IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P. and PURDUE PHARMACEUTICALS L.P.,	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
ALVOGEN PINE BROOK, LLC and ACTAVIS LABORATORIES FL, INC.,	)	
Defendants.	)	

COMPLAINT

Purdue Pharma L.P. ("Purdue Pharma") and Purdue Pharmaceuticals L.P ("Purdue Pharmaceuticals") (collectively, "Purdue" or the "Plaintiffs"), for their Complaint against Alvogen Pine Brook, LLC ("Alvogen") and Actavis Laboratories FL, Inc. ("Actavis") (collectively, "Defendants"), aver as follows:

A. NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent Nos. 9,486,412 ("the '412 patent"); 9,486,413 ("the '413 patent"); 9,492,389 ("the '389 patent"); 9,492,390 ("the '390 patent"); 9,492,391 ("the '391 patent"); 9,545,380 ("the '380 patent"); 9,517,236 ("the '236 patent"); 9,572,779 ("the '779 patent"); and 9,572,804 ("the '804 patent") (collectively, the "Subsequently-Issued Patents"); and for declaratory judgment of infringement of the Subsequently-Issued Patents under 28 U.S.C. §§ 2201 and 2202. This action relates to Plaintiffs' Hysingla® ER (hydrocodone bitartrate) product ("Hysingla® ER").

(a) **Hysingla® ER**

2. The United States Food & Drug Administration ("FDA") maintains the *Approved Drug Products With Therapeutic Equivalence Evaluation* (the "Orange Book"). Each of the Subsequently-Issued Patents – the patents asserted in this case – is listed in the Orange Book as, *inter alia*, covering Plaintiffs' Hysingla® ER.

3. Hysingla® ER is the subject of New Drug Application ("NDA") No. 206627 for 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, and 120 mg dosage strengths. NDA No. 206627 has been approved by the FDA.

4. As set out more fully below, each Defendant has filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market generic versions of Plaintiffs' Hysingla® ER product in each of the dosage strengths, and each Defendant seeks to market its generic version before the expiration of the Subsequently-Listed Patents.

(b) **Defendants' ANDA Products and The Consolidated Action**

5. Alvogen submitted ANDA No. 208269 ("Alvogen's ANDA") to the FDA seeking approval to market generic versions of Hysingla® ER in 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, and 120 mg dosage strengths ("Alvogen's ANDA Products").

6. Actavis submitted ANDA No. 208389 ("Actavis's ANDA") to the FDA seeking approval to market generic versions of Hysingla® ER in 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg and 120 mg dosage strengths ("Actavis's ANDA Products").

7. On August 5, 2015, Purdue Pharma, Purdue Pharmaceuticals, The P.F. Laboratories, Inc. ("P.F. Labs"), and Grünenthal GmbH ("Grünenthal") filed a complaint against Alvogen, C.A. No. 15-687-GMS, for patent infringement of United States Patent Nos. 6,733,783 ("the '783 patent"); 8,361,499 ("the '499 patent"); 8,551,520 ("the '520 patent"); 8,647,667 ("the '667 patent"); 9,023,401 ("the '401 patent"); 8,529,948 ("the '948 patent"); 8,808,740 ("the '740

patent"); and 8,309,060 ("the '060 patent") based upon Alvogen's ANDA and Paragraph IV Notice.

8. On August 5, 2015, Purdue Pharma, Purdue Pharmaceuticals, P.F. Labs, and Grünenthal filed a complaint against Actavis, C.A. No. 15-686-GMS, for patent infringement of the '783 patent, the '499 patent, the '520 patent, the '667 patent, the '401 patent, the '948 patent, the '740 patent, and the '060 patent based upon Actavis's ANDA and Paragraph IV Notice.

9. On September 4, 2015, Purdue Pharma filed C.A. No. 15-784-GMS against Alvogen for patent infringement of United States Patent Nos. 9,056,052 ("the '052 patent") and 9,060,940 ("the '940 patent") based upon Alvogen's ANDA and Paragraph IV Notice.

10. On October 16, 2015, Purdue Pharma and Purdue Pharmaceuticals filed C.A. No. 15-940-GMS against Alvogen for patent infringement of United States Patent Nos. 9,084,816 ("the '816 patent"); 9,095,614 ("the '614 patent"); and 9,095,615 ("the '615 patent") based upon Alvogen's ANDA and Paragraph IV Notice.

11. On November 3, 2015, Purdue Pharma and Purdue Pharmaceuticals filed C.A. No. 15-1008-GMS against Actavis for patent infringement of the '052 patent; the '940 patent; the '816 patent; and the '614 patent based upon Actavis's ANDA and Paragraph IV Notice.

12. On November 17, 2015, cases 15-686-GMS, 15-687-GMS, 15-784-GMS, 15-940-GMS, and 15-1008-GMS were consolidated under lead case *Purdue Pharma L.P., et al. v. Alvogen Pine Brook, LLC, et al.*, C.A. No. 15-687-GMS (consolidated) ("the Consolidated Action").

13. On January 20, 2016, Purdue Pharma filed C.A. No. 16-26-GMS against Alvogen for patent infringement of United States Patents Nos. 9,198,863 ("the '863 patent") and 9,205,056 ("the '056 patent") based upon Alvogen's ANDA and Paragraph IV Notice.

14. On February 2, 2016, C.A. No. 16-26-GMS was consolidated into the Consolidated Action.

15. On March 11, 2016, Purdue Pharma filed C.A. No. 16-156-GMS against Actavis for patent infringement of the '863 patent and the '056 patent based upon Actavis's ANDA and Paragraph IV Notice.

16. On April 4, 2016, C.A. No. 16-156-GMS was consolidated into the Consolidated Action.

17. Both Alvogen and Actavis have filed responsive pleadings to each Complaint directed at them in the Consolidated Action. Neither Alvogen nor Actavis have contested venue in this Court for the purposes of the Consolidated Action nor have they raised any defense or objection based upon venue for the Consolidated Action either in a responsive pleading or by motion; in fact, in the Consolidated Action both Alvogen and Actavis asserted counterclaims alleging venue to be proper in this District.

(c) **The Subsequently-Issued Patents**

18. The Subsequently-Issued Patents issued to Plaintiffs and were listed in the Orange Book after the filing of last action consolidated into the Consolidated Action, C.A. No. 16-156-GMS. None of the patents asserted in this Complaint has been asserted in the Consolidated Action, nor were they listed in the Orange Book at the time any of the Complaints in the Consolidated Action were filed.

19. Each of the Subsequently-Issued Patents asserted in this Complaint is related to (*i.e.*, claims priority from) the same family as at least one of the patents asserted in the Consolidated Action.

20. The facts concerning each Defendant's ANDA that will be relevant in this case are substantially the same as the facts relevant to the Consolidated Action.

21. There is an existing case and controversy between Plaintiffs and Alvogen relating to Alvogen's ANDA, which seeks FDA approval to market generic versions of Purdue's Hysingla® ER prior to the expiration of the patents listed in the Orange Book, including the Subsequently-Issued Patents.

22. There is an existing case and controversy between Plaintiffs and Actavis relating to Actavis's ANDA, which seeks FDA approval to market generic versions of Purdue's Hysingla® ER prior to the expiration of the patents listed in the Orange Book, including the Subsequently-Issued Patents.

B. THE PARTIES

23. Purdue Pharma is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue Pharma is an owner of the '412 patent, '413 patent, '389 patent, '390 patent, '391 patent, and '380 patent. Purdue Pharma is the owner of the '236 patent, '804 patent, and '779 patent. Purdue Pharma also is the holder of approved NDA No. 206627 for Hysingla® ER, indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment in patients for whom alternative treatment options are inadequate. Purdue Pharma sells Hysingla® ER in the United States.

24. Purdue Pharmaceuticals is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, North Carolina 27893. Purdue Pharmaceuticals is an owner of the '412 patent, '413 patent, '389 patent, '390 patent, '391 patent, and '380 patent.

25. Plaintiffs Purdue Pharma and Purdue Pharmaceuticals are associated companies.

26. On information and belief, Alvogen is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 10B Bloomfield Ave., Pine Brook, New Jersey 07058.

27. On information and belief, Actavis is a corporation organized and existing under the laws of the State of Florida, having a place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

C. SUBJECT MATTER JURISDICTION AND VENUE

28. This action arises under the patent laws of the United States, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

30. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b), and under the doctrine of pendent venue.

31. Additionally, jurisdiction and venue are proper in this judicial district for this action based upon the Defendants' appearances and actions in the related Consolidated Action, including but not limited to their filing of counterclaims in the Consolidated Action, the fact that the facts and issues underlying the Consolidated Action arise from a common nucleus of

operative facts as the issues raised herein, and that maintaining venue in this Court furthers the goal of judicial economy, convenience, and fairness to the litigants.

D. PERSONAL JURISDICTION

32. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, Defendants' systematic and continuous contacts with Delaware in connection with the submission of their ANDAs, as set forth herein.

33. On information and belief, Defendants distribute generic drugs in the State of Delaware as well as throughout the United States and are in the business of preparing generic pharmaceuticals that they intend to distribute in the State of Delaware as well as throughout the United States. On information and belief, one of the generic pharmaceuticals that Alvogen intends to distribute is Alvogen's ANDA Products, and one of the generic pharmaceuticals that Actavis intends to distribute is Actavis's ANDA Products, and both intend to do so in the State of Delaware as well as throughout the United States.

34. On information and belief, if Defendants' ANDAs are approved, their ANDA Products would, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

35. In addition, Defendant Alvogen has previously submitted to the jurisdiction of this judicial district and has asserted counterclaims in civil actions initiated in this jurisdiction. *See, e.g.*, the Consolidated Action; *Reckitt Benckiser Pharm., Inc. v. Alvogen Pine Brook, Inc.*, C.A. No 13-2003-RGA (D.I. 30) (D. Del. Feb. 4, 2014); *Novartis Pharm. Corp. v. Alvogen Pine Brook, Inc.*, C.A. No. 13-52-RGA (D.I. 14) (D. Del. Jan. 31, 2013).

36. In addition, Defendant Actavis has previously submitted to the jurisdiction of this judicial district and has asserted counterclaims in civil actions initiated in this jurisdiction. *See, e.g.*, the Consolidated Action; *Cephalon, Inc. v. Actavis Laboratories FL, Inc. et al.*, C.A. No. 14-776-SLR-SRF (D.I. 16) (D. Del. July 25, 2014); *Forest Laboratories, Inc. et al. v. Apotex Corp. and Watson Laboratories, Inc. - Florida*, C.A. No. 14-200-LPS (D.I. 22 and D.I. 48) (D. Del. Apr. 22, 2014).

37. Further, this Court has personal jurisdiction over Defendants by virtue of the fact that Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, which has led to foreseeable harm and injury to Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware.

E. THE PATENTS-IN-SUIT

38. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '412 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '412 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '412 patent, attached hereto as Exhibit A, was duly and legally issued on November 8, 2016, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

39. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '413 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '413 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '413 patent, attached hereto as

Exhibit B, was duly and legally issued on November 8, 2016, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

40. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '389 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '389 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '389 patent, attached hereto as Exhibit C, was duly and legally issued on November 15, 2016, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

41. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '390 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '390 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '390 patent, attached hereto as Exhibit D, was duly and legally issued on November 15, 2016, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

42. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '391 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '391 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '391 patent, attached hereto as Exhibit E, was duly and legally issued on November 15, 2016, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

43. Purdue Pharma and Purdue Pharmaceuticals are the lawful owners of all right, title, and interest in the '380 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '380 patent is listed

in the Orange Book as covering Hysingla® ER. A copy of the '380 patent, attached hereto as Exhibit F, was duly and legally issued on January 17, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

44. Purdue Pharma is the lawful owner of all right, title, and interest in the '236 patent, titled "CONTROLLED RELEASE HYDROCODONE FORMULATIONS," including the right to sue and to recover for past infringement thereof. The '236 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '236 patent, attached hereto as Exhibit G, was duly and legally issued on December 13, 2016, naming Benjamin Oshlack, Hua-pin Huang, John K. Masselink, and Alfred Tonelli as the inventors.

45. Purdue Pharma is the lawful owner of all right, title, and interest in the '779 patent, titled "ENCASED TAMPER RESISTANT CONTROLLED RELEASE DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '779 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '779 patent, attached hereto as Exhibit H, was duly and legally issued on February 21, 2017, naming Haiyong Hugh Huang as the inventor.

46. Purdue Pharma is the lawful owner of all right, title, and interest in the '804 patent, titled "CONTROLLED RELEASE HYDROCODONE FORMULATIONS," including the right to sue and to recover for past infringement thereof. The '804 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '804 patent, attached hereto as Exhibit I, was duly and legally issued on February 21, 2017, naming Benjamin Oshlack, Hua-pin Huang, John K. Masselink, and Alfred Tonelli as the inventors.

F. DEFENDANT ALVOGEN'S ANDA

47. On information and belief, on or before June 19, 2015, Alvogen filed its ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of its ANDA Products, generic products based on the Reference Listed Drug Hysingla® ER.

48. On information and belief, in order to maintain its ANDA Alvogen will have to submit one or more additional amendments to its ANDA addressing each of the Subsequently-Issued Patents and will assert that each of those patents is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale or importation of" the drug products described in Alvogen's ANDA. On information and belief, Alvogen's assertions as to these patents will be essentially the same as the reasons Alvogen has asserted as to the patents in suit in the Consolidated Action.

49. Defendant Alvogen has not provided a Paragraph IV Notice as to any of the Subsequently-Issued Patents.

50. On information and belief, all of the issues that will be presented to this Court concerning the validity, enforceability and infringement of the Subsequently-Issued Patents are substantially the same as those that will be presented in the Consolidated Action.

G. DEFENDANT ACTAVIS'S ANDA

51. On information and belief, on or before June 23, 2015, Actavis filed its ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or

importation of its ANDA Products, generic products based on the Reference Listed Drug Hysingla® ER.

52. In a letter dated May 5, 2017, addressed to Purdue Pharma, Actavis provided what purports to be "Notification of Certification for U.S. Patents Nos. 9,486,412; 9,486,413; 9,492,389; 9,492,390; 9,492,391; and 9,545,380 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" ("May 5, 2017 Notice Letter"), indicating that Actavis has amended its ANDA to include a Paragraph IV certification that those patents are "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of" products described in Actavis's ANDA. *See* 35 U.S.C. § 271(e)(2). Actavis has not provided any Paragraph IV Notice as to other of the Subsequently-Issued Patents (namely, the '236 patent, the '804 patent, and the '779 patent).

53. This action has been filed within 45 days of Purdue's receipt of the May 5, 2017 Notice Letter.

54. On information and belief, in order to maintain its ANDA Actavis will have to submit one or more additional amendments to its ANDA addressing the remainder of the Subsequently-Issued Patents and will assert that each of those patents is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale or importation of" the drug products described in Actavis's ANDA. On information and belief, Actavis's assertions as to those other patents will be essentially the same as the reasons Actavis has asserted as to the '412 patent and '390 patent and also as asserted as to the patents in suit in the Consolidated Action.

55. On information and belief, all of the issues that will be presented to this Court concerning the validity, enforceability and infringement of the '412 patent, '390 patent,

‘236 patent, ‘779 patent, and ‘804 patent are substantially the same as those that will be presented in the Consolidated Action.

FIRST CLAIM FOR RELIEF
Infringement of the ‘412 Patent Under 35 USC § 271(e)(2) Against All Defendants

56. Purdue incorporates by reference and realleges paragraphs 1 through 55 above as though fully restated herein.

57. On information and belief, Alvogen intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the ‘412 patent, thereby infringing the ‘412 patent under 35 U.S.C. § 271(e)(2)(A).

58. Alvogen’s ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the ‘412 patent.

59. If approved by the FDA, Alvogen’s commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen’s ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the ‘412 patent under 35 U.S.C. § 271(a)-(c).

60. Alvogen’s ANDA Products constitute a material part of the inventions covered by the claims of the ‘412 patent.

61. On information and belief, Alvogen knows that Alvogen’s ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the ‘412 patent.

62. On information and belief, Alvogen has had and continues to have knowledge that there is no substantial non-infringing use for Alvogen’s ANDA Products.

63. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '412 patent by others, with knowledge that their acts are encouraging infringement.

64. Upon information and belief, Alvogen has been aware of the existence of the '412 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '412 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

65. Unless Alvogen is enjoined by the Court, Purdue will be substantially and irreparably harmed by Alvogen's infringement of the '412 patent. Purdue does not have an adequate remedy at law.

66. Actavis intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '412 patent, thereby infringing the '412 patent under 35 U.S.C. § 271(e)(2)(A).

67. Actavis's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '412 patent.

68. If approved by the FDA, Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '412 patent under 35 U.S.C. § 271(a)-(c).

69. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '412 patent.

70. On information and belief, Actavis knows that Actavis's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '412 patent.

71. On information and belief, Actavis has had and continues to have knowledge that there is no substantial non-infringing use for Actavis's ANDA Products.

72. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '412 patent by others, with knowledge that their acts are encouraging infringement.

73. Upon information and belief, Actavis has been aware of the existence of the '412 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '412 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

74. Unless Actavis is enjoined by the Court, Purdue will be substantially and irreparably harmed by Actavis's infringement of the '412 patent. Purdue does not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
Infringement of the '413 Patent Under 35 USC § 271(e)(2) Against Alvogen

75. Purdue incorporates by reference and realleges paragraphs 1 through 74 above as though fully restated herein.

76. On information and belief, Alvogen intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '413 patent, thereby infringing the '413 patent under 35 U.S.C. § 271(e)(2)(A).

77. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '413 patent.

78. If approved by the FDA, Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '413 patent under 35 U.S.C. § 271(a)-(c).

79. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '413 patent.

80. On information and belief, Alvogen knows that Alvogen's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '413 patent.

81. On information and belief, Alvogen has had and continues to have knowledge that there is no substantial non-infringing use for Alvogen's ANDA Products.

82. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '413 patent by others, with knowledge that their acts are encouraging infringement.

83. Upon information and belief, Alvogen has been aware of the existence of the '413 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '413 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

84. Unless Alvogen is enjoined by the Court, Purdue will be substantially and irreparably harmed by Alvogen's infringement of the '413 patent. Purdue does not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF
Infringement of the '389 Patent Under 35 USC § 271(e)(2) Against Alvogen

85. Purdue incorporates by reference and realleges paragraphs 1 through 84 above as though fully restated herein.

86. On information and belief, Alvogen intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '389 patent, thereby infringing the '389 patent under 35 U.S.C. § 271(e)(2)(A).

87. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '389 patent.

88. If approved by the FDA, Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '389 patent under 35 U.S.C. § 271(a)-(c).

89. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '389 patent.

90. On information and belief, Alvogen knows that Alvogen's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '389 patent.

91. On information and belief, Alvogen has had and continues to have knowledge that there is no substantial non-infringing use for Alvogen's ANDA Products.

92. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '389 patent by others, with knowledge that their acts are encouraging infringement.

93. Upon information and belief, Alvogen has been aware of the existence of the '389 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '389 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

94. Unless Alvogen is enjoined by the Court, Purdue will be substantially and irreparably harmed by Alvogen's infringement of the '389 patent. Purdue does not have an adequate remedy at law.

FOURTH CLAIM FOR RELIEF
Infringement of the '390 Patent Under 35 USC § 271(e)(2) Against All Defendants

95. Purdue incorporates by reference and realleges paragraphs 1 through 94 above as though fully restated herein.

96. On information and belief, Alvogen intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '390 patent, thereby infringing the '390 patent under 35 U.S.C. § 271(e)(2)(A).

97. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '390 patent.

98. If approved by the FDA, Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '390 patent under 35 U.S.C. § 271(a)-(c).

99. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '390 patent.

100. On information and belief, Alvogen knows that Alvogen's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '390 patent.

101. On information and belief, Alvogen has had and continues to have knowledge that there is no substantial non-infringing use for Alvogen's ANDA Products.

102. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '390 patent by others, with knowledge that their acts are encouraging infringement.

103. Upon information and belief, Alvogen has been aware of the existence of the '390 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '390 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

104. Unless Alvogen is enjoined by the Court, Purdue will be substantially and irreparably harmed by Alvogen's infringement of the '390 patent. Purdue does not have an adequate remedy at law.

105. Actavis intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '390 patent, thereby infringing the '390 patent under 35 U.S.C. § 271(e)(2)(A).

106. Actavis's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '390 patent.

107. If approved by the FDA, Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products will infringe, contribute to

the infringement of, and induce the infringement of one or more claims of the '390 patent under 35 U.S.C. § 271(a)-(c).

108. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '390 patent.

109. On information and belief, Actavis knows that Actavis's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '390 patent.

110. On information and belief, Actavis has had and continues to have knowledge that there is no substantial non-infringing use for Actavis's ANDA Products.

111. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '390 patent by others, with knowledge that their acts are encouraging infringement.

112. Upon information and belief, Actavis has been aware of the existence of the '390 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '390 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

113. Unless Actavis is enjoined by the Court, Purdue will be substantially and irreparably harmed by Actavis's infringement of the '390 patent. Purdue does not have an adequate remedy at law.

FIFTH CLAIM FOR RELIEF
Infringement of the '391 Patent Under 35 USC § 271(e)(2) Against Alvogen

114. Purdue incorporates by reference and realleges paragraphs 1 through 113 above as though fully restated herein.

115. On information and belief, Alvogen intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '391 patent, thereby infringing the '391 patent under 35 U.S.C. § 271(e)(2)(A).

116. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '391 patent.

117. If approved by the FDA, Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '391 patent under 35 U.S.C. § 271(a)-(c).

118. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '391 patent.

119. On information and belief, Alvogen knows that Alvogen's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '391 patent.

120. On information and belief, Alvogen has had and continues to have knowledge that there is no substantial non-infringing use for Alvogen's ANDA Products.

121. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '391 patent by others, with knowledge that their acts are encouraging infringement.

122. Upon information and belief, Alvogen has been aware of the existence of the '391 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '391 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

123. Unless Alvogen is enjoined by the Court, Purdue will be substantially and irreparably harmed by Alvogen's infringement of the '391 patent. Purdue does not have an adequate remedy at law.

SIXTH CLAIM FOR RELIEF
Infringement of the '380 Patent Under 35 USC § 271(e)(2) Against Alvogen

124. Purdue incorporates by reference and realleges paragraphs 1 through 123 above as though fully restated herein.

125. On information and belief, Alvogen intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '380 patent, thereby infringing the '380 patent under 35 U.S.C. § 271(e)(2)(A).

126. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '380 patent.

127. If approved by the FDA, Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '380 patent under 35 U.S.C. § 271(a)-(c).

128. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '380 patent.

129. On information and belief, Alvogen knows that Alvogen's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '380 patent.

130. On information and belief, Alvogen has had and continues to have knowledge that there is no substantial non-infringing use for Alvogen's ANDA Products.

131. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '380 patent by others, with knowledge that their acts are encouraging infringement.

132. Upon information and belief, Alvogen has been aware of the existence of the '380 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '380 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

133. Unless Alvogen is enjoined by the Court, Purdue will be substantially and irreparably harmed by Alvogen's infringement of the '380 patent. Purdue does not have an adequate remedy at law.

SEVENTH CLAIM FOR RELIEF
Infringement of the '236 Patent Under 35 USC § 271(e)(2) Against All Defendants

134. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 133 above as though fully restated herein.

135. On information and belief, Alvogen intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '236 patent, thereby infringing the '236 patent under 35 U.S.C. § 271(e)(2)(A).

136. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '236 patent.

137. If approved by the FDA, Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '236 patent under 35 U.S.C. § 271(a)-(c).

138. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '236 patent.

139. On information and belief, Alvogen knows that Alvogen's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '236 patent.

140. On information and belief, Alvogen has had and continues to have knowledge that there is no substantial non-infringing use for Alvogen's ANDA Products.

141. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '236 patent by others, with knowledge that their acts are encouraging infringement.

142. Upon information and belief, Alvogen has been aware of the existence of the '236 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '236 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

143. Unless Alvogen is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Alvogen's infringement of the '236 patent. Purdue Pharma does not have an adequate remedy at law.

144. On information and belief, Actavis intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '236 patent, thereby infringing the '236 patent under 35 U.S.C. § 271(e)(2)(A).

145. Actavis's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '236 patent.

146. If approved by the FDA, Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '236 patent under 35 U.S.C. § 271(a)-(c).

147. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '236 patent.

148. On information and belief, Actavis knows that Actavis's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '236 patent.

149. On information and belief, Actavis has had and continues to have knowledge that there is no substantial non-infringing use for Actavis's ANDA Products.

150. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '236 patent by others, with knowledge that their acts are encouraging infringement.

151. Upon information and belief, Actavis has been aware of the existence of the '236 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '236 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

152. Unless Actavis is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Actavis's infringement of the '236 patent. Purdue Pharma does not have an adequate remedy at law.

EIGTH CLAIM FOR RELIEF
Infringement of the '779 Patent Under 35 USC § 271(e)(2) Against All Defendants

153. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 152 above as though fully restated herein.

154. On information and belief, Alvogen intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '779 patent, thereby infringing the '779 patent under 35 U.S.C. § 271(e)(2)(A).

155. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '779 patent.

156. If approved by the FDA, Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '779 patent under 35 U.S.C. § 271(a)-(c).

157. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '779 patent.

158. On information and belief, Alvogen knows that Alvogen's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '779 patent.

159. On information and belief, Alvogen has had and continues to have knowledge that there is no substantial non-infringing use for Alvogen's ANDA Products.

160. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '779 patent by others, with knowledge that their acts are encouraging infringement.

161. Upon information and belief, Alvogen has been aware of the existence of the '779 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '779 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

162. Unless Alvogen is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Alvogen's infringement of the '779 patent. Purdue Pharma does not have an adequate remedy at law.

163. On information and belief, Actavis intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '779 patent, thereby infringing the '779 patent under 35 U.S.C. § 271(e)(2)(A).

164. Actavis's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '779 patent.

165. If approved by the FDA, Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '779 patent under 35 U.S.C. § 271(a)-(c).

166. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '779 patent.

167. On information and belief, knows that Actavis's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '779 patent.

168. On information and belief, Actavis has had and continues to have knowledge that there is no substantial non-infringing use for Actavis's ANDA Products.

169. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '779 patent by others, with knowledge that their acts are encouraging infringement.

170. Upon information and belief, Actavis has been aware of the existence of the '779 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '779 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

171. Unless Actavis is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Actavis's infringement of the '779 patent. Purdue Pharma does not have an adequate remedy at law.

NINTH CLAIM FOR RELIEF
Infringement of the '804 Patent Under 35 USC § 271(e)(2) Against All Defendants

172. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 171 above as though fully restated herein.

173. On information and belief, Alvogen intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '804 patent, thereby infringing the '804 patent under 35 U.S.C. § 271(e)(2)(A).

174. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '804 patent.

175. If approved by the FDA, Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '804 patent under 35 U.S.C. § 271(a)-(c).

176. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '804 patent.

177. On information and belief, Alvogen knows that Alvogen's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '804 patent.

178. On information and belief, Alvogen has had and continues to have knowledge that there is no substantial non-infringing use for Alvogen's ANDA Products.

179. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '804 patent by others, with knowledge that their acts are encouraging infringement.

180. Upon information and belief, Alvogen has been aware of the existence of the '804 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '804 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

181. Unless Alvogen is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Alvogen's infringement of the '804 patent. Purdue Pharma does not have an adequate remedy at law.

182. On information and belief, Actavis intends to seek approval to engage in commercial manufacture, use, or sale of its ANDA Products prior to expiration of the '804 patent, thereby infringing the '804 patent under 35 U.S.C. § 271(e)(2)(A).

183. Actavis's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '804 patent.

184. If approved by the FDA, Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '804 patent under 35 U.S.C. § 271(a)-(c).

185. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '804 patent.

186. On information and belief, knows that Actavis's ANDA Products are especially made or especially adapted for use in the infringement of one or more claims of the '804 patent.

187. On information and belief, Actavis has had and continues to have knowledge that there is no substantial non-infringing use for Actavis's ANDA Products.

188. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '804 patent by others, with knowledge that their acts are encouraging infringement.

189. Upon information and belief, Actavis has been aware of the existence of the '804 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '804 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

190. Unless Actavis is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Actavis's infringement of the '804 patent. Purdue Pharma does not have an adequate remedy at law.

TENTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '412 Patent Under 35 USC § 271(a), (b), and/or (c) Against All Defendants

191. Purdue incorporates by reference and realleges paragraphs 1 through 190 above as though fully restated herein.

192. These claims arise under 28 U.S.C. §§ 2201 and 2202.

193. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

194. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '412 patent.

195. Alvogen's actions prior to the expiration of the '412 patent indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

196. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '412 patent under 35 U.S.C. § 271(a), (b), and/or (c).

197. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '412 patent by others, with knowledge that their acts are encouraging infringement.

198. Plaintiffs are entitled to a declaratory judgment that Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '412 patent.

199. Alvogen was aware of the '412 patent prior to the filing date of this Complaint. This is an exceptional case.

200. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '412 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

201. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '412 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '412 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

202. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '412 patent.

203. Actavis's actions prior to the expiration of the '412 patent indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

204. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '412 patent under 35 U.S.C. § 271(a), (b), and/or (c).

205. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '412 patent by others, with knowledge that their acts are encouraging infringement.

206. Plaintiffs are entitled to a declaratory judgment that Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe,

contribute to the infringement of, and induce the infringement of one or more claims of the '412 patent.

207. Actavis was aware of the '412 patent prior to the filing date of this Complaint. This is an exceptional case.

208. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '412 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

209. Unless Actavis is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '412 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products prior to the expiration of the '412 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

ELEVENTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '413 Patent Under 35 USC § 271(a), (b), and/or (c) Against Alvogen

210. Purdue incorporates by reference and realleges paragraphs 1 through 209 above as though fully restated herein.

211. These claims arise under 28 U.S.C. §§ 2201 and 2202.

212. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

213. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '413 patent.

214. Alvogen's actions prior to the expiration of the '413 patent indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

215. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '413 patent under 35 U.S.C. § 271(a), (b), and/or (c).

216. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '413 patent by others, with knowledge that their acts are encouraging infringement.

217. Plaintiffs are entitled to a declaratory judgment that Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '413 patent.

218. Alvogen was aware of the '413 patent prior to the filing date of this Complaint. This is an exceptional case.

219. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '413 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

220. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '413 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '413 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

TWELFTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '389 Patent Under 35 USC § 271(a), (b), and/or (c) Against Alvogen

221. Purdue incorporates by reference and realleges paragraphs 1 through 220 above as though fully restated herein.

222. These claims arise under 28 U.S.C. §§ 2201 and 2202.

223. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

224. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '389 patent.

225. Alvogen's actions prior to the expiration of the '389 patent indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

226. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '389 patent under 35 U.S.C. § 271(a), (b), and/or (c).

227. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '389 patent by others, with knowledge that their acts are encouraging infringement.

228. Plaintiffs are entitled to a declaratory judgment that Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '389 patent.

229. Alvogen was aware of the '389 patent prior to the filing date of this Complaint. This is an exceptional case.

230. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '389 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

231. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '389 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '389 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

THIRTEENTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '390 Patent Under 35 USC § 271(a), (b), and/or (c) Against All Defendants

232. Purdue incorporates by reference and realleges paragraphs 1 through 231 above as though fully restated herein.

233. These claims arise under 28 U.S.C. §§ 2201 and 2202.

234. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

235. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '390 patent.

236. Alvogen's actions prior to the expiration of the '390 patent indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

237. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '390 patent under 35 U.S.C. § 271(a), (b), and/or (c).

238. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '390 patent by others, with knowledge that their acts are encouraging infringement.

239. Plaintiffs are entitled to a declaratory judgment that Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '390 patent.

240. Alvogen was aware of the '390 patent prior to the filing date of this Complaint. This is an exceptional case.

241. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '390 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

242. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '390 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '390 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

243. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '390 patent.

244. Actavis's actions prior to the expiration of the '390 patent indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

245. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '390 patent under 35 U.S.C. § 271(a), (b), and/or (c).

246. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '390 patent by others, with knowledge that their acts are encouraging infringement.

247. Plaintiffs are entitled to a declaratory judgment that Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '390 patent.

248. Actavis was aware of the '390 patent prior to the filing date of this Complaint. This is an exceptional case.

249. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '390 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

250. Unless Actavis is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '390 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products prior to the expiration of the '390 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

FOURTEENTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '391 Patent Under 35 USC § 271(a), (b), and/or (c) Against Alvogen

251. Purdue incorporates by reference and realleges paragraphs 1 through 250 above as though fully restated herein.

252. These claims arise under 28 U.S.C. §§ 2201 and 2202.

253. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

254. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '391 patent.

255. Alvogen's actions prior to the expiration of the '391 patent indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

256. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '391 patent under 35 U.S.C. § 271(a), (b), and/or (c).

257. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '391 patent by others, with knowledge that their acts are encouraging infringement.

258. Plaintiffs are entitled to a declaratory judgment that Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '391 patent.

259. Alvogen was aware of the '391 patent prior to the filing date of this Complaint. This is an exceptional case.

260. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '391 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

261. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '391 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '391 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

FIFTEENTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '380 Patent Under 35 USC § 271(a), (b), and/or (c) Against Alvogen

262. Purdue incorporates by reference and realleges paragraphs 1 through 261 above as though fully restated herein.

263. These claims arise under 28 U.S.C. §§ 2201 and 2202.

264. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

265. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '380 patent.

266. Alvogen's actions prior to the expiration of the '380 patent indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

267. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '380 patent under 35 U.S.C. § 271(a), (b), and/or (c).

268. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '380 patent by others, with knowledge that their acts are encouraging infringement.

269. Plaintiffs are entitled to a declaratory judgment that Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '380 patent.

270. Alvogen was aware of the '380 patent prior to the filing date of this Complaint. This is an exceptional case.

271. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '380 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

272. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '380 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '380 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

SIXTEENTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '236 Patent Under 35 USC § 271(a), (b), and/or (c) Against All Defendants

273. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 272 above as though fully restated herein.

274. These claims arise under 28 U.S.C. §§ 2201 and 2202.

275. There is an actual case or controversy such that the Court may entertain Purdue Pharma's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

276. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '236 patent.

277. Alvogen's actions prior to the expiration of the '236 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

278. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '236 patent under 35 U.S.C. § 271(a), (b), and/or (c).

279. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '236 patent by others, with knowledge that their acts are encouraging infringement.

280. Purdue Pharma's is entitled to a declaratory judgment that Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '236 patent.

281. Alvogen was aware of the '236 patent prior to the filing date of this Complaint. This is an exceptional case.

282. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '236 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

283. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '236 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '236 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

284. On information and belief, Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '236 patent.

285. Actavis's actions prior to the expiration of the '236 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

286. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '236 patent under 35 U.S.C. § 271(a), (b), and/or (c).

287. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '236 patent by others, with knowledge that their acts are encouraging infringement.

288. Purdue Pharma is entitled to a declaratory judgment that Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will

infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '236 patent.

289. Actavis was aware of the '236 patent prior to the filing date of this Complaint. This is an exceptional case.

290. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '236 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

291. Unless Actavis is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '236 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products prior to the expiration of the '236 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

SEVENTEENTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '779 Patent Under 35 USC § 271(a), (b), and/or (c) Against All Defendants

292. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 290 above as though fully restated herein.

293. These claims arise under 28 U.S.C. §§ 2201 and 2202.

294. There is an actual case or controversy such that the Court may entertain Purdue Pharma's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

295. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '779 patent.

296. Alvogen's actions prior to the expiration of the '779 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

297. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '779 patent under 35 U.S.C. § 271(a), (b), and/or (c).

298. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '779 patent by others, with knowledge that their acts are encouraging infringement.

299. Purdue Pharma is entitled to a declaratory judgment that Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '779 patent.

300. Alvogen was aware of the '779 patent prior to the filing date of this Complaint. This is an exceptional case.

301. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '779 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

302. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '779 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '779 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

303. On information and belief, Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '779 patent.

304. Actavis's actions prior to the expiration of the '779 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

305. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '779 patent under 35 U.S.C. § 271(a), (b), and/or (c).

306. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '779 patent by others, with knowledge that their acts are encouraging infringement.

307. Purdue Pharma is entitled to a declaratory judgment that Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '779 patent.

308. Actavis was aware of the '779 patent prior to the filing date of this Complaint. This is an exceptional case.

309. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '779 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

310. Unless Actavis is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '779 patent, the

commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products prior to the expiration of the '779 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

EIGHTEENTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '804 Patent Under 35 USC § 271(a), (b), and/or (c) Against All Defendants

311. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 309 above as though fully restated herein.

312. These claims arise under 28 U.S.C. §§ 2201 and 2202.

313. There is an actual case or controversy such that the Court may entertain Purdue Pharma's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

314. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '804 patent.

315. Alvogen's actions prior to the expiration of the '804 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

316. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '804 patent under 35 U.S.C. § 271(a), (b), and/or (c).

317. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '804 patent by others, with knowledge that their acts are encouraging infringement.

318. Purdue Pharma is entitled to a declaratory judgment that Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '804 patent.

319. Alvogen was aware of the '804 patent prior to the filing date of this Complaint. This is an exceptional case.

320. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '804 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

321. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '804 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '804 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

322. On information and belief, Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the its ANDA Products into the United States prior to the expiration of the '804 patent.

323. Actavis's actions prior to the expiration of the '804 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

324. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '804 patent under 35 U.S.C. § 271(a), (b), and/or (c).

325. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '804 patent by others, with knowledge that their acts are encouraging infringement.

326. Purdue Pharma is entitled to a declaratory judgment that Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products will infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '804 patent.

327. Actavis was aware of the '804 patent prior to the filing date of this Complaint. This is an exceptional case.

328. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '804 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

329. Unless Actavis is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '804 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products prior to the expiration of the '804 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for judgment as follows:

A. Adjudging that Defendant Alvogen has infringed one or more claims of each of the '412 patent, '413 patent, '389 patent, '390 patent, '391 patent, '380 patent, '236 patent, '779 patent, and '804 patent, and that the commercial sale, offer for sale, use, importation, and/or manufacture of its ANDA Products would infringe, induce infringement of,

and/or contribute to the infringement of one or more claims of each of the '412 patent, '413 patent, '389 patent, '390 patent, '391 patent, '380 patent, '236 patent, '779 patent, and '804 patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Alvogen's ANDA and its ANDA Products, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the last date of expiration of the '412 patent, '413 patent, '389 patent, '390 patent, '391 patent, '380 patent, '236 patent, '779 patent, and '804 patent, plus any additional periods of extension or exclusivity attached thereto;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Alvogen, its 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 drug product that is the subject of Alvogen's ANDA, including Alvogen's ANDA Products or any other drug product that infringes the '412 patent, '413 patent, '389 patent, '390 patent, '391 patent, '380 patent, '236 patent, '804 patent, and '779 patent;

D. That a declaration be issued under 28 U.S.C. § 2201 that if Alvogen, its 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, engage in the commercial sale, offer for sale, use, importation, and/or manufacture of Alvogen's ANDA Products prior to expiration the

‘412 patent, ‘413 patent, ‘389 patent, ‘390 patent, ‘391 patent, ‘380 patent, ‘236 patent, ‘779 patent, and ‘804 patent, it will constitute an act of infringement of one or more claims of each of the ‘412 patent, ‘413 patent, ‘389 patent, ‘390 patent, ‘391 patent, ‘380 patent, ‘236 patent, ‘779 patent, and ‘804 patent;

E. Adjudging that Defendant Actavis has infringed one or more claims of each of the ‘412 patent, ‘390 patent, ‘236 patent, ‘779 patent, and ‘804 patent, and that the commercial sale, offer for sale, use, importation, and/or manufacture of its ANDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the ‘412 patent, ‘390 patent, ‘236 patent, ‘779 patent, and ‘804 patent;

F. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Actavis’s ANDA and its ANDA Products, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the last date of expiration of the ‘412 patent, ‘390 patent, ‘236 patent, ‘779 patent, and ‘804 patent, plus any additional periods of extension or exclusivity attached thereto;

G. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Actavis, its 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 drug product that is the subject of Actavis’s ANDA, including Actavis’s ANDA Products or any other drug product that infringes the ‘412 patent, ‘390 patent, ‘236 patent, ‘779 patent, and ‘804 patent;

H. That a declaration be issued under 28 U.S.C. § 2201 that if Actavis, its 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, engage in the commercial sale, offer for sale, use, importation, and/or manufacture of Actavis's ANDA Products prior to expiration the '412 patent, '390 patent, '236 patent, '779 patent, and '804 patent, it will constitute an act of infringement of one or more claims of each of the '412 patent, '390 patent, '236 patent, '779 patent, and '804 patent;

I. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285;

J. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

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