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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

DEPOMED, INC.

CIVIL ACTION NO: 3:12-cv-01358-JAP-TJB

Plaintiff,

v.

ACTAVIS ELIZABETH LLC, ACTAVIS, INC., INCEPTA PHARMACEUTICALS CO. LTD. and ABON PHARMACEUTICALS, LLC,

Defendants.

FOURTH AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Depomed, Inc., complains against defendants Actavis Elizabeth LLC and Actavis Inc. (collectively "Actavis"), Abon Pharmaceuticals LLC and Incepta Pharmaceuticals Co. Ltd. (collectively "Incepta") as follows:

THE PARTIES

- 1. Plaintiff Depomed, Inc. ("Depomed"), is a corporation organized under the laws of California, having its principal place of business in Menlo Park, California.
- 2. Upon information and belief, Actavis Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.
- 3. Upon information and belief, Actavis Elizabeth LLC is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202. On information and belief, Actavis Elizabeth LLC is a wholly-owned subsidiary of Actavis Inc. On information and belief, Actavis Elizabeth LLC's preparation and submission of ANDA No. 203611 was done collaboratively with, and for the benefit of, Actavis Inc. On information and belief, Actavis Elizabeth LLC is the alter ego of Actavis Inc. where a unity of interest and ownership exists between Actavis Elizabeth LLC and Actavis Inc. such that separate personalities of the two do not in reality exist.
- 4. Upon information and belief, Incepta Pharmaceuticals Co. Ltd. is a Bangladeshi company located at 40 Shahid Tajuddin Ahmed Sarani, Tejgaon I/A, Dhaka-1209, Bangladesh. On information and belief, Incepta Pharmaceuticals Co. Ltd is in the business of manufacturing and marketing pharmaceutical products; it manufactures more than 600 products and markets its products globally.
- 5. Upon information and belief, Abon Pharmaceuticals, LLC ("Abon") is a company organized and existing under the laws of the State of New Jersey, having a principal place of business at 140 Legrand Ave, Northvale, New Jersey 07647. Upon information and belief, Abon is in the business of designing and marketing generic drug lines. Upon information and belief,

Abon participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 203643, the ANDA at issue in this litigation. Upon information and belief, the submission of ANDA No. 203643 was done by Abon collaboratively and in partnership with Incepta Pharmaceuticals Co. Ltd. for their mutual benefit.

- 6. Upon information and belief, Abon signed and filed ANDA 203643 on behalf of Incepta Pharmaceuticals Co. Ltd. as its U.S. agent.
- 7. Upon information and belief, Abon authorized and actively participated in preparing information and data for ANDA 203643.
- 8. Upon information and belief, Abon has continued to actively participate in the submission and approval of ANDA 203643 through this litigation and during its submission to the FDA.

JURISDICTION AND VENUE

- 9. This is an action for patent infringement arising under the patent laws of the United States (Title 35 of the United States Code) and arising from Actavis, Abon, and Incepta filing Abbreviated New Drug Applications ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Depomed's product Gralise® prior to the expiration of U.S. Patent Nos. 6,340,475, 6,635,280, 7,438,927, 7,731,989, 8,192,756, 8,252,332 and 8,333,992. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 10. This Court has personal jurisdiction over Actavis because, among other things, Actavis resides in New Jersey, conducts business in the State of New Jersey, has availed itself of the rights and benefits under New Jersey law, and has engaged in substantial and continuous contacts in the State of New Jersey. Moreover, Actavis has a past practice of consenting to

personal jurisdiction in this Court for other litigation matters. For example, Actavis consented to personal jurisdiction in *Shire LLC and Shire Development, Inc. v. Actavis Elizabeth LLC et al.*, Civil Action No. 2:11-cv-04053 and *Sanofi-Aventis U.S. LLC et al. v. Actavis Inc. et al.*, Civil Action No. 2:10-cv-02795.

- 11. This Court has personal jurisdiction over Incepta because Depomed's claims arise under federal law, Incepta Pharmaceuticals Co. Ltd., upon information and belief, is not subject to jurisdiction in any state's court of general jurisdiction and the exercise of jurisdiction over Incepta comports with due process because Incepta purposely directed activities at the United States and availed itself of the laws of the United States by submitting an ANDA with the FDA to obtain approval to engage in the commercial manufacture, importation, use and/or sale of 300mg and 600mg gabapentin oral tablets and Depomed's claims arise out of this activity. Moreover, Incepta has availed itself of the rights and benefits under New Jersey law by purposely choosing the law of the State of New Jersey to govern the Offer of Confidential Access that Incepta has provided to Plaintiff in its Paragraph IV certification letter.
- 12. This Court has personal jurisdiction over Abon because, among other things, Abon resides in New Jersey, is incorporated in New Jersey, conducts business in the State of New Jersey, has availed itself of the rights and benefits under New Jersey law, and has engaged in substantial and continuous contacts in the State of New Jersey.
 - 13. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1400.

THE PATENTS-IN-SUIT

14. On January 22, 2002, United States Patent No. 6,340,475 (the "475 Patent") entitled "Extending the Duration of Drug Release Within the Stomach During the Fed Mode"

issued to Depomed as assignee of the inventors. (A copy of the '475 Patent is attached as Exhibit 1.)

- 15. On December 3, 2002, United States Patent No. 6,488,962 (the "'962 Patent") entitled "Tablet Shapes To Enhance Gastric Retention of Swellable Controlled-Release Oral Dosage Forms" issued to Depomed as assignee of the inventors. (A copy of the '962 Patent is attached as Exhibit 2.)
- 16. On October 21, 2003, United States Patent No. 6,635,280 (the "280 Patent") entitled "Extending the Duration of Drug Release Within the Stomach During the Fed Mode" issued to Depomed as assignee of the inventors. (A copy of the '280 Patent is attached as Exhibit 3.)
- 17. On October 21, 2008, United States Patent No. 7,438,927 (the "'927 Patent") entitled "Methods of Treatment Using a Gastric Retained Gabapentin Dosage" issued to Depomed as assignee of the inventors. (A copy of the '927 Patent is attached as Exhibit 4.)
- 18. On June 8, 2010, United States Patent No. 7,731,989 (the "'989 Patent") entitled "Gastric Retained Gabapentin Dosage Form" issued to Depomed as assignee of the inventors. (A copy of the '989 Patent is attached as Exhibit 5.)
- 19. On June 5, 2012, United States Patent No. 8,192,756 (the "'756 Patent") entitled "Gastric Retained Gabapentin Dosage Form" issued to Depomed as assignee of the inventors. (A copy of the '756 Patent is attached as Exhibit 6.)
- 20. On August 28, 2012, United States Patent No. 8,252,332 B2 (the "332 Patent") entitled "Gastric Retained Gabapentin Dosage Form" issued to Depomed as assignee of the inventors. (A copy of the '332 Patent is attached as Exhibit 7.)

21. On December 18, 2012, United States Patent No. 8,333,992 (the "'992 Patent") entitled "Gastric Retained Gabapentin Dosage Form" issued to Depomed as assignee of the inventors. (A copy of the '992 Patent is attached as Exhibit 8.)

GRALISE®

- 22. Depomed holds approved New Drug Application No. 022544 (the "Depomed NDA") for gabapentin extended-release tablets in 300 and 600 mg dosage strengths, which are sold under the trade name Gralise[®].
- 23. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), and attendant FDA regulations, the '475, '962, '280, '340, '927, '989, '756, '332 and '992 Patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Gralise[®] in the 300 mg dosage.
- 24. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), and attendant FDA regulations, the '475, '962, '280, '340, '927, '989, '756, '332 and '992 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Gralise[®] in the 600 mg dosage.

ACTAVIS'S ANDA

25. On information and belief, Actavis submitted ANDA No. 203611 to the FDA, seeking approval to engage in the commercial manufacture, use or sale of Gabapentin Extended-Release Tablets in the 300 and 600 mg dosage strengths. The Gabapentin Extended-Release Tablets described in the Actavis ANDA are herein referred to as the "Actavis Products," the 300 mg dosage strength is referred to as the "Actavis 300 mg Product," and the 600 mg dosage strength is referred to as the "Actavis 600 mg Product."

- 26. On information and belief, Actavis contends that the Actavis 300 mg Product is bioequivalent to the 300 mg dosage form of Gralise and that the Actavis 600 mg Product is bioequivalent to the 600 mg dosage form of Gralise.
- 27. On information and belief, the Actavis ANDA refers to and relies upon the Gralise® NDA and contains data that demonstrate the bioequivalence of the Actavis Products and Gralise®.
- 28. Depomed received from Actavis a letter, dated January 19, 2012, stating that Actavis had included a certification in the Actavis ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '475, '280, '989, '927, '340, and '962 Patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis Products (the "Actavis Notification Letter"). (A true and correct copy of the Actavis Notification Letter is attached hereto as Exhibit 9.)
- 29. Depomed received from Actavis a letter, dated June 26, 2012, stating that Actavis had included a certification in its ANDA contending that the claims of the '756 patent are invalid, unenforceable or will not be infringed by the commercial manufacture, use, importation, or sale of the Actavis Products (the "Second Actavis Notification Letter"). (A true and correct copy of the Actavis Notification Letter is attached hereto as Exhibit 10.)
- 30. Depomed received from Actavis a letter, dated November 16, 2012, stating that Actavis had included a certification in its ANDA contending that the claims of the '332 patent are invalid, unenforceable or will not be infringed by the commercial manufacture, use, importation, or sale of the Actavis Products (the "Third Actavis Notification Letter"). (A true and correct copy of the Actavis Notification Letter is attached hereto as Exhibit 11.)

INCEPTA'S ANDA

- 31. On information and belief, Incepta submitted ANDA No. 203643 to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use or sale of gabapentin oral tablets in the 300 and 600 mg dosage strengths. The gabapentin oral tablets described in the Incepta ANDA are herein referred to as the "Incepta Products," the 300 mg dosage strength is referred to as the "Incepta 300 mg Product," and the 600 mg dosage strength is referred to as the "Incepta 600 mg Product."
- 32. On information and belief, Incepta contends that the Incepta 300 mg Product is bioequivalent to the 300 mg dosage form of Gralise and that the Incepta 600 mg Product is bioequivalent to the 600 mg dosage form of Gralise.
- 33. On information and belief, the Incepta ANDA refers to and relies upon the Gralise® NDA and contains data that demonstrate the bioequivalence of the Incepta Products and Gralise®.
- 34. Depomed received from Incepta a letter, dated February 27, 2012, stating that Incepta had included a certification in the Incepta ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '475, '280, '989, '927, '340, and '962 Patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the Incepta Products (the "Incepta Notification Letter"). (A true and correct copy of the Incepta Notification Letter is attached hereto as Exhibit 12.)
- 35. Depomed received from Incepta a letter, dated August 17, 2012, stating that Incepta had included a certification in its ANDA contending that the claims of the '756 patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use,

importation, or sale of the Incepta Products (the "Second Incepta Notification Letter"). (A true and correct copy of the Incepta Notification Letter is attached hereto as Exhibit 13.)

FIRST CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '475 Patent by Actavis)

- 36. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 37. On information and belief, Actavis has infringed the '475 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '475 Patent.
- 38. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the asserted claims of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 39. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '475 Patent, would further infringe the asserted claims of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 40. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the asserted claims of the '475 Patent.
 - 41. Plaintiff has no adequate remedy at law.
- 42. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

SECOND CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '475 Patent by Incepta)

- 43. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 44. On information and belief, Incepta has infringed the '475 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '475 Patent.
- 45. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the asserted claims of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 46. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '475 Patent, would further infringe the asserted claims of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 47. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the asserted claims of the '475 Patent.
 - 48. Plaintiff has no adequate remedy at law.
- 49. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

THIRD CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '962 Patent by Actavis)

- 50. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 51. On information and belief, Actavis has infringed the '962 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from

the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '962 Patent.

- 52. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the asserted claims of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 53. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '962 Patent, would further infringe the asserted claims of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 54. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the asserted claims of the '962 Patent.
 - 55. Plaintiff has no adequate remedy at law.
- 56. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

FOURTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '962 Patent by Incepta)

- 57. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 58. On information and belief, Incepta has infringed the '962 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '962 Patent.
- 59. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the asserted claims of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

- 60. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '962 Patent, would further infringe the asserted claims of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 61. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the asserted claims of the '962 Patent.
 - 62. Plaintiff has no adequate remedy at law.
- 63. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

FIFTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '280 Patent by Actavis)

- 64. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 65. On information and belief, Actavis has infringed the '280 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '280 Patent.
- 66. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the asserted claims of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 67. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '280 Patent, would further infringe the asserted claims of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 68. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the asserted claims of the '280 Patent.

- 69. Plaintiff has no adequate remedy at law.
- 70. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

SIXTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '280 Patent by Incepta)

- 71. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 72. On information and belief, Incepta has infringed the '280 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '280 Patent.
- 73. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the asserted claims of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 74. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '280 Patent, would further infringe the asserted claims of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 75. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the asserted claims of the '280 Patent.
 - 76. Plaintiff has no adequate remedy at law.
- 77. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

SEVENTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '927 Patent by Actavis)

- 78. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 79. On information and belief, Actavis has infringed the '927 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '927 Patent.
- 80. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the asserted claims of the '927 patent under 35 U.S.C. §§ 271 (b) and/or (c).
- 81. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '927 Patent, would further infringe the asserted claims of the '927 Patent under 35 U.S.C. §§ 271 (b) and/or (c).
- 82. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the asserted claims of the '927 Patent.
 - 83. Plaintiff has no adequate remedy at law.
- 84. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

EIGHTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '927 Patent by Incepta)

- 85. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 86. On information and belief, Incepta has infringed the '927 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from

the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '927 Patent.

- 87. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the asserted claims of the '927 Patent under 35 U.S.C. §§ 271 (b) and/or (c).
- 88. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '927 Patent, would further infringe the asserted claims of the '927 Patent under 35 U.S.C. §§ 271 (b) and/or (c).
- 89. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the asserted claims of the '927 Patent.
 - 90. Plaintiff has no adequate remedy at law.
- 91. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285

NINTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '989 Patent by Actavis)

- 92. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 93. On information and belief, Actavis has infringed the '989 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '989 Patent.
- 94. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the asserted claims of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

- 95. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '989 Patent, would further infringe the asserted claims of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 96. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the asserted claims of the '989 Patent.
 - 97. Plaintiff has no adequate remedy at law.
- 98. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

TENTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '989 Patent by Incepta)

- 99. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 100. On information and belief, Incepta has infringed the '989 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '989 Patent.
- 101. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the asserted claims of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 102. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '989 Patent, would further infringe the asserted claims of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 103. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the asserted claims of the '989 Patent.

- 104. Plaintiff has no adequate remedy at law.
- 105. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

ELEVENTH CAUSE OF ACTION(Infringement and Declaratory Judgment of Infringement of the '756 Patent by Actavis)

- 106. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 107. On information and belief, Actavis has infringed the '756 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '756 Patent.
- 108. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the asserted claims of the '756 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 109. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '756 Patent, would further infringe the asserted claims of the '756 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 110. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the asserted claims of the '756 Patent.
 - 111. Plaintiff has no adequate remedy at law.
- 112. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

TWELFTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '756 Patent by Incepta)

- 113. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 114. On information and belief, Incepta has infringed the '756 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '756 Patent.
- 115. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the asserted claims of the '756 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 116. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '756 Patent, would further infringe the asserted claims of the '756 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 117. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the asserted claims of the '756 Patent.
 - 118. Plaintiff has no adequate remedy at law.
- 119. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

THIRTEENTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '332 Patent by Actavis)

- 120. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 121. On information and belief, Actavis has infringed the '332 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from

the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '332 Patent.

- 122. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the asserted claims of the '332 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 123. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '332 Patent, would further infringe the asserted claims of the '332 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 124. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the asserted claims of the '332 Patent.
 - 125. Plaintiff has no adequate remedy at law.
- 126. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

FOURTEENTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '332 Patent by Incepta)

- 127. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 128. On information and belief, Incepta has infringed the '332 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '332 Patent.
- 129. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the asserted claims of the '332 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

- 130. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '332 Patent, would further infringe the asserted claims of the '332 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 131. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the asserted claims of the '332 Patent.
 - 132. Plaintiff has no adequate remedy at law.
- 133. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

FIFTEENTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '992 Patent by Actavis)

- 134. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 135. On information and belief, Actavis has infringed the '992 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Products prior to the expiration of the '992 Patent.
- 136. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Actavis Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the asserted claims of the '992 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 137. Actavis's commercial manufacture, use, offer to sell, or sale of the Actavis Products within the United States, or importation of the Actavis Products into the United States during the term of the '992 Patent, would further infringe the asserted claims of the '992 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 138. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the asserted claims of the '992 Patent.

- 139. Plaintiff has no adequate remedy at law.
- 140. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

SIXTEENTH CAUSE OF ACTION (Infringement and Declaratory Judgment of Infringement of the '992 Patent by Incepta)

- 141. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-35.
- 142. On information and belief, Incepta has infringed the '992 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Incepta ANDA, by which Incepta seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Incepta Products prior to the expiration of the '992 Patent.
- 143. Incepta has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Incepta Products in the event that the FDA approves the Incepta ANDA. Accordingly, an actual and immediate controversy exists regarding Incepta's infringement of the asserted claims of the '992 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 144. Incepta's commercial manufacture, use, offer to sell, or sale of the Incepta Products within the United States, or importation of the Incepta Products into the United States during the term of the '992 Patent, would further infringe the asserted claims of the '992 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).
- 145. Plaintiff will be substantially and irreparably harmed if Incepta is not enjoined from infringing the asserted claims of the '992 Patent.
 - 146. Plaintiff has no adequate remedy at law.
- 147. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against defendants Actavis Elizabeth LLC and Actavis Inc. ("Actavis"), Abon Pharmaceuticals LLC and Incepta Pharmaceuticals Co. Ltd.

(collectively "Incepta"), and respectfully requests the following relief:

- 1. A judgment that the asserted claims of the '475, '962, '280, '927, '989, '756, '332 and '992 Patents have been infringed by Actavis;
- 2. A judgment that the asserted claims of the '475, '962, '280, '927, '989, '756, '332 and '992 Patents have been infringed by Incepta;
- 3. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Actavis, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Actavis Products within the United States, or importing the Actavis Products into the United States, prior to the expiration of the '475, '962, '280, '927, '989, '756, '332 and/or '992 Patents, including any extensions;
- 4. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Incepta, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Incepta Products within the United States, or importing the Incepta Products into the United States, prior to the expiration of the '475, '962, '280, '927, '989, '756, '332 and/or '992 Patents, including any extensions;
- 5. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203611 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '475, '962, '280, '927, '989, '756, '332 and/or '992 Patents, including any extensions;
- 6. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203643 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '475, '962, '280, '927, '989, '756, '332 and/or '992 Patents, including any extensions;
- 7. A judgment declaring and enjoining Actavis, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them

from manufacturing, using, offering to sell, or selling Actavis Products within the United States, or importing the Actavis Products into the United States, prior to the expiration dates of the '475, '962, '280, '927, '989, '756, '332 and/or '992 Patents, including any extensions;

- 8. A judgment declaring and enjoining Incepta, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Incepta Products within the United States, or importing the Incepta Products into the United States, prior to the expiration dates of the '475, '962, '280, '927, '989, '332 and/or '992 Patents, including any extensions;
- 9. If Actavis commercially manufactures, uses, offers to sell, or sells the Actavis Products within the United States, or imports the Actavis Products into the United States, prior to the expiration of any of the '475, '962, '280, '927, '989, '756, '332 and/or '992 Patents, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;
- 10. If Incepta commercially manufactures, uses, offers to sell, or sells the Incepta Products within the United States, or imports the Incepta Products into the United States, prior to the expiration of any of the '475, '962, '280, '927, '989, '756, '332 and/or '992 Patents, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;
- 11. An award of damages together with interest, and a judgment that the damages so adjudged be trebled pursuant to 35 U.S.C. §§ 283 and 284;
- 12. Judgment that this is an exceptional case and that Plaintiff be awarded its attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;
 - 13. Costs and expenses in this action; and
 - 14. Such other and further relief as the Court deems just and appropriate.

Dated: March 6, 2013 Respectfully submitted,

By: <u>s/Leda Dunn Wettre</u>

Leda Dunn Wettre

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Attorneys for Plaintiff Depomed, Inc.

CERTIFICATE OF SERVICE

I certify that on March 6, 2013, I caused a copy of the attached Fourth Amended Complaint and all of the exhibits referenced herein to be served upon Defendants' counsel of record via the Court's electronic filing system.

<u>s/ Leda Dunn Wettre</u> Leda Dunn Wettre