

JUDGE BERMAN

10 CV 7310

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BIOVAIL LABORATORIES
INTERNATIONAL SRL,

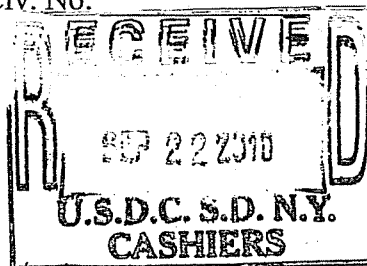
Plaintiff,

vs.

PAR PHARMACEUTICAL COMPANIES,
INC., and PAR PHARMACEUTICAL, INC.

Defendant.

Civ. No.



COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Biovail Laboratories International SRL ("Biovail") for its Complaint against Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, "Par"), to the best of its knowledge, information, and belief, alleges:

PARTIES

1. Plaintiff Biovail is an international society with restricted liability organized and existing under the laws of Barbados having a principal place of business at Welches, Christ Church, Barbados, West Indies.
2. Upon information and belief, Defendant Par Pharmaceutical Companies, Inc. is a Delaware holding company having principal executive offices at 300 Tice Boulevard, Woodcliff Lake, New Jersey, 07677.
3. Upon information and belief, Defendant Par Pharmaceutical, Inc. is a Delaware company having places of business at, *inter alia*, One Ram Ridge Road, Spring Valley, New York 10977, and 30 Dunnigan Drive, Suffern, New York 10901.
4. Upon information and belief, Par Pharmaceutical, Inc. is a wholly-owned operating subsidiary of Par Pharmaceutical Companies, Inc. and is engaged in the business of

developing, licensing, manufacturing and distributing generic and branded drugs in the United States.

JURISDICTION AND VENUE

5. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, and in particular under 35 U.S.C. § 271, and 28 U.S.C. §§ 2201 and 2202.

6. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

7. This Court has personal jurisdiction over Par Pharmaceutical Companies, Inc. by virtue of; *inter alia*, its registration as a business corporation with the New York Department of State, Division of Corporations and its multiple places of business within this District.

8. This Court has personal jurisdiction over Par Pharmaceutical, Inc. by virtue of; *inter alia*, its registration as a business corporation with the New York Department of State, Division of Corporations and its multiple places of business within this District.

9. This Court has personal jurisdiction over Defendants Par Pharmaceutical Companies, and Par Pharmaceutical, Inc. by virtue of the fact that, *inter alia*, they have committed, aided, abetted, contributed to, and/or participated in the commission of the tortuous act of patent infringement, or have actively induced another to do so, leading to foreseeable harm and injury to Biovail.

10. Upon information and belief, Par Pharmaceutical Companies, Inc., through its own actions and the actions of one or more Par subsidiaries, actively engages in a concerted effort to manufacture, market, and sells pharmaceutical products including generic drug products, which are marketed and sold throughout the United States, including to customers in New York.

11. Upon information and belief, Par Pharmaceutical Companies, Inc.'s wholly-owned operating subsidiary Par Pharmaceutical, Inc. is Par Pharmaceutical Companies, Inc.'s "Generic Products Division" as identified in Par Pharmaceutical Companies, Inc.'s 2009 Form

10-K, and maintains a distribution facility in Suffern, New York, and research, manufacturing, and quality and administrative facilities in Spring Valley, New York.

12. This Court has personal jurisdiction over Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. because they, either directly or through an agent, including each other, regularly do or solicit business in New York, engage in other persistent courses of conduct in New York, and/or derive substantial revenue from services or things used or consumed in New York. These activities demonstrate that Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. have continuous and systematic contacts with New York.

13. Venue is proper in this Judicial District under 28 U.S.C. § 1391 and § 1400(b).

14. An actual, substantial, and justiciable controversy exists between Biovail and Par as to the infringement and validity of United States Patent Numbers 7,569,610, 7,572,935, 7,649,019, 7,553,992, 7,671,094, 7,241,805, 7,645,802, 7,662,407, and 7,645,901.

PATENTS IN SUIT

15. Biovail is the lawful owner by assignment of exclusive rights to United States Patent Numbers 7,569,610, 7,572,935, 7,649,019, 7,553,992, 7,671,094, 7,241,805, 7,645,802, 7,662,407, and 7,645,901, including all right to sue and recover for infringement.

16. United States Patent No. 7,569,610 (“’610 patent”), entitled “Modified Release Formulations of a Bupropion Salt,” duly and legally issued August 4, 2009, naming Werner Oberegger, Paul Maes, and Mohammad Ashty Saleh as inventors. The ’610 patent is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the ’610 patent is attached as Exhibit A.

17. United States Patent No. 7,572,935 (“’935 patent”), entitled “Modified Release Formulations of a Bupropion Salt,” duly and legally issued August 11, 2009, naming Werner Oberegger, Paul Maes, Stefano Turchetta, Pietro Massardo, and Mohammad Ashty Saleh as inventors. The ’935 patent is a continuation of Application No. 11/751,768, filed on May 22, 2007, which is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United

States Patent No. 7,241,805, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the '935 patent is attached as Exhibit B.

18. United States Patent No. 7,649,019 ("019 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued January 19, 2010, naming Werner Oberegger, Fang Zhou, Paul Maes, Graham Jackson, and Mohammad Ashty Saleh as inventors. The '019 patent is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the '019 patent is attached as Exhibit C.

19. United States Patent No. 7,553,992 ("992 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued June 30, 2009, naming Werner Oberegger, Paul Maes, Stefano Turchetta, Pietro Massardo, and Mohammad Ashty Saleh as inventors. The '992 patent is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the '992 patent is attached as Exhibit D.

20. United States Patent No. 7,671,094 ("094 patent"), entitled "Bupropion Hydrobromide and Therapeutic Applications," duly and legally issued March 2, 2010, naming Robert Perry Williams and Peter Harris Silverstone as inventors. The '094 patent is a continuation-in-part of Application No. 11/751,768, filed May 22, 2007, now United States Patent No. 7,569,610; and a continuation-in-part of Application No. 11/755,946 filed on May 31, 2007, now United States Patent No. 7,553,992, both of which are continuations of Application No. 11/475,252, filed Jun. 27, 2006, now United States Patent No. 7,241,805, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the '094 patent is attached as Exhibit E.

21. United States Patent No. 7,241,805 ("805 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued July 10, 2007, naming Werner Oberegger, Fang Zhou, Paul Maes, Stefano Turchetta, Graham Jackson, Pietro Massardo, and

Mohammad Ashty Saleh as inventors, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the '805 patent is attached as Exhibit F.

22. United States Patent No. 7,645,802 ("802 patent"), entitled "Bupropion Hydrobromide and Therapeutic Applications," duly and legally issued January 12, 2010, naming Werner Oberegger, Paul Maes, Mohammad Ashty Saleh, and Graham Jackson as inventors. The '802 patent is a continuation-in-part of Application No. 11/755,946, filed on May 31, 2007, now United States Patent No. 7,553,992, which is a continuation of Application No. 11/475,252, filed on June 27, 2006, now United States Patent No. 7,241,805, said Application No. 11/930,644 is a continuation-in-part of Application No. 11/751,768, filed on May 22, 2007, now United States Patent No. 7,569,610, which is a continuation of Application No. 11/475,252, filed on June 27, 2006, now United States Patent No. 7,241,805, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the '802 patent is attached as Exhibit G.

23. United States Patent No. 7,662,407 ("407 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued February 16, 2010, naming Werner Oberegger, Paul Maes, Graham Jackson, and Mohammad Ashty Saleh as inventors. The '407 patent is a continuation of Application No. 11/751,768 filed on May 22, 2007, now United States Patent No. 7,569,610, which a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the '407 patent is attached as Exhibit H.

24. United States Patent No. 7,645,901 ("901 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued January 12, 2010, naming Werner Oberegger, Paul Maes, Stefano Turchetta, Pietro Massardo, and Mohammad Ashty Saleh as inventors. The '901 patent is a continuation of Application No. 11/751,768, filed on May 22, 2007, not United States Patent No. 7,569,610, which is a continuation of Application No. 11/475,252, filed on June 27, 2006, now United States Patent No. 7,241,805, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the '901 patent is attached at Exhibit I.

APLENZIN™ ER

25. Biovail is the holder of New Drug Application (“NDA”) No. 22-108 for Aplenzin™ (bupropion hydrobromide) ER Tablets, 174 mg, 348 mg, and 522 mg.

26. On April 23, 2008, the U.S. Food and Drug Administration (“FDA”) approved NDA No. 22-108 for the manufacture, marketing, and sale of a product containing the drug bupropion hydrobromide for treatment of depression. The drug bupropion hydrobromide with the trademark Aplenzin™ ER has been sold under NDA 22-108 since approval.

27. In compliance with 21 U.S.C. § 355(b)(1), Biovail certified to the FDA that the ’935, ’019, ’094, ’805, ’802 and ’407 patent claims cover Aplenzin™ ER. The ’935, ’019, ’094, ’805, ’802 and ’407 patents are accordingly listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”). The ’610 patent is also listed in the Orange Book covering methods of using Aplenzin™ ER.

PAR’S ANDA

28. Upon information and belief, Par submitted an Abbreviated New Drug Application No. 20-2216 (“ANDA”) to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in commercial manufacture, use, and/or sale of bupropion hydrobromide extended-release tablets (“Par’s Generic Product”), a generic version of Aplenzin™ ER, before expiration of the ’610, ’935, ’019, ’992, ’094, ’805, ’802, ’407, and ’901 patents. Par’s ANDA currently includes two dosage forms of Par’s Generic Product, 174 mg and 348 mg.

29. Upon information and belief, Par’s ANDA contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging at least the ’610, ’935, ’019, ’094, ’805, ’802, and ’407 patents listed in the FDA’s Orange Book as covering Aplenzin™ ER and its use are invalid and/or will not be infringed by commercial manufacture, use, or sale of Par’s Generic Product.

30. On August 20, 2010, Biovail received written notification of Par’s ANDA under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. 314.95 (“Paragraph IV letter”). The stated purpose of

the letter was to notify Biovail that Par filed a certification with the FDA under 21 C.F.R. § 314.95 in conjunction with its ANDA for approval to commercially manufacture and sell generic bupropion hydrobromide extended release tablets. The Paragraph IV letter alleges Biovail's patents listed in the Orange Book covering Aplenzin™ ER and its use are invalid, unenforceable, and/or will not be infringed by commercial manufacture, use, or sale of Par's Generic Product.

31. Biovail commenced this action within 45 days of receiving Par's Paragraph IV letter.

COUNT I
(Infringement of the '610 Patent Under 35 U.S.C. § 271(e)(2))

32. Biovail incorporates paragraphs 1-31.

33. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '610 patent before its expiration, Par has infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT II
(Declaratory Judgment of Infringement of the '610 Patent
Under 35 U.S.C. § 271(a)-(c))

34. Biovail incorporates paragraphs 1-33.

35. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

36. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

37. Upon information and belief, Par intends, soon after the FDA has approved its ANDA, to begin manufacturing, marketing, offering to sell, or selling within the United States Par's Generic Product with a product insert directing physicians and patients in the use of Par's Generic Product.

38. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or selling within the United States, and/or import into the United States Par's Generic Product before expiration of the '610 patent.

39. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '610 patent.

40. Par's actions, including without limitation the filing of its ANDA, exhibit a refusal to change the course of its action despite Biovail's patent rights.

41. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '610 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '610 patent.

42. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '610 patent by Par or its agents, will infringe the '610 patent.

COUNT III
(Infringement of the '935 Patent Under 35 U.S.C. § 271(e)(2))

43. Biovail incorporates paragraphs 1-42.

44. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '935 patent before its expiration, Par has infringed the '935 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT IV
(Declaratory Judgment of Infringement of the '935 Patent
Under 35 U.S.C. § 271(a)-(c))

45. Biovail incorporates paragraphs 1-44.

46. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

47. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

48. Upon information and belief, Par intends, soon after the FDA has approved its ANDA, to begin manufacturing, marketing, offering to sell, or selling within the United States Par's Generic Product with a product insert directing physicians and patients in the use of Par's Generic Product.

49. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Par's Generic Product before expiration of the '935 patent.

50. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '935 patent.

51. Par's actions, including without limitation the filing of its ANDA, exhibit a refusal to change the course of its action despite Biovail's patent rights.

52. Upon information and belief, commercial manufacture; use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '935 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '935 patent.

53. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of

Par's Generic Product before expiration of the '935 patent by Par or its agents, will infringe the '935 patent.

COUNT V
(Infringement of the '019 Patent Under 35 U.S.C. § 271(e)(2))

54. Biovail incorporates paragraphs 1-53.

55. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '019 patent before its expiration, Par has infringed the '019 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT VI
(Declaratory Judgment of Infringement of the '019 Patent
Under 35 U.S.C. § 271(a)-(c))

56. Biovail incorporates paragraphs 1-55.

57. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

58. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

59. Upon information and belief, Par intends, soon after the FDA has approved its ANDA, to begin manufacturing, marketing, offering to sell, or selling within the United States Par's Generic Product with a product insert directing physicians and patients in the use of Par's Generic Product.

60. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Par's Generic Product before expiration of the '019 patent.

61. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '019 patent.

62. Par's actions, including without limitation the filing of its ANDA, exhibit a refusal to change the course of its action despite Biovail's patent rights.

63. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '019 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '019 patent.

64. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '019 patent by Par or its agents, will infringe the '019 patent.

COUNT VII
(Infringement of the '992 Patent Under 35 U.S.C. § 271(e)(2))

65. Biovail incorporates paragraphs 1-64.

66. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '992 patent before its expiration, Par has infringed the '992 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT VIII
(Declaratory Judgment of Infringement of the '992 Patent
Under 35 U.S.C. § 271(a)-(c))

67. Biovail incorporates paragraphs 1-66.

68. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

69. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

70. Upon information and belief, Par intends, soon after the FDA has approved its ANDA, to begin manufacturing, marketing, offering to sell, or selling within the United States Par's Generic Product with a product insert directing physicians and patients in the use of Par's Generic Product.

71. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Par's Generic Product before expiration of the '992 patent.

72. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '992 patent.

73. Par's actions, including without limitation the filing of its ANDA, exhibit a refusal to change the course of its action despite Biovail's patent rights.

74. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '992 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '992 patent.

75. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '992 patent by Par or its agents, will infringe the '992 patent.

COUNT IX
(Infringement of the '094 Patents Under 35 U.S.C. § 271(e)(2))

76. Biovail incorporates paragraphs 1-75.

77. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '094 patent before its expiration, Par has infringed the '094 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT X
(Declaratory Judgment of Infringement of the '094 Patent
Under 35 U.S.C. § 271(a)-(c))

78. Biovail incorporates paragraphs 1-77.

79. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

80. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

81. Upon information and belief, Par intends, soon after the FDA has approved its ANDA, to begin manufacturing, marketing, offering to sell, or selling within the United States Par's Generic Product with a product insert directing physicians and patients in the use of Par's Generic Product.

82. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Par's Generic Product before expiration of the '094 patent.

83. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '094 patent.

84. Par's actions, including without limitation the filing of its ANDA, exhibit a refusal to change the course of its action despite Biovail's patent rights.

85. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product

before expiration of the '094 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '094 patent.

86. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '094 patent by Par or its agents, will infringe the '094 patent.

COUNT XI
(Infringement of the '805 Patent Under 35 U.S.C. § 271(e)(2))

87. Biovail incorporates paragraphs 1-86.

88. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '805 patent before its expiration, Par has infringed the '805 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT XII
(Declaratory Judgment of Infringement of the '805 Patent
Under 35 U.S.C. § 271(a)-(c))

89. Biovail incorporates paragraphs 1-88.

90. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

91. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

92. Upon information and belief, Par intends, soon after the FDA has approved its ANDA, to begin manufacturing, marketing, offering to sell, or selling within the United States Par's Generic Product with a product insert directing physicians and patients in the use of Par's Generic Product.

93. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Par's Generic Product before expiration of the '805 patent.

94. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '805 patent.

95. Par's actions, including without limitation the filing of its ANDA, exhibit a refusal to change the course of its action despite Biovail's patent rights.

96. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '805 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '805 patent.

97. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '805 patent by Par or its agents, will infringe the '805 patent.

COUNT XIII
(Infringement of the '802 Patent Under 35 U.S.C. § 271(e)(2))

98. Biovail incorporates paragraphs 1-97.

99. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '802 patent before its expiration, Par has infringed the '802 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT XIV
(Declaratory Judgment of Infringement of the '802 Patent
Under 35 U.S.C. § 271(a)-(c))

100. Biovail incorporates paragraphs 1-99.

101. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

102. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

103. Upon information and belief, Par intends, soon after the FDA has approved its ANDA, to begin manufacturing, marketing, offering to sell, or selling within the United States Par's Generic Product with a product insert directing physicians and patients in the use of Par's Generic Product.

104. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Par's Generic Product before expiration of the '802 patent.

105. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '802 patent.

106. Par's actions, including without limitation the filing of its ANDA, exhibit a refusal to change the course of its action despite Biovail's patent rights.

107. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '802 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '802 patent.

108. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of

Par's Generic Product before expiration of the '802 patent by Par or its agents, will infringe the '802 patent.

**COUNT XV
(Infringement of the '407 Patent Under 35 U.S.C. § 271(e)(2))**

109. Biovail incorporates paragraphs 1-108.

110. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '407 patent before its expiration, Par has infringed the '407 patent under 35 U.S.C. § 271(e)(2)(A).

**COUNT XVI
(Declaratory Judgment of Infringement of the '805 Patent
Under 35 U.S.C. § 271(a)-(c))**

111. Biovail incorporates paragraphs 1-110.

112. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

113. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

114. Upon information and belief, Par intends, soon after the FDA has approved its ANDA, to begin manufacturing, marketing, offering to sell, or selling within the United States Par's Generic Product with a product insert directing physicians and patients in the use of Par's Generic Product.

115. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Par's Generic Product before expiration of the '407 patent.

116. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '407 patent.

117. Par's actions, including without limitation the filing of its ANDA, exhibit a refusal to change the course of its action despite Biovail's patent rights.

118. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '407 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '407 patent.

119. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '407 patent by Par or its agents, will infringe the '407 patent.

COUNT XVII
(Infringement of the '901 Patent Under 35 U.S.C. § 271(e)(2))

120. Biovail incorporates paragraphs 1-119.

121. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '901 patent before its expiration, Par has infringed the '901 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT XVIII
(Declaratory Judgment of Infringement of the '901 Patent
Under 35 U.S.C. § 271(a)-(c))

122. Biovail incorporates paragraphs 1-121.

123. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

124. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Biovail's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

125. Upon information and belief, Par intends, soon after the FDA has approved its ANDA, to begin manufacturing, marketing, offering to sell, or selling within the United States Par's Generic Product with a product insert directing physicians and patients in the use of Par's Generic Product.

126. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Par's Generic Product before expiration of the '901 patent.

127. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '901 patent.

128. Par's actions, including without limitation the filing of its ANDA, exhibit a refusal to change the course of its action despite Biovail's patent rights.

129. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '901 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '901 patent.

130. Biovail is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Par's Generic Product before expiration of the '901 patent by Par or its agents, will infringe the '901 patent.

INJUNCTIVE RELIEF

131. Biovail will be substantially and irreparably damaged and harmed by Par's infringing activities unless those activities are enjoined by this Court. Biovail does not have an adequate remedy at law.

PRAYER FOR RELIEF

Biovail respectfully prays for the following relief:

a. A judgment that Par has infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Par's Generic Product before expiration of the '610 patent.

b. A judgment that Par has infringed the '935 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Par's Generic Product before expiration of the '935 patent.

c. A judgment that Par has infringed the '019 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Par's Generic Product before expiration of the '019 patent.

d. A judgment that Par has infringed the '992 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Par's Generic Product before expiration of the '992 patent.

e. A judgment that Par has infringed the '094 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Par's Generic Product before expiration of the '094 patent.

f. A judgment that Par has infringed the '805 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Par's Generic Product before expiration of the '805 patent.

g. A judgment that Par has infringed the '802 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Par's Generic Product before expiration of the '802 patent.

h. A judgment that Par has infringed the '407 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Par's Generic Product before expiration of the '407 patent.

i. A judgment that Par has infringed the '901 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Par's Generic Product before expiration of the '901 patent.

j. A declaration issued under 28 U.S.C. § 2201 that Par would infringe one or more claims of the '610 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Par's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '610 patent.

k. A declaration issued under 28 U.S.C. § 2201 that Par would infringe one or more claims of the '935 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Par's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '935 patent.

l. A declaration issued under 28 U.S.C. § 2201 that Par would infringe one or more claims of the '019 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Par's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '019 patent.

m. A declaration issued under 28 U.S.C. § 2201 that Par would infringe one or more claims of the '992 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Par's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '992 patent.

n. A declaration issued under 28 U.S.C. § 2201 that Par would infringe one or more claims of the '094 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Par's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '094 patent.

o. A declaration issued under 28 U.S.C. § 2201 that Par would infringe one or more claims of the '805 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Par's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '805 patent.

p. A declaration issued under 28 U.S.C. § 2201 that Par would infringe one or more claims of the '802 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Par's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '802 patent.

q. A declaration issued under 28 U.S.C. § 2201 that Par would infringe one or more claims of the '407 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Par's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '407 patent.

r. A declaration issued under 28 U.S.C. § 2201 that Par would infringe one or more claims of the '901 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use,

offer to sell, sale in, or importation into the United States of Par's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '901 patent.

s. An order issued under 35 U.S.C. § 271(e)(4)(A) that the earliest effective approval date of Par's ANDA, if any, shall be no earlier than the date of expiration of any patent-in-suit Par is found to infringe, including any extensions.

t. An injunction issued under 35 U.S.C. §§ 271(e)(4)(b) and 283 permanently enjoining Par, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with them or on their behalf, from engaging in commercial manufacture, use, offers to sell, or sale within the United States, or importation into the United States, of Par's Generic Product not colorably different from Par's Generic Product before the date of expiration of any patent-in-suit Par is found to infringe, including any extensions.

u. A declaration that Par has no legal or equitable defense to Biovail's allegations of infringement.

v. An award declaring this case exceptional under 35 U.S.C. § 285 and granting Biovail its attorneys' fees.

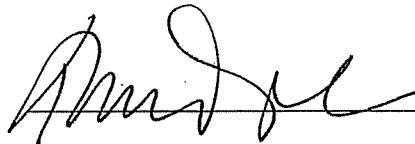
w. An award of Biovail's costs and expenses in this action.

x. An award of damages or other monetary relief to Biovail under 35 U.S.C. § 271(e)(4)(C), including by an accounting, as appropriate.

y. An award of any further and additional relief as this Court may deem just and proper.

New York, New York
Dated: September 22, 2010

Respectfully submitted,



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