IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Purdue Pharma L.P. ("Purdue Pharma" or "Purdue") and Grünenthal GmbH ("Grünenthal") (collectively, "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 under 35 U.S.C. § 271; and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202 of United States Patents Nos. 9,669,023 ("the '023 patent"); 9,669,024 ("the '024 patent"); 9,675,610 ("the '610 patent"); 9,675,611 ("the '611 patent"); and 9,682,077 ("the '077 patent"). This action relates to Purdue's 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 patents asserted in this Complaint is listed in the Orange Book as, *inter alia*, covering Purdue's 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 Purdue's Hysingla® ER product in each of the dosage strengths, and each Defendant seeks to market its generic version before the expiration of the patents asserted in this Complaint.

(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 L.P. ("Purdue Pharmaceuticals"), The P.F. Laboratories, Inc. ("P.F. Labs"), and Grünenthal filed a complaint against Alvogen, C.A. No. 15-687-GMS, for patent infringement of United States Patents 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 Patents 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 Patents 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, 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, 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.

18. On June 5, 2017, Purdue Pharma and Purdue Pharmaceuticals filed C.A. No. 17-677-GMS against Alvogen and Actavis for patent infringement and declaratory judgment of patent infringement of United States Patents 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").

19. On July 31, 2017, 17-677-GMS was consolidated into the Consolidated Action.

(c) **The Patents Asserted in this Complaint**

20. The patents asserted in this Complaint were listed in the Orange Book after the filing of the last action consolidated into the Consolidated Action, No. 17-677-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.

21. 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.

22. 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 patents asserted in this Complaint and in the Consolidated Action.

23. 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 patents asserted in this Complaint and in the Consolidated Action.

B. THE PARTIES

24. 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 the owner of the '023 patent, '024 patent, '611 patent, and '077 patent. Purdue Pharma is an exclusive licensee of the '610

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.

25. Grünenthal is a corporation organized and existing under the laws of Germany, having an address at 52078 Aachen, Zieglerstrasse 6, Germany. Grünenthal is the owner of the '610 patent.

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, 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 goals 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-cv-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-cv-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, which is a limited partnership organized and existing under the laws of the State of Delaware.

E. THE PATENTS-IN-SUIT

38. Purdue Pharma is the lawful owner of all right, title, and interest in the '023 patent, titled "CONTROLLED RELEASE HYDROCODONE FORMULATIONS," including the right to sue and to recover for past infringement thereof. The '023 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '023 patent, attached hereto as Exhibit A, was duly and legally issued on June 6, 2017, naming Benjamin Oshlack, Hua-pin Huang, John K Masselink, and Alfred Tonelli as the inventors.

39. Purdue Pharma is the lawful owner of all right, title, and interest in the '024 patent, titled "CONTROLLED RELEASE HYDROCODONE FORMULATIONS," including the right to sue and to recover for past infringement thereof. The '024 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '024 patent, attached hereto as

Exhibit B, was duly and legally issued on June 6, 2017, naming Benjamin Oshlack, Hua-pin Huang, John Masselink, and Alfred Tonelli as the inventors.

40. Purdue Pharma is the lawful owner of all right, title, and interest in the '611 patent, titled "METHODS OF PROVIDING ANALGESIA," including the right to sue and to recover for past infringement thereof. The '611 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '611 patent, attached hereto as Exhibit C, was duly and legally issued on June 13, 2017, naming Benjamin Oshlack, Hua-pin Huang, John Masselink, and Alfred Tonelli as the inventors.

41. Purdue Pharma is the lawful owner of all right, title, and interest in the '077 patent, titled "METHODS OF PROVIDING ANALGESIA," including the right to sue and to recover for past infringement thereof. The '077 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '077 patent, attached hereto as Exhibit D, was duly and legally issued on June 20, 2017, naming Benjamin Oshlack, Hua-pin Huang, John K Masselink, and Alfred Tonelli as the inventors.

42. Grünenthal is the lawful owner of all right, title, and interest in the '610 patent, titled "ABUSE-PROOFED DOSAGE FORM," including the right to sue and to recover for past infringement thereof. Purdue Pharma is an exclusive licensee of the '610 patent from Grünenthal, with the right to enforce the '610 patent. The '610 patent is listed in the Orange Book as covering Hysingla® ER. A copy of the '610 patent, attached hereto as Exhibit E, was duly and legally issued on June 13, 2017, naming Johannes Bartholomaeus and Henrich Kugelmann as the inventors.

F. DEFENDANT ALVOGEN'S ANDA

43. 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.

44. On information and belief, Alvogen's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '023 patent, '024 patent, '610 patent, '611 patent, and '077 patent listed in the FDA's Orange Book as, *inter alia*, covering the use of Hysingla® ER, which is the subject of approved NDA No. 206627, are "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.

45. In a letter dated August 7, 2017, addressed to Purdue Pharma, Purdue Pharmaceuticals, and Grünenthal, Alvogen provided what purports to be "Notification Pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act for U.S. Patent Nos. 9,289,391, 9,486,412, 9,486,413, 9,492,389, 9,492,390, 9,492,391, 9,517,236, 9,545,380, 9,572,779, 9,572,804, 9,669,023, 9,669,024, 9,675,610, 9,675,611, and 9,682,077 (NDA No. 206627)" with respect to Alvogen's ANDA and Alvogen's ANDA Products, and the patents asserted in this Complaint ("August 7, 2017 Notice Letter").[1]

[1] Alvogen also included the patents asserted in 17-677-GMS in the August 7, 2017 Notice Letter.

46. Alvogen's assertions as to the patents asserted in this Complaint are essentially the same as or substantially overlap with their assertions as to the patents in suit in the Consolidated Action.

47. This action has been filed within 45 days of Purdue's receipt of the August 7, 2017 Notice Letter.

48. On information and belief, all or most of the issues that will be presented to this Court concerning the validity, enforceability and infringement of the patents asserted in this Complaint are substantially the same as or substantially overlap with those that will be presented in the Consolidated Action.

G. DEFENDANT ACTAVIS'S ANDA

49. 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.

50. On information and belief, in order to maintain its ANDA Actavis will have to submit one or more additional amendments to its ANDA addressing each of the patents asserted in this Complaint 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 patents will be essentially the same as or substantially overlap with their assertions as to the patents in suit in the Consolidated Action.

51. Defendant Actavis has not provided a Paragraph IV Notice as to any of the patents asserted in this Complaint.

52. On information and belief, all or most of the issues that will be presented to this Court concerning the validity, enforceability and infringement of the patents asserted in this Complaint are substantially the same as or substantially overlap with those that will be presented in the Consolidated Action.

FIRST CLAIM FOR RELIEF
Infringement of the '023 Patent Under 35 U.S.C. § 271(e)(2)
Against All Defendants

53. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 52 above as though fully restated herein.

54. 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 '023 patent, thereby infringing the '023 patent under 35 U.S.C. § 271(e)(2)(A).

55. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '023 patent.

56. 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 '023 patent under 35 U.S.C. § 271(a)-(c).

57. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '023 patent.

58. 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 '023 patent.

59. 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.

60. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '023 patent by others, with knowledge that their acts are encouraging infringement.

61. Upon information and belief, Alvogen has been and continues to be aware of the existence of the '023 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '023 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

62. Unless Alvogen is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Alvogen's infringement of the '023 patent. Purdue Pharma does not have an adequate remedy at law.

63. 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 '023 patent, thereby infringing the '023 patent under 35 U.S.C. § 271(e)(2)(A).

64. Actavis's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '023 patent.

65. 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 '023 patent under 35 U.S.C. § 271(a)-(c).

66. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '023 patent.

67. 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 '023 patent.

68. 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.

69. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '023 patent by others, with knowledge that their acts are encouraging infringement.

70. Upon information and belief, Actavis has been and continues to be aware of the existence of the '023 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '023 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

71. Unless Actavis is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Actavis's infringement of the '023 patent. Purdue Pharma does not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
Infringement of the '024 Patent Under 35 U.S.C. § 271(e)(2)
Against All Defendants

72. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 71 above as though fully restated herein.

73. 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 '024 patent, thereby infringing the '024 patent under 35 U.S.C. § 271(e)(2)(A).

74. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '024 patent.

75. 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 '024 patent under 35 U.S.C. § 271(a)-(c).

76. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '024 patent.

77. 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 '024 patent.

78. 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.

79. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '024 patent by others, with knowledge that their acts are encouraging infringement.

80. Upon information and belief, Alvogen has been and continues to be aware of the existence of the '024 patent, and has no reasonable basis for believing that Alvogen's

ANDA Products will not infringe the '024 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

81. Unless Alvogen is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Alvogen's infringement of the '024 patent. Purdue Pharma does not have an adequate remedy at law.

82. 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 '024 patent, thereby infringing the '024 patent under 35 U.S.C. § 271(e)(2)(A).

83. Actavis's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '024 patent.

84. 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 '024 patent under 35 U.S.C. § 271(a)-(c).

85. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '024 patent.

86. 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 '024 patent.

87. 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.

88. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '024 patent by others, with knowledge that their acts are encouraging infringement.

89. Upon information and belief, Actavis has been and continues to be aware of the existence of the '024 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '024 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

90. Unless Actavis is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Actavis's infringement of the '024 patent. Purdue Pharma does not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF
Infringement of the '611 Patent Under 35 U.S.C. § 271(e)(2)
Against All Defendants

91. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 90 above as though fully restated herein.

92. 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 '611 patent, thereby infringing the '611 patent under 35 U.S.C. § 271(e)(2)(A).

93. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '611 patent.

94. 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 '611 patent under 35 U.S.C. § 271(a)-(c).

95. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '611 patent.

96. 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 '611 patent.

97. 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.

98. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '611 patent by others, with knowledge that their acts are encouraging infringement.

99. Upon information and belief, Alvogen has been and continues to be aware of the existence of the '611 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '611 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

100. Unless Alvogen is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Alvogen's infringement of the '611 patent. Purdue Pharma does not have an adequate remedy at law.

101. 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 '611 patent, thereby infringing the '611 patent under 35 U.S.C. § 271(e)(2)(A).

102. Actavis's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '611 patent.

103. 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 '611 patent under 35 U.S.C. § 271(a)-(c).

104. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '611 patent.

105. 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 '611 patent.

106. 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.

107. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '611 patent by others, with knowledge that their acts are encouraging infringement.

108. Upon information and belief, Actavis has been and continues to be aware of the existence of the '611 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '611 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

109. Unless Actavis is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Actavis's infringement of the '611 patent. Purdue Pharma does not have an adequate remedy at law.

FOURTH CLAIM FOR RELIEF
Infringement of the '077 Patent Under 35 U.S.C. § 271(e)(2)
Against All Defendants

110. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 109 above as though fully restated herein.

111. 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 '077 patent, thereby infringing the '077 patent under 35 U.S.C. § 271(e)(2)(A).

112. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '077 patent.

113. 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 '077 patent under 35 U.S.C. § 271(a)-(c).

114. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '077 patent.

115. 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 '077 patent.

116. 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.

117. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '077 patent by others, with knowledge that their acts are encouraging infringement.

118. Upon information and belief, Alvogen has been and continues to be aware of the existence of the '077 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '077 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

119. Unless Alvogen is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Alvogen's infringement of the '077 patent. Purdue Pharma does not have an adequate remedy at law.

120. 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 '077 patent, thereby infringing the '077 patent under 35 U.S.C. § 271(e)(2)(A).

121. Actavis's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '077 patent.

122. 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 '077 patent under 35 U.S.C. § 271(a)-(c).

123. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '077 patent.

124. 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 '077 patent.

125. 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.

126. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '077 patent by others, with knowledge that their acts are encouraging infringement.

127. Upon information and belief, Actavis has been and continues to be aware of the existence of the '077 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '077 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

128. Unless Actavis is enjoined by the Court, Purdue Pharma will be substantially and irreparably harmed by Actavis's infringement of the '077 patent. Purdue Pharma does not have an adequate remedy at law.

FIFTH CLAIM FOR RELIEF
Infringement of the '610 Patent Under 35 U.S.C. § 271(e)(2)
Against All Defendants

129. Plaintiffs incorporate by reference and reallege paragraphs 1 through 128 above as though fully restated herein.

130. 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 '610 patent, thereby infringing the '610 patent under 35 U.S.C. § 271(e)(2)(A).

131. Alvogen's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '610 patent.

132. 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 '610 patent under 35 U.S.C. § 271(a)-(c).

133. Alvogen's ANDA Products constitute a material part of the inventions covered by the claims of the '610 patent.

134. 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 '610 patent.

135. 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.

136. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '610 patent by others, with knowledge that their acts are encouraging infringement.

137. Upon information and belief, Alvogen has been and continues to be aware of the existence of the '610 patent, and has no reasonable basis for believing that Alvogen's ANDA Products will not infringe the '610 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

138. Unless Alvogen is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Alvogen's infringement of the '610 patent. Plaintiffs do not have an adequate remedy at law.

139. 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 '610 patent, thereby infringing the '610 patent under 35 U.S.C. § 271(e)(2)(A).

140. Actavis's ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '610 patent.

141. 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 '610 patent under 35 U.S.C. § 271(a)-(c).

142. Actavis's ANDA Products constitute a material part of the inventions covered by the claims of the '610 patent.

143. 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 '610 patent.

144. 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.

145. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '610 patent by others, with knowledge that their acts are encouraging infringement.

146. Upon information and belief, Actavis has been and continues to be aware of the existence of the '610 patent, and has no reasonable basis for believing that Actavis's ANDA Products will not infringe the '610 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

147. Unless Actavis is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Actavis's infringement of the '610 patent. Plaintiffs do not have an adequate remedy at law.

SIXTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '023 Patent Under 35 U.S.C. § 271(a), (b), and/or (c) Against All Defendants

148. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 147 above as though fully restated herein.

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

150. 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.

151. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, sell, and/or import its ANDA Products into the United States prior to the expiration of the '023 patent.

152. Alvogen's actions prior to the expiration of the '023 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

153. 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 '023 patent under 35 U.S.C. § 271(a), (b), and/or (c).

154. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '023 patent by others, with knowledge that their acts are encouraging infringement.

155. 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 '023 patent.

156. Alvogen was aware of the '023 patent prior to the filing date of this Complaint. This is an exceptional case.

157. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '023 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

158. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '023 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '023 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

159. On information and belief, Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, sell, and/or import its ANDA Products into the United States prior to the expiration of the '023 patent.

160. Actavis's actions prior to the expiration of the '023 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

161. 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 '023 patent under 35 U.S.C. § 271(a), (b), and/or (c).

162. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '023 patent by others, with knowledge that their acts are encouraging infringement.

163. 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 '023 patent.

164. Actavis was aware of the '023 patent prior to the filing date of this Complaint. This is an exceptional case.

165. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '023 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

166. Unless Actavis is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '023 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products prior to the expiration of the '023 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

SEVENTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '024 Patent
Under 35 U.S.C. § 271(a), (b), and/or (c) Against All Defendants

167. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 166 above as though fully restated herein.

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

169. 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.

170. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, sell, and/or import its ANDA Products into the United States prior to the expiration of the '024 patent.

171. Alvogen's actions prior to the expiration of the '024 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

172. 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 '024 patent under 35 U.S.C. § 271(a), (b), and/or (c).

173. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '024 patent by others, with knowledge that their acts are encouraging infringement.

174. 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 '024 patent.

175. Alvogen was aware of the '024 patent prior to the filing date of this Complaint. This is an exceptional case.

176. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '024 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

177. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '024 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '024 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

178. On information and belief, Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, sell, and/or import its ANDA Products into the United States prior to the expiration of the '024 patent.

179. Actavis's actions prior to the expiration of the '024 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

180. 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 '024 patent under 35 U.S.C. § 271(a), (b), and/or (c).

181. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '024 patent by others, with knowledge that their acts are encouraging infringement.

182. 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 '024 patent.

183. Actavis was aware of the '024 patent prior to the filing date of this Complaint. This is an exceptional case.

184. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '024 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

185. Unless Actavis is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '024 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products prior to the expiration of the '024 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

EIGHTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '611 Patent Under 35 U.S.C. § 271(a), (b), and/or (c) Against All Defendants

186. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 185 above as though fully restated herein.

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

188. 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.

189. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, sell, and/or import its ANDA Products into the United States prior to the expiration of the '611 patent.

190. Alvogen's actions prior to the expiration of the '611 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

191. 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 '611 patent under 35 U.S.C. § 271(a), (b), and/or (c).

192. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '611 patent by others, with knowledge that their acts are encouraging infringement.

193. 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 '611 patent.

194. Alvogen was aware of the '611 patent prior to the filing date of this Complaint. This is an exceptional case.

195. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '611 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

196. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '611 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '611 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

197. On information and belief, Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, sell, and/or import its ANDA Products into the United States prior to the expiration of the '611 patent.

198. Actavis's actions prior to the expiration of the '611 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

199. 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 '611 patent under 35 U.S.C. § 271(a), (b), and/or (c).

200. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '611 patent by others, with knowledge that their acts are encouraging infringement.

201. 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 '611 patent.

202. Actavis was aware of the '611 patent prior to the filing date of this Complaint. This is an exceptional case.

203. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '611 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

204. Unless Actavis is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '611 patent, the

commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products prior to the expiration of the '611 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

NINTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '077 Patent Under 35 U.S.C. § 271(a), (b), and/or (c) Against All Defendants

205. Purdue Pharma incorporates by reference and realleges paragraphs 1 through 204 above as though fully restated herein.

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

207. 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.

208. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, sell, and/or import its ANDA Products into the United States prior to the expiration of the '077 patent.

209. Alvogen's actions prior to the expiration of the '077 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

210. 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 '077 patent under 35 U.S.C. § 271(a), (b), and/or (c).

211. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '077 patent by others, with knowledge that their acts are encouraging infringement.

212. 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 '077 patent.

213. Alvogen was aware of the '077 patent prior to the filing date of this Complaint. This is an exceptional case.

214. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '077 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

215. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '077 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '077 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

216. On information and belief, Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, sell, and/or import its ANDA Products into the United States prior to the expiration of the '077 patent.

217. Actavis's actions prior to the expiration of the '077 patent indicate a refusal to change the course of its action in the face of acts by Purdue Pharma.

218. 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 '077 patent under 35 U.S.C. § 271(a), (b), and/or (c).

219. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '077 patent by others, with knowledge that their acts are encouraging infringement.

220. 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 '077 patent.

221. Actavis was aware of the '077 patent prior to the filing date of this Complaint. This is an exceptional case.

222. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '077 patent in violation of Purdue Pharma's patent rights will cause harm to Purdue Pharma for which damages are inadequate.

223. Unless Actavis is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '077 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products prior to the expiration of the '077 patent will cause Purdue Pharma irreparable injury for which damages are an inadequate remedy.

TENTH CLAIM FOR RELIEF
Declaratory Judgment of Infringement of the '610 Patent Under 35 U.S.C. § 271(a), (b), and/or (c) Against All Defendants

224. Plaintiffs incorporate by reference and reallege paragraphs 1 through 223 above as though fully restated herein.

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

226. 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.

227. On information and belief, Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, sell, and/or import its ANDA Products into the United States prior to the expiration of the '610 patent.

228. Alvogen's actions prior to the expiration of the '610 patent indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

229. 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 '610 patent under 35 U.S.C. § 271(a), (b), and/or (c).

230. If Alvogen's ANDA Products are approved by the FDA, Alvogen will intentionally encourage acts of direct infringement of the '610 patent by others, with knowledge that their acts are encouraging infringement.

231. 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 '610 patent.

232. Alvogen was aware of the '610 patent prior to the filing date of this Complaint. This is an exceptional case.

233. Alvogen's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '610 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

234. Unless Alvogen is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '610 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Alvogen's ANDA Products prior to the expiration of the '610 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

235. On information and belief, Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer for sale, sell, and/or import its ANDA Products into the United States prior to the expiration of the '610 patent.

236. Actavis's actions prior to the expiration of the '610 patent indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

237. 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 '610 patent under 35 U.S.C. § 271(a), (b), and/or (c).

238. If Actavis's ANDA Products are approved by the FDA, Actavis will intentionally encourage acts of direct infringement of the '610 patent by others, with knowledge that their acts are encouraging infringement.

239. 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 '610 patent.

240. Actavis was aware of the '610 patent prior to the filing date of this Complaint. This is an exceptional case.

241. Actavis's commercial manufacture, use, importation, sale, and/or offer for sale of its ANDA Products prior to the expiration of the '610 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

242. Unless Actavis is enjoined from infringing, contributing to the infringement of, and inducing the infringement of one or more claims of the '610 patent, the commercial manufacture, use, importation, sale, and/or offer for sale of Actavis's ANDA Products prior to the expiration of the '610 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging that Defendant Alvogen has infringed one or more claims of each of the '023 patent, '024 patent, '611 patent, '077 patent, and '610 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 '023 patent, '024 patent, '611 patent, '077 patent, and '610 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 ‘023 patent, ‘024 patent, ‘611 patent, ‘077 patent, and ‘610 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 ‘023 patent, ‘024 patent, ‘611 patent, ‘077 patent, and ‘610 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 ‘023 patent, ‘024 patent, ‘611 patent, ‘077 patent, and ‘610 patent, it will constitute an act of infringement of one or more claims of each of the ‘023 patent, ‘024 patent, ‘611 patent, ‘077 patent, and ‘610 patent;

E. Adjudging that Defendant Actavis has infringed one or more claims of each of the ‘023 patent, ‘024 patent, ‘611 patent, ‘077 patent, and ‘610 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 '023 patent, '024 patent, '611 patent, '077 patent, and '610 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 '023 patent, '024 patent, '611 patent, '077 patent, and '610 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 '023 patent, '024 patent, '611 patent, '077 patent, and '610 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 '023 patent, '024 patent, '611 patent, '077 patent, and '610 patent, it will constitute an act of

infringement of one or more claims of each of the '023 patent, '024 patent, '611 patent, '077 patent, and '610 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.

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