

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BIOVAIL LABORATORIES  
INTERNATIONAL SRL,

Plaintiff,

v.

WATSON PHARMACEUTICALS, INC.,  
WATSON LABORATORIES, INC.—  
FLORIDA, and WATSON PHARMA, INC.,

Defendants.

)  
)  
)  
) C.A. No. \_\_\_\_\_  
)  
)  
)  
)  
)  
)

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Biovail Laboratories International SRL (“Biovail”) for its Complaint against Watson Pharmaceuticals, Inc., Watson Laboratories, Inc.—Florida, and Watson Pharma, Inc. (collectively, “Watson”), 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 Watson Pharmaceuticals, Inc. (“Watson Pharmaceuticals”) is a Nevada corporation having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

3. Upon information and belief, Defendant Watson Laboratories, Inc.—Florida (“Watson Laboratories”) is a Florida corporation with a registered mailing address of 311 Bonnie Circle, Corona, California 92880.

4. Upon information and belief, Watson Laboratories formerly did business as Andrx Pharmaceuticals, Inc. Upon information and belief, Watson Laboratories is a wholly-owned subsidiary of Andrx Corporation, a Delaware corporation that is a wholly-owned subsidiary of Defendant Watson Pharmaceuticals.

5. Upon information and belief, Defendant Watson Pharma, Inc. (“Watson Pharma”) is a Delaware corporation having a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07960.

6. Upon information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals.

7. Upon information and belief, Watson Pharmaceuticals sells pharmaceutical products through its wholly-owned subsidiary Watson Pharma. Upon information and belief, Watson Pharma distributes pharmaceutical products throughout the United States including in this judicial district and is the distributor of drugs that Watson Laboratories manufactures or for which Watson Laboratories is the named applicant on approved Abbreviated New Drug Applications.

#### **JURISDICTION AND VENUE**

8. 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.

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

10. This Court has personal jurisdiction over Watson Pharma by virtue of its incorporation in Delaware.

11. This Court has personal jurisdiction over Defendants Watson Pharmaceuticals, Watson Pharma, and Watson Laboratories by virtue of the fact that, *inter alia*, they have committed, aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement, or have actively induced another to do so, leading to foreseeable harm and injury to Biovail.

12. This Court has personal jurisdiction over Defendants Watson Pharmaceuticals, Watson Pharma, and Watson Laboratories because they, either directly or through an agent, including each other, regularly do or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or

consumed in Delaware. These activities demonstrate that Watson Pharmaceuticals, Watson Pharma, and Watson Laboratories have continuous and systematic contacts with Delaware. 10 Del. C. § 3104(c)(4).

13. Watson Pharmaceuticals, Watson Pharma, and Watson Laboratories, are agents of each other and/or work in concert with each other and/or other direct and indirect subsidiaries of Watson Pharmaceuticals with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products throughout the United States, including in this district.

14. Watson Pharmaceuticals, through its own actions and the actions of one or more Watson subsidiaries, actively engages in a concerted effort to sell generic products throughout the United States, including Delaware. Upon information and belief, Watson Pharmaceuticals organizes its operation by division—Generic, Brand, and Distribution—and reports its financial results to investors by reference to the divisions rather than to its subsidiaries. Watson Pharmaceuticals consolidated its financial results in its 2008 Securities and Exchange Commission filing and did not provide separate financial reports for each Watson subsidiary.

15. Upon information and belief, the Generic Division, which is responsible for developing and submitting ANDAs, as well as manufacturing and marketing generic pharmaceuticals, relies on contributions from Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma. Upon information and belief, Watson Laboratories submits ANDAs and manufactures Generic Division products. These and other Generic Division products are marketed and sold by Watson Pharma.

16. Upon information and belief, Watson Pharmaceuticals, Watson Pharma, and Watson Laboratories, share common employees, officers, and directors. Upon information and belief, Watson Pharmaceuticals and Watson Pharma share common employees, officers, and directors. Upon information and belief, Watson Laboratories and Watson Pharma share common employees, officers, and directors.

17. Further demonstrating the close interconnections between the Watson entities, Watson Laboratories provided Watson Pharmaceuticals' Corona, California address as Watson

Laboratories' registered mailing address in its annual report filed with the Secretary of State in Florida on February 9, 2010.

18. Watson Pharmaceuticals' website states its Generic Division has a portfolio of 150 pharmaceutical products, which includes Watson Laboratories products, and that the Generic Division filed 13 new ANDAs and launched 11 new products in 2008. Watson generated approximately \$1.5 billion in revenue from sales of generic drugs in 2008, accounting for approximately 60% of Watson's total revenue. Watson Pharmaceuticals' 2008 Annual Report explains that "We sell our generic products primarily under the 'Watson Laboratories' and 'Watson Pharma' labels." The ANDAs for the majority of these products in Watson Pharmaceuticals' portfolio are nominally in the name of Watson Laboratories and another subsidiary, Watson Laboratories, Inc.—Nevada.

19. Upon information and belief, Watson Laboratories is the named applicant in ANDAs for numerous generic drugs, including many that are actively being manufactured, sold and used in the United States. Drugs manufactured under these ANDAs are sold and used in Delaware and elsewhere.

20. Upon information and belief, Watson Laboratories also manufactures at least some of the drugs for which it is the nominal ANDA applicant.

21. Upon information and belief, Watson Pharma, a Delaware entity, is the distributor of drugs for which Watson Laboratories is the named applicant in the FDA's Approved Drug Product List. Upon information and belief, Watson Pharma, acting as the agent of Watson Laboratories and Watson Pharmaceuticals, markets and sells Watson's drug products in Delaware and elsewhere in the United States. Watson's 2008 Corporate Overview describes its distribution arm as "boasting penetration into 75 percent of all retail pharmacies, independents, and national/retail chains." Upon information and belief, Watson Laboratories and Watson Pharma are parties to one or more contractual agreements for distributing drugs made under Watson Laboratories' ANDAs. Upon information and belief, these agreements are less than arms-length.

22. Watson Pharma is licensed to do business in Delaware. For example, Watson Pharma, with a mailing address in Corona, California, maintains active “Pharmacy-Wholesale” and “Distributor/Manufacturer CSR” licenses in Delaware. Other Watson Pharma entities with various mailing addresses maintain at least five other pharmacy-related licenses in Delaware. A Watson entity with a mailing address in Florida maintained a pharmacy-related license in Delaware until 2004.

23. Upon information and belief, Watson has sales personnel assigned to cover Delaware for marketing and selling Generic Division Products, including Watson Laboratories’ products. Upon information and belief, various drugs for which Watson Laboratories is the named ANDA applicant are distributed by Watson Pharma and are available at retail pharmacies in Delaware including Walgreens/Happy Harry's and Rite Aid. Upon information and belief, Watson Pharmaceuticals and/or Watson Laboratories realize revenue from the distribution of Watson Laboratories’ drugs by Watson Pharma through sales of drugs in Delaware or to persons in Delaware.

24. Besides using Watson Pharma’s channels to distribute drugs in Delaware and elsewhere, Watson Laboratories has other contacts with Delaware. In particular, Watson Laboratories purposefully availed itself of Delaware courts by joining as a plaintiff with other parties filing a complaint for patent infringement in the District of Delaware on January 15, 2009 against Lupin, another generic manufacturer. *Sciele Pharma, Inc., et al. v. Lupin Ltd.*, Case No. 1:09-cv-00037-JJF, Complaint (Jan. 15, 2009). Watson Laboratories has also purposefully availed itself of Delaware courts by filing counterclaims in the District of Delaware in at least *Allergan, Inc. v. Watson Pharmaceuticals, Inc.*, C.A. No. 09-511-GMS, Answer and Counterclaims (Dkt. No. 13) (D. Del. Aug. 24, 2009) and *Takeda Pharmaceutical Co. v. Watson Laboratories, Inc.*, C.A. No. 09-917-SLR, Answer and Counterclaims (Dkt. No. 8) (D. Del. Dec. 23, 2009).

25. In addition, upon information and belief, Watson Laboratories is a wholly-owned subsidiary of Andrx Corporation, a Delaware corporation, and several of Watson Laboratories’ drugs are still manufactured and sold under the Andrx trademark.

26. Watson Pharmaceuticals' website also contains links to its distribution network where consumers in Delaware and elsewhere are able to directly order Watson's products via the internet. For example, Watson Pharmaceuticals' website provides links to Watson's AndaNet®, AndaMeds™, AndaCSOS™, and AndaConnect™ product-ordering systems. The Anda-related ordering websites are registered to Andrx Corporation, a Watson subsidiary incorporated in Delaware and of which Watson Laboratories is a subsidiary. Upon information and belief, physicians and pharmacies located in Delaware directly order Watson's products, including Watson Laboratories' products, through Watson's Anda product-ordering systems accessible via Watson Pharmaceuticals' website.

27. Watson Pharmaceuticals' website also provides links to Watson's VIPConnect™, VIPpharm™, and VIPCSOS.com™ product-ordering systems. VIP describes itself as "A Generic Distributor You Can Believe In." The VIP-related websites, accessible through Watson's website, are also registered to Andrx Corporation incorporated in Delaware. Watson Pharmaceuticals' Corona, California address is the registered contact address for the VIP websites. Upon information and belief, physicians and pharmacies located in Delaware directly order Watson's products, including Watson Laboratories' products, through the VIP ordering systems accessible via Watson Pharmaceuticals' website.

28. Upon information and belief, each of Watson Pharmaceuticals, Watson Pharma, and Watson Laboratories, as part of Watson Pharmaceuticals' Generic Division, will manufacture, market, and/or sell within the United States the generic bupropion hydrobromide extended release tablets described in Watson's ANDA No. 91-500 if FDA approval is granted. If ANDA No. 91-500 is approved, the generic bupropion hydrobromide extended release tablets charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

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

30. An actual, substantial, and justiciable controversy exists between Biovail and Watson as to the infringement and validity of United States Patent Numbers 7,569,610, 7,572,935, 7,649,019, 7,563,823, and 7,553,992.

#### **PATENTS IN SUIT**

31. Biovail is the lawful owner by assignment of exclusive rights to United States Patent Numbers 7,569,610, 7,572,935, 7,649,019, 7,563,823, and 7,553,992, including all right to sue and recover for infringement.

32. 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. A copy of the ’610 patent is attached as Exhibit A.

33. 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. A copy of the ’935 patent is attached as Exhibit B.

34. 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. A copy of the ’019 patent is attached as Exhibit C.

35. United States Patent No. 7,563,823 (“’823 patent”), entitled “Modified Release Formulations of a Bupropion Salt,” duly and legally issued June 21, 2009, naming Werner Oberegger, Paul Maes, Graham Jackson, and Mohammad Ashty Saleh as inventors. The ’823 patent is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805. A copy of the ’823 patent is attached as Exhibit D.

36. 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. A copy of the ’992 patent is attached as Exhibit E.

#### **APLENZIN™ ER**

37. 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.

38. 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.

39. In compliance with 21 U.S.C. § 355(b)(1), Biovail certified to the FDA that the ’935 and ’019 patent claims cover Aplenzin™ ER. The ’935 and ’019 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.

#### **WATSON’S ANDA**

40. Upon information and belief, Watson submitted Abbreviated New Drug Application No. 91-500 (“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, 174 mg and 348 mg (“Watson’s Generic Product”), a generic version of Aplenzin™ ER, before expiration of the ’610, ’935, ’019, ’823, and ’992 patents.

41. Upon information and belief, Watson’s ANDA contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging at least the ’610, ’935, and ’019 patents, listed in the FDA’s Orange Book as covering Aplenzin™ ER and its use, are invalid

and/or will not be infringed by the commercial manufacture, use, or sale of Watson's Generic Product.

42. On January 5, 2010, Biovail received written notification of ANDA No. 91-500 and Watson's allegations under 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. 314.95(c)(6) ("Paragraph IV letter"). A month later, Biovail received Watson's second Paragraph IV letter. The stated purpose of the Paragraph IV letters was to notify Biovail that Watson filed a certification with the FDA under 21 C.F.R. § 314.95 in conjunction with ANDA No. 91-500 for approval to commercially manufacture and sell a generic version of Aplenzin™ ER. The Paragraph IV letters allege Biovail's patents listed in the Orange Book covering Aplenzin™ ER and its use are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Watson's Generic Product.

43. Biovail commenced this action within 45 days of receiving Watson's first Paragraph IV letter.

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

44. Biovail incorporates paragraphs 1-43.

45. Defendants, acting jointly, submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By submitting the application before expiration of the '610 patent, Defendants, individually and collectively, committed an act of infringement with respect to the '610 patent under 35 U.S.C. § 271(e)(2)(A).

46. Watson Laboratories, acting jointly with Watson Pharmaceuticals and/or Watson Pharma and/or acting as an agent of Watson Pharmaceuticals and/or Watson Pharma, submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By submitting the application before expiration of the '610 patent, Watson Laboratories committed an act of infringement with respect to the '610 patent under 35 U.S.C. § 271(e)(2)(A).

47. When Watson Laboratories submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product, it was acting jointly with Watson Pharmaceuticals and/or acting as an agent of Watson Pharmaceuticals. By acting jointly with Watson Laboratories to submit the application and/or causing its agent to submit the application, Watson Pharmaceuticals committed an act of infringement with respect to the '610 patent under 35 U.S.C. § 271(e)(2)(A).

48. When Watson Laboratories submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product, it was acting jointly with Watson Pharma and/or acting as an agent of Watson Pharma. By acting jointly with Watson Laboratories to submit the application and/or causing its agent to submit the application, Watson Pharma committed an act of infringement with respect to the '610 patent under 35 U.S.C. § 271(e)(2)(A).

49. Any commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson's Generic Product prior to expiration of the '610 patent will infringe the '610 patent.

**COUNT II**  
**(Infringement of the '610 Patent Under 35 U.S.C. § 271(b))**

50. Biovail incorporates paragraphs 1-49.

51. Watson Pharmaceuticals and/or Watson Pharma actively induced Watson Laboratories to submit ANDA No. 91-500 to the FDA to obtain approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By actively inducing submission of the ANDA, Watson Pharmaceuticals and/or Watson Pharma committed an act of indirect infringement with respect to the '610 patent under 35 U.S.C. § 271(b).

52. Any commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson's Generic Product prior to expiration of the '610 patent will infringe the '610 patent.

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

53. Biovail incorporates paragraphs 1-52.

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

55. 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.

56. Upon information and belief, Watson intends, soon after the FDA has approved its ANDA 91-500, to begin manufacturing, marketing, offering to sell, and selling Watson's Generic Product with a product insert directing physicians and patients in the use of Watson's Generic Product.

57. Upon information and belief, Watson 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 Watson's Generic Product before expiration of the '610 patent.

58. Upon information and belief, Watson 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 Watson's Generic Product before expiration of the '610 patent.

59. Watson's actions, including without limitation the filing of ANDA No. 91-500, exhibit a refusal to change the course of its action despite Biovail's patent rights.

60. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson'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.

61. 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 Watson'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 Watson's Generic Products before expiration of the '610 patent by Watson, will infringe the '610 patent.

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

62. Biovail incorporates paragraphs 1-61.

63. Defendants, acting jointly, submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By submitting the application before expiration of the '935 patent, Defendants, individually and collectively, committed an act of infringement with respect to the '935 patent under 35 U.S.C. § 271(e)(2)(A).

64. Watson Laboratories, acting jointly with Watson Pharmaceuticals and/or Watson Pharma and/or acting as an agent of Watson Pharmaceuticals and/or Watson Pharma, submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By submitting the application before expiration of the '935 patent, Watson Laboratories committed an act of infringement with respect to the '935 patent under 35 U.S.C. § 271(e)(2)(A).

65. When Watson Laboratories submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product, it was acting jointly with Watson Pharmaceuticals and/or acting as an agent of Watson Pharmaceuticals. By acting jointly with Watson Laboratories to submit the application and/or causing its agent to submit the application, Watson Pharmaceuticals committed an act of infringement with respect to the '935 patent under 35 U.S.C. § 271(e)(2)(A).

66. When Watson Laboratories submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product, it was acting jointly with Watson Pharma and/or acting as an agent of Watson Pharma. By acting jointly with Watson Laboratories to submit the application and/or causing its agent to submit the application, Watson Pharma committed an act of infringement with respect to the '935 patent under 35 U.S.C. § 271(e)(2)(A).

67. Any commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson's Generic Product prior to expiration of the '935 patent will infringe the '935 patent.

**COUNT V**  
**(Infringement of the '935 Patent Under 35 U.S.C. § 271(b))**

68. Biovail incorporates paragraphs 1-67.

69. Watson Pharmaceuticals and/or Watson Pharma actively induced Watson Laboratories to submit ANDA No. 91-500 to the FDA to obtain approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By actively inducing submission of the ANDA, Watson Pharmaceuticals and/or Watson Pharma committed an act of indirect infringement with respect to the '935 patent under 35 U.S.C. § 271(b).

70. Any commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson's Generic Product prior to expiration of the '935 patent will infringe the '935 patent.

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

71. Biovail incorporates paragraphs 1-70.

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

73. 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.

74. Upon information and belief, Watson intends, soon after the FDA has approved its ANDA 91-500, to begin manufacturing, marketing, offering to sell, and selling Watson's Generic Product with a product insert directing physicians and patients in the use of Watson's Generic Product.

75. Upon information and belief, Watson 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 Watson's Generic Product before expiration of the '935 patent.

76. Upon information and belief, Watson 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 Watson's Generic Product before expiration of the '935 patent.

77. Watson's actions, including without limitation the filing of ANDA No. 91-500, exhibit a refusal to change the course of its action despite Biovail's patent rights.

78. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson'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.

79. 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 Watson'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 Watson's Generic Products before expiration of the '935 patent by Watson, will infringe the '935 patent.

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

80. Biovail incorporates paragraphs 1-79.

81. Defendants, acting jointly, submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By submitting the application before expiration of the '019 patent, Defendants, individually and collectively, committed an act of infringement with respect to the '019 patent under 35 U.S.C. § 271(e)(2)(A).

82. Watson Laboratories, acting jointly with Watson Pharmaceuticals and/or Watson Pharma and/or acting as an agent of Watson Pharmaceuticals and/or Watson Pharma, submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By submitting the application before expiration of the '019 patent, Watson Laboratories committed an act of infringement with respect to the '019 patent under 35 U.S.C. § 271(e)(2)(A).

83. When Watson Laboratories submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product, it was acting jointly with Watson Pharmaceuticals and/or acting as an agent of Watson Pharmaceuticals. By acting jointly with Watson Laboratories to submit the application and/or causing its agent to submit the application, Watson Pharmaceuticals committed an act of infringement with respect to the '019 patent under 35 U.S.C. § 271(e)(2)(A).

84. When Watson Laboratories submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product, it was acting jointly with Watson Pharma and/or acting as an agent of Watson Pharma. By acting jointly with Watson Laboratories to submit the application and/or causing its agent to submit the application, Watson Pharma committed an act of infringement with respect to the '019 patent under 35 U.S.C. § 271(e)(2)(A).

85. Any commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson's Generic Product prior to expiration of the '019 patent will infringe the '019 patent.

**COUNT VIII**  
**(Infringement of the '019 Patent Under 35 U.S.C. § 271(b))**

86. Biovail incorporates paragraphs 1-85.

87. Watson Pharmaceuticals and/or Watson Pharma actively induced Watson Laboratories to submit ANDA No. 91-500 to the FDA to obtain approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By actively inducing submission of the ANDA, Watson Pharmaceuticals and/or Watson Pharma committed an act of indirect infringement with respect to the '019 patent under 35 U.S.C. § 271(b).

88. Any commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson's Generic Product prior to expiration of the '019 patent will infringe the '019 patent.

**COUNT IX**  
**(Declaratory Judgment of Patent Infringement of the '019 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, Watson intends, soon after the FDA has approved its ANDA 91-500, to begin manufacturing, marketing, offering to sell, or selling Watson's Generic Product with a product insert directing physicians and patients in the use of Watson's Generic Product.

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

94. Upon information and belief, Watson 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 Watson's Generic Product before expiration of the '019 patent.

95. Watson's actions, including without limitation the filing of ANDA No. 91-500, 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 Watson'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.

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 Watson'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 Watson's Generic Products before expiration of the '019 patent by Watson, will infringe the '019 patent.

**COUNT X**  
**(Infringement of the '823 Patent Under 35 U.S.C. § 271(e)(2))**

98. Biovail incorporates paragraphs 1-97.

99. Defendants, acting jointly, submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By submitting the application before expiration of the '823 patent, Defendants, individually and collectively, committed an act of infringement with respect to the '823 patent under 35 U.S.C. § 271(e)(2)(A).

100. Watson Laboratories, acting jointly with Watson Pharmaceuticals and/or Watson Pharma and/or acting as an agent of Watson Pharmaceuticals and/or Watson Pharma, submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By submitting the application before expiration of the '823 patent, Watson Laboratories committed an act of infringement with respect to the '823 patent under 35 U.S.C. § 271(e)(2)(A).

101. When Watson Laboratories submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product, it was acting jointly with Watson Pharmaceuticals and/or acting as an agent of Watson Pharmaceuticals. By acting jointly with Watson Laboratories to submit the application and/or causing its agent to submit the application, Watson Pharmaceuticals committed an act of infringement with respect to the '823 patent under 35 U.S.C. § 271(e)(2)(A).

102. When Watson Laboratories submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product, it was acting jointly with Watson Pharma and/or acting as an agent of Watson Pharma. By acting jointly with Watson Laboratories to submit the application and/or causing its agent to submit the application, Watson Pharma committed an act of infringement with respect to the '823 patent under 35 U.S.C. § 271(e)(2)(A).

103. Any commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson's Generic Product prior to expiration of the '823 patent will infringe the '823 patent.

**COUNT XI**  
**(Infringement of the '823 Patent Under 35 U.S.C. § 271(b))**

104. Biovail incorporates paragraphs 1-103.

105. Watson Pharmaceuticals and/or Watson Pharma actively induced Watson Laboratories to submit ANDA No. 91-500 to the FDA to obtain approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of

Watson's Generic Product. By actively inducing submission of the ANDA, Watson Pharmaceuticals and/or Watson Pharma committed an act of indirect infringement with respect to the '823 patent under 35 U.S.C. § 271(b).

106. Any commercial manufacture, use, offer for sale, sale within the United States, and/or importation into the United States of Watson's Generic Product prior to expiration of the '823 patent will infringe the '823 patent.

**COUNT XII**  
**(Declaratory Judgment of Patent Infringement of the '823 Patent**  
**Under 35 U.S.C. § 271(a)-(c))**

107. Biovail incorporates paragraphs 1-106.

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

109. 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.

110. Upon information and belief, Watson intends, soon after the FDA has approved its ANDA 91-500, to begin manufacturing, marketing, offering to sell, or selling Watson's Generic Product with a product insert directing physicians and patients in the use of Watson's Generic Product.

111. Upon information and belief, Watson 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 Watson's Generic Product before expiration of the '823 patent.

112. Upon information and belief, Watson 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 Watson's Generic Product before expiration of the '823 patent.

113. Watson's actions, including without limitation the filing of ANDA No. 91-500, exhibit a refusal to change the course of its action despite Biovail's patent rights.

114. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States and/or importation into the United States of Watson's Generic Product before expiration of the '823 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '823 patent.

115. 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 Watson'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 Watson's Generic Products, before expiration of the '823 patent by Watson, will infringe the '823 patent.

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

116. Biovail incorporates paragraphs 1-115.

117. Defendants, acting jointly, submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By submitting the application before expiration of the '992 patent, Defendants, individually and collectively, committed an act of infringement with respect to the '992 patent under 35 U.S.C. § 271(e)(2)(A).

118. Watson Laboratories, acting jointly with Watson Pharmaceuticals and/or Watson Pharma and/or acting as an agent of Watson Pharmaceuticals and/or Watson Pharma, submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By submitting the application before expiration of the '992 patent, Watson Laboratories committed an act of infringement with respect to the '992 patent under 35 U.S.C. § 271(e)(2)(A).

119. When Watson Laboratories submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States

including Delaware of Watson's Generic Product, it was acting jointly with Watson Pharmaceuticals and/or acting as an agent of Watson Pharmaceuticals. By acting jointly with Watson Laboratories to submit the application and/or causing its agent to submit the application, Watson Pharmaceuticals committed an act of infringement with respect to the '992 patent under 35 U.S.C. § 271(e)(2)(A).

120. When Watson Laboratories submitted ANDA No. 91-500 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product, it was acting jointly with Watson Pharma and/or acting as an agent of Watson Pharma. By acting jointly with Watson Laboratories to submit the application and/or causing its agent to submit the application, Watson Pharma committed an act of infringement with respect to the '992 patent under 35 U.S.C. § 271(e)(2)(A).

121. Any commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson's Generic Product prior to expiration of the '992 patent will infringe the '992 patent.

**COUNT XIV**  
**(Infringement of the '992 Patent Under 35 U.S.C. § 271(b))**

122. Biovail incorporates paragraphs 1-121.

123. Watson Pharmaceuticals and/or Watson Pharma actively induced Watson Laboratories to submit ANDA No. 91-500 to the FDA to obtain approval to engage in commercial manufacture, use, or sale throughout the United States including Delaware of Watson's Generic Product. By actively inducing submission of the ANDA, Watson Pharmaceuticals and/or Watson Pharma committed an act of indirect infringement with respect to the '992 patent under 35 U.S.C. § 271(b).

124. Any commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson's Generic Product prior to expiration of the '992 patent will infringe the '992 patent.

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

125. Biovail incorporates paragraphs 1-124.

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

127. 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.

128. Upon information and belief, Watson intends, soon after the FDA has approved its ANDA 91-500, to begin manufacturing, marketing, offering to sell, or selling Watson's Generic Product with a product insert directing physicians and patients in the use of Watson's Generic Product.

129. Upon information and belief, Watson 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 Watson's Generic Product before expiration of the '992 patent.

130. Upon information and belief, Watson 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 Watson's Generic Product before expiration of the '992 patent.

131. Watson's actions, including without limitation the filing of ANDA No. 91-500, exhibit a refusal to change the course of its action despite Biovail's patent rights.

132. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Watson'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.

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 Watson'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 Watson's Generic Products before expiration of the '992 patent by Watson, will infringe the '992 patent.

### **INJUNCTIVE RELIEF**

133. Biovail will be substantially and irreparably damaged and harmed by Watson'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 Watson has infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 91-500 to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Watson's Generic Product before expiration of the '610 patent.

b. A judgment that Watson has infringed the '935 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 91-500 to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Watson's Generic Product before expiration of the '935 patent.

c. A judgment that Watson has infringed the '019 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 91-500 to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Watson's Generic Product before expiration of the '019 patent.

d. A judgment that Watson has infringed the '823 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 91-500 to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Watson's Generic Product before expiration of the '823 patent.

e. A judgment that Watson has infringed the '992 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 91-500 to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Watson's Generic Product before expiration of the '992 patent.

f. A declaration issued under 28 U.S.C. § 2201 that Watson 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 Watson's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '610 patent.

g. A declaration issued under 28 U.S.C. § 2201 that Watson 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 Watson's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '935 patent.

h. A declaration issued under 28 U.S.C. § 2201 that Watson 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 Watson's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '019 patent.

i. A declaration issued under 28 U.S.C. § 2201 that Watson would infringe one or more claims of the '823 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 Watson's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '823 patent.

j. A declaration issued under 28 U.S.C. § 2201 that Watson 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 Watson's Generic Product, or

inducement of or contribution to any of the above-listed activities, before expiration of the '992 patent.

k. An order issued under 35 U.S.C. § 271(e)(4)(A) that the earliest effective approval date of ANDA No. 91-500, if any, shall be no earlier than the date of expiration of any patent-in-suit Watson is found to infringe, including any extensions.

l. An injunction issued under 35 U.S.C. §§ 271(e)(4)(B) and 283 permanently enjoining Watson, 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 for sale, or sale within the United States, or importation into the United States, of Watson's Generic Product, or products not colorably different from Watson's Generic Product, before the date of expiration of any patent-in-suit Watson is found to infringe, including any extensions.

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

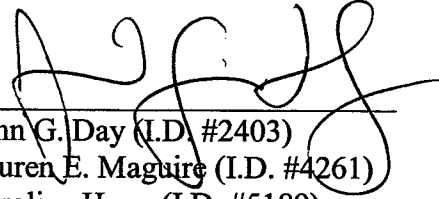
n. An award declaring this case exceptional under 35 U.S.C. § 285 and granting Biovail its attorneys' fees.

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

p. 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.

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

ASHBY & GEDDES



John G. Day (I.D. #2403)  
Lauren E. Maguire (I.D. #4261)  
Caroline Hong (I.D. #5189)  
500 Delaware Avenue, 8<sup>th</sup> Floor  
P.O. Box 1150  
Wilmington, DE 19801  
(302) 6541-1888  
jday@ashby-geddes.com  
lmauire@ashby-geddes.com  
chong@ashby-geddes.com

*Attorneys for Plaintiff*

*Of Counsel:*

Theresa M. Gillis  
HOWREY LLP  
601 Lexington Avenue, Floor 54  
New York, NY 10022-4629  
(212) 896-6500

Thomas W. Jenkins, Jr.  
HOWREY LLP  
321 North Clark Street  
Suite 3400  
Chicago, IL 60654  
(312) 595-1239

Dated: February 18, 2010  
00382166