14. This Court has personal jurisdiction over Actavis LLC. On information and belief, Actavis LLC regularly conducts and/or solicits business in the State of New Jersey, engages in other persistent courses of conduct in the State of New Jersey, and/or derives substantial revenue from services or things used or consumed in the State of New Jersey, purposefully availing itself of the jurisdiction of the State of New Jersey. On information and belief, Actavis LLC, formerly as Actavis Inc., a Delaware corporation, is registered with the New Jersey Department of Treasury under the business entity identification number 0101005391. On information and belief, Actavis LLC, formerly as Actavis Inc., a Delaware corporation, maintains a corporate agent for service of process at 80 Main Street, 5th Floor, West Orange, New Jersey.

15. On information and belief, Actavis LLC has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Actavis LLC engages in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey and to the residents of the State of New Jersey. On information and belief, Actavis LLC is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Actavis LLC directly or through its subsidiaries, affiliates and agents develops, formulates, manufactures, markets, imports and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in this Judicial District. On information and belief, Actavis, Inc. as the parent company and Actavis LLC as the trade name holds an active wholesale drug license for the State of New Jersey under License No. 5003899.

16. On information and belief, Actavis LLC has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in the matters of *Novartis Pharmaceuticals Corporation v. Actavis LLC. et al.*, Civil Action No. 2:12-cv-03967 (SDW)(SCM), D.I. 354 at 8, 15-19 (D.N.J. May 16, 2014); and *Novartis Pharmaceuticals Corporation v. Actavis LLC. et al.*, Civil Action No. 2:13-cv-01028 (SDW)(MCA), D.I. 119 at 9, 15-18 (D.N.J. Mar. 13, 2013).

17. On information and belief, upon approval of Actavis's ANDA application, Actavis and/or its subsidiaries, affiliates or agents will market, sell and/or distribute Actavis's ANDA Products throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

18. On information and belief, upon approval of Actavis's ANDA application, Actavis and/or its subsidiaries, affiliates or agents will place Actavis's ANDA Products into the stream of commerce with the reasonable expectation or knowledge and the intent that such products will ultimately be purchased and used by consumers in this Judicial District.

19. This Court has personal jurisdiction over each of the Actavis defendants by virtue of the fact that, *inter alia*, each Actavis defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in New Jersey by one or more of the Actavis defendants. In particular, on information and belief, Actavis is actively preparing to make the proposed ANDA Products described herein (*see infra* ¶¶ 30-38), and to use, sell and offer for sale such generic copies in this State and this judicial district. This Court has personal jurisdiction over each of the Actavis defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

SUBJECT MATTER JURISDICTION

20. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally and 35 U.S.C. § 271(e)(2) specifically.

21. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

VENUE

22. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

23. The '130 Patent, entitled "USE OF 1 PHENYL-3-DIMETHYLAMINO-PROPANE COMPOUNDS FOR TREATING NEUROPATHIC PAIN," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on September 17, 2013, naming Thomas Christoph, Elmar Friderichs, Babette-Yvonne Koegel and Murielle Meen as inventors. A copy of the '130 Patent is attached hereto as Exhibit 1.

24. Claims 1, 2 and 4 of the '130 Patent claim, *inter alia*, "a method of treating polyneuropathic pain in a subject suffering therefrom." *See id.*, claim 1.

25. Claims 3, 5 and 6 of the '130 Patent claim, *inter alia*, a method of treating polyneuropathic pain, "wherein said polyneuropathic pain is diabetic polyneuropathic pain." *See, e.g., id.,* claim 3.

26. Plaintiff Grünenthal lawfully owns all right, title and interest in the '130 Patent, including the right to sue and to recover for past infringement thereof.

27. Plaintiff Depomed is an exclusive licensee of the '130 Patent, holding an exclusive license to import, market, distribute, promote, offer to sell, and/or sell pharmaceutical formulations

containing tapentadol for human use in the field of pain within the United States, along with a right to enforce the '130 Patent.

28. The FDA issues a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") in which it publishes all patents which claim an approved drug or a method of using an approved 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.

29. In accordance with 21 U.S.C. § 355(b)(1), the '130 Patent is listed in the Orange Book in connection with NDA No. 200533 as a patent "which claims a method of using [NUCYNTA® ER] 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."

ACTAVIS'S ANDA

30. On information and belief, sometime prior to June 12, 2013, Actavis Elizabeth submitted ANDA No. 204972 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of generic tapentadol hydrochloride extended release tablets in 50 mg, 100 mg, 150 mg, 200 mg and 250 mg dosages (the "ANDA Products").

31. On information and belief, Actavis Elizabeth is the owner of ANDA No. 204972, and Actavis LLC and Actavis, Inc. were involved in the decision to submit ANDA No. 204972.

32. On information and belief, the acts of Actavis Elizabeth complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of, and at least in part for the benefit of, Actavis, LLC and Actavis, Inc.

[redacted]

37. On information and belief, if ANDA No. 204972 is approved by the FDA before the expiration of the '130 Patent, Actavis will begin manufacturing, using, importing, offering for sale, selling and/or marketing the ANDA Products [redacted], and doctors, pharmacists, and patients will use each of the dosage strengths of the ANDA Products for that purpose and will infringe the '130 Patent.

38. On information and belief, if ANDA No. 204972 is approved by the FDA before the expiration of the '130 Patent, Actavis will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA Products with a label that specifically instructs and directs doctors to prescribe, pharmacists to dispense, and patients to use the ANDA products for the treatments and methods claimed by the '130 Patent.

COUNT I
PATENT INFRINGEMENT

39. Plaintiffs incorporate and reallege paragraphs 1-38 above.

40. The submission of ANDA No. 204972 was an act of infringement by Actavis of one or more claims of the '130 Patent under 35 U.S.C. § 271(e)(2)(A).

41. On information and belief, the method of using Actavis's ANDA Products are covered by one or more claims of the '130 Patent.

42. On information and belief, Actavis's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA Products before the expiration of the '130 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '130 Patent.

43. On information and belief, the use of Actavis's ANDA Products, in accordance with and as directed by, Actavis's proposed labeling for the [redacted] will infringe one or more claims of the '130 Patent.

44. On information and belief, by seeking approval to distribute the ANDA Products with their proposed labeling, Actavis intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Actavis knows will infringe one or more claims of the '130 Patent.

45. On information and belief, unless enjoined by this Court, Actavis plans on and intends to, and will, actively induce infringement of one or more claims of the '130 Patent immediately following approval of ANDA No. 204972.

46. On information and belief, Actavis has been aware of the existence of the '130 Patent since September 17, 2013.

47. On information and belief, Actavis has no reasonable basis for believing that their ANDA Products will not infringe one or more valid claims of the '130 Patent.

48. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

49. On information and belief, unless enjoined by this Court, Actavis plans on and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Products with their proposed labeling immediately following approval of ANDA No. 204972.

50. The acts of infringement by Actavis set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

51. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for the Actavis's ANDA No. 204972 to be a date which is not any earlier than the expiration date of the '130 Patent, including any extensions of that date.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT

52. Plaintiffs incorporate and reallege paragraphs 1-51 above.

53. On information and belief, Actavis actively and knowingly filed, and is pursuing ANDA No. 204972, to obtain approval to engage in the commercial manufacture, use, or sale of a drug for the methods that are claimed in the '130 Patent before expiration of the patent.

54. On information and belief, Actavis actively and knowingly sought to avoid filing a patent certification to the '130 Patent as required by 21 U.S.C. § 355(j)(2)(A)(vii).

55. On information and belief, Actavis knows that its proposed label containing the [redacted] will infringe one or more of the method of treatment claims of the '130 Patent.

56. On information and belief, if and when ANDA No. 204972 is approved, Actavis will commit an act of patent infringement under 35 U.S.C. § 271.

57. On information and belief, Actavis's infringement of the '130 Patent is imminent, and thus creates a real and actual controversy between Plaintiffs and Actavis. Actavis's imminent infringement is demonstrated by, at least, its active participation in the FDA approval process and having obtained tentative approval on or about May 18, 2015.

58. Imminent infringement is also demonstrated by the impending expiration of the FDA stay of approval set forth in 21 U.S.C. §§ 355(j)(5)(B)(iii) & (j)(5)(F)(ii) as a result of Actavis's certification to the other patents listed in the Orange Book as covering NUCYNTA® ER and the related litigation. *See Janssen, et. al. v. Actavis Elizabeth, et. al.*, Case No. 13-cv-4507 CCC (D.N.J.).

59. On information and belief, during the pendency of ANDA No. 204972, Actavis was fully aware of the '130 Patent after its issuance.

60. On information and belief, Actavis acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '130 Patent. As a result, Actavis's imminent infringement will be willful and deliberate, making this an exceptional case under the United States patent laws.

61. On information and belief, unless enjoined by this Court, Actavis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Products with their proposed labeling immediately following approval of ANDA No. 204972.

62. The acts of infringement by Actavis set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

RELIEF SOUGHT

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment in favor of Plaintiffs and against Actavis;

B. Judgment that Actavis has infringed the '130 Patent by the submission of ANDA No. 204972 and/or will infringe, literally or by the doctrine of equivalents, one or more claims of the '130 Patent by the commercial importation, sale, offer for sale, use, and/or manufacture of the ANDA Products, in the United States;

C. Declaratory judgment that Actavis's imminent manufacture, use, offer for sale, sale, and/or importation of the ANDA Products will infringe one or more claims of the '130 Patent;

D. Judgment that the '130 Patent has not been proven invalid and unenforceable;

E. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of approval of ANDA No. 204972 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall be a date not earlier than the date of expiration of the '130 Patents plus any additional periods of exclusivity;

F. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Actavis Elizabeth, Actavis LLC, Actavis, Inc., and their officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any

commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any ANDA No. 204972 Product, and any product that is similar to or only colorably different from those products, before the date of expiration of the '130 Patent and any additional periods of exclusivity;

G. A declaration that this an exceptional case and an award to Plaintiffs Depomed and Grünenthal of their reasonable attorneys' fees and expenses, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

H. Damages or other monetary relief, including prejudgment interest, if Actavis engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of ANDA Products, or any other products that infringe the '130 Patent, or the inducement of or contribution to the foregoing, prior to the expiration of the '130 Patent;

I. An award of pre-judgment and post-judgment interest;

J. An award of costs in bringing and prosecuting this action; and

K. Such other and further relief as this Court may deem just and proper.

Dated: September 11, 2015

Respectfully submitted,

/s/ Keith J. Miller
Keith J. Miller

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Dated: September 11, 2015

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Plaintiffs, by their undersigned counsel, hereby certify that the matter in controversy in this action is related to the following matters presently before the District Court for the District of New Jersey: *Janssen Pharmaceuticals, Inc. and Grünenthal GmbH, and Depomed, Inc. v. Actavis Elizabeth, LLC*, et al., Civil Action No. 2:13-cv-4507 (CCC) (MF), *Janssen Pharmaceuticals, Inc. and Grünenthal GmbH, and Depomed, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 2:13-cv-6929 (CCC) (MF), *Janssen Pharmaceuticals, Inc. and Grünenthal GmbH, and Depomed, Inc. v. Alkem Laboratories Limited,* Civil Action No. 2:13-cv-7803 (CCC) (MF), *Janssen Pharmaceuticals, Inc. and Grünenthal GmbH, and Depomed, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 2:14-cv-3941 (CCC) (MF), and *Janssen Pharmaceuticals, Inc. and Grünenthal GmbH, and Depomed, Inc. v. Actavis Laboratories UT, Inc.*, Civil Action No. 2:14-cv-4617 (CCC) (MF).

Dated: September 11, 2015

Respectfully submitted,

/s/ Keith J. Miller
Keith J. Miller

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