

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF FLORIDA**

BIOVAIL LABORATORIES  
INTERNATIONAL SRL,

Plaintiff,

vs.

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, 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.

5. Upon information and belief, Defendant Watson Pharma, Inc. is also a registered corporation in Florida having a registered agent of C T Corporation System, 1200 South Pine Island Road, Plantation, Florida 33324.

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

6. 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**

7. 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.

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

9. This Court has personal jurisdiction over Watson Laboratories by virtue of its incorporation in Florida.

10. This Court has personal jurisdiction over Watson Pharma by virtue of its corporate registration in Florida.

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 Florida, engage in other persistent courses of conduct in Florida, and/or derive substantial revenue from services or things used or consumed in Florida. These activities demonstrate that Watson Pharmaceuticals, Watson Pharma, and Watson Laboratories have continuous and systematic contacts with Florida.

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 Florida. 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 Laboratories, and Watson Pharma 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 Florida 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 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 Florida 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 Pharmaceuticals, d/b/a Watson Pharma, is licensed to do business in Florida. For example, Watson Pharma, Inc., providing the address of Watson Pharmaceuticals' headquarters in Corona, California, is licensed as a drug wholesaler in Florida. Watson Pharmaceuticals, d/b/a Watson Pharma, maintains at least six other drug manufacturer, wholesaler, or distributor licenses in Florida.

23. Upon information and belief, Watson Pharma has sales personnel assigned to cover Florida 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 Florida. 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 drug products in Florida or to persons in Florida.

24. Watson Pharmaceuticals' website also contains links to its distribution network where consumers in Florida and elsewhere are able to directly order Watson's products via the internet. For example, Watson Pharmaceuticals' website provides links to Watson's AndaNNet®, AndaMeds™, AndaCSOS™, and AndaConnect™ product-ordering systems. The Anda-related ordering websites are registered to Andrx Corporation, a Watson subsidiary of which Watson Laboratories is a subsidiary. An address for Andrx, Inc. in Florida is the registered contact address for Watson's Anda-related websites. Anda, Inc., a company associated with Watson's Anda-related ordering systems, is a Watson subsidiary incorporated in Florida with a registered mailing address of Watson Pharmaceuticals' headquarters in Corona, California. Upon information and belief, physicians and pharmacies located in Florida directly order Watson's products, including Watson Laboratories' products, through Watson's Anda product-ordering systems accessible via Watson Pharmaceuticals' website.

25. 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 Watson's subsidiary Andrx Corporation. Watson

Pharmaceuticals' Corona, California address is the registered contact address for Watson's VIP product-ordering system websites. Upon information and belief, physicians and pharmacies located in Florida directly order Watson's products, including Watson Laboratories' products, through the VIP product-ordering systems accessible via Watson Pharmaceuticals' website.

26. 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 Nos. 91-500 and 20-0835 if FDA approval is granted. If ANDA No. 91-500 or 20-0835 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 Florida, prescribed by physicians practicing in Florida, and dispensed by pharmacies located within Florida, and/or used by persons in Florida, all of which would have a substantial effect on Florida.

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

28. 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, 7,553,992 and 7,671,094.

#### **PATENTS IN SUIT**

29. 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, 7,553,992, and 7,671,094 including all right to sue and recover for infringement.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

35. 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 June 27, 2006, now United States Patent No. 7,241,805. A copy of the '094 patent is attached as Exhibit F.

#### **APLENZIN™ ER**

36. 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.

37. 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.

38. In compliance with 21 U.S.C. § 355(b)(1), Biovail certified to the FDA that the '935, '019, and '094 patent claims cover Aplenzin™ ER. The '935, '019, and '094 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**

39. Upon information and belief, Watson submitted Abbreviated New Drug Application Nos. 91-500 and 20-0835 (“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 (“Watson's Generic Product”), a generic version of Aplenzin™ ER, before expiration of the '610, '935, '019, '823, '992, and '094 patents.

40. Watson's ANDAs include three dosage forms of Watson's Generic Product, 174 mg, 348 mg, and 522 mg.

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, '019, and '094 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) ("First Paragraph IV letter"). About 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 Watson's Generic Product before the expiration of Biovail's Orange Book listed patents covering Aplenzin™ ER and its use. The Paragraph IV letters allege that Biovail's Orange Book listed patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Watson's Generic Product.

43. Biovail commenced its first action February 19, 2010 within 45 days of receiving Watson's First and Second Paragraph IV letters. The case is currently pending in this court (Case No. 10-20526-CIV-KING).

44. In a letter dated March 10, 2010, Biovail received a Third Paragraph IV notice from Watson in conjunction with its ANDA No. 91-500. The stated purpose of this letter 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 Watson's Generic Product before the expiration date of U.S. Patent Number 7,662,407 and the '094 patent. The Third Paragraph IV letter alleges that these Biovail 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 Watson's Generic Product.

45. In a letter dated April 9, 2010, Biovail received written notification of ANDA No. 20-0835 and Watson's allegations under 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. 314.95(c)(6). ("Fourth Paragraph IV letter"). The stated purpose of the Fourth Paragraph IV letter was to notify Biovail that Watson filed a certification with the FDA under 21 C.F.R. § 314.95 in conjunction with ANDA No. 20-0835 for approval to commercially manufacture and sell Watson's Generic Product before the expiration of Biovail's Orange Book listed patents covering Aplenzin™ ER and its use. The Fourth Paragraph IV letter alleges that Biovail's

Orange Book listed patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Watson's Generic Product.

46. Biovail commenced this action within 45 days of receiving Watson's Third and Fourth Paragraph IV letters.

47. This action is being filed in light of Watson's multiple ANDA filings and Paragraph IV certifications.

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

48. Biovail incorporates paragraphs 1-47.

49. Defendants, acting jointly, submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications 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).

50. 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 Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications 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).

51. When Watson Laboratories submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharmaceuticals committed an act of infringement with respect to the '610 patent under 35 U.S.C. § 271(e)(2)(A).

52. When Watson Laboratories submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharma committed an act of infringement with respect to the '610 patent under 35 U.S.C. § 271(e)(2)(A).

53. 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))**

54. Biovail incorporates paragraphs 1-53.

55. Watson Pharmaceuticals and/or Watson Pharma actively induced Watson Laboratories to submit ANDA Nos. 91-500 and 20-0835 to the FDA to obtain approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By actively inducing submission of the ANDAs, 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).

56. 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))**

57. Biovail incorporates paragraphs 1-56.

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

59. 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.

60. Upon information and belief, Watson intends, soon after the FDA has approved either ANDA No. 91-500 or 20-0835, 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.

61. 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.

62. 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.

63. Watson's actions, including without limitation the filing of ANDA Nos. 91-500 and 20-0835, exhibit a refusal to change the course of its action despite Biovail's patent rights.

64. 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.

65. 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 Product 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))**

66. Biovail incorporates paragraphs 1-65.

67. Defendants, acting jointly, submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications 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).

68. 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 Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications 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).

69. When Watson Laboratories submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharmaceuticals committed an act of infringement with respect to the '935 patent under 35 U.S.C. § 271(e)(2)(A).

70. When Watson Laboratories submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharma committed an act of infringement with respect to the '935 patent under 35 U.S.C. § 271(e)(2)(A).

71. 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))**

72. Biovail incorporates paragraphs 1-71.

73. Watson Pharmaceuticals and/or Watson Pharma actively induced Watson Laboratories to submit ANDA Nos. 91-500 and 20-0835 to the FDA to obtain approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By actively inducing submission of the ANDAs, 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).

74. 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))**

75. Biovail incorporates paragraphs 1-74.

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

77. 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.

78. Upon information and belief, Watson intends, soon after the FDA has approved either ANDA No. 91-500 or 20-0835, 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.

79. 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.

80. 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.

81. Watson's actions, including without limitation the filing of ANDA Nos. 91-500 and 20-0835, exhibit a refusal to change the course of its action despite Biovail's patent rights.

82. 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.

83. 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 Product 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))**

84. Biovail incorporates paragraphs 1-83.

85. Defendants, acting jointly, submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications 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).

86. 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 Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications 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).

87. When Watson Laboratories submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharmaceuticals committed an act of infringement with respect to the '019 patent under 35 U.S.C. § 271(e)(2)(A).

88. When Watson Laboratories submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharma committed an act of infringement with respect to the '019 patent under 35 U.S.C. § 271(e)(2)(A).



89. 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))**

90. Biovail incorporates paragraphs 1-89.

91. Watson Pharmaceuticals and/or Watson Pharma actively induced Watson Laboratories to submit ANDA Nos. 91-500 and 20-0835 to the FDA to obtain approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By actively inducing submission of the ANDAs, 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).

92. 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))**

93. Biovail incorporates paragraphs 1-92.

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

95. 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.

96. Upon information and belief, Watson intends, soon after the FDA has approved either ANDA No. 91-500 or 20-0835, 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.

97. 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.

98. 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.

99. Watson's actions, including without limitation the filing of ANDA Nos. 91-500 and 20-0835, exhibit a refusal to change the course of its action despite Biovail's patent rights.

100. 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.

101. 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 Product 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))**

102. Biovail incorporates paragraphs 1-101.

103. Defendants, acting jointly, submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications 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).

104. 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 Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications 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).

105. When Watson Laboratories submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharmaceuticals committed an act of infringement with respect to the '823 patent under 35 U.S.C. § 271(e)(2)(A).

106. When Watson Laboratories submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharma committed an act of infringement with respect to the '823 patent under 35 U.S.C. § 271(e)(2)(A).

107. 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))**

108. Biovail incorporates paragraphs 1-107.

109. Watson Pharmaceuticals and/or Watson Pharma actively induced Watson Laboratories to submit ANDA Nos. 91-500 and 20-0835 to the FDA to obtain approval to

engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By actively inducing submission of the ANDAs, 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).

110. 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))**

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, Watson intends, soon after the FDA has approved either ANDA No. 91-500 or 20-0835, 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.

115. 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.

116. 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.

117. Watson's actions, including without limitation the filing of ANDA Nos. 91-500 and 20-0835, 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 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.

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 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 Product, 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))**

120. Biovail incorporates paragraphs 1-119.

121. Defendants, acting jointly, submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications 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).

122. 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 Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications 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).

123. When Watson Laboratories submitted ANDA Nos. 19-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharmaceuticals committed an act of infringement with respect to the '992 patent under 35 U.S.C. § 271(e)(2)(A).

124. When Watson Laboratories submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharma committed an act of infringement with respect to the '992 patent under 35 U.S.C. § 271(e)(2)(A).

125. 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))**

126. Biovail incorporates paragraphs 1-125.

127. Watson Pharmaceuticals and/or Watson Pharma actively induced Watson Laboratories to submit ANDA Nos. 91-500 and 20-0835 to the FDA to obtain approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By actively inducing submission of the ANDAs, 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).

128. 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))**

129. Biovail incorporates paragraphs 1-128.

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

131. 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.

132. Upon information and belief, Watson intends, soon after the FDA has approved either ANDA No. 91-500 or 20-0835, 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.

133. 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.

134. 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.

135. Watson's actions, including without limitation the filing of ANDA Nos. 91-500 and 20-0835, exhibit a refusal to change the course of its action despite Biovail's patent rights.

136. 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.

137. 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 Product before expiration of the '992 patent by Watson, will infringe the '992 patent.

**COUNT XVI**  
**(Infringement of the '094 Patent Under 35 U.S.C. § 271(e)(2))**

138. Biovail incorporates paragraphs 1-137.

139. Defendants, acting jointly, submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications before expiration of the '094 patent, Defendants, individually and collectively, committed an act of infringement with respect to the '094 patent under 35 U.S.C. § 271(e)(2)(A).

140. 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 Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By submitting the applications before expiration of the '094 patent, Watson Laboratories committed an act of infringement with respect to the '094 patent under 35 U.S.C. § 271(e)(2)(A).

141. When Watson Laboratories submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharmaceuticals committed an act of infringement with respect to the '094 patent under 35 U.S.C. § 271(e)(2)(A).



142. When Watson Laboratories submitted ANDA Nos. 91-500 and 20-0835 to the FDA seeking approval to engage in commercial manufacture, use, or sale throughout the United States including Florida 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 applications and/or causing its agent to submit the applications, Watson Pharma committed an act of infringement with respect to the '094 patent under 35 U.S.C. § 271(e)(2)(A).

143. 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 '094 patent will infringe the '094 patent.

**COUNT XVII**  
**(Infringement of the '094 Patent Under 35 U.S.C. § 271(b))**

144. Biovail incorporates paragraphs 1-143.

145. Watson Pharmaceuticals and/or Watson Pharma actively induced Watson Laboratories to submit ANDA Nos. 91-500 and 20-0835 to the FDA to obtain approval to engage in commercial manufacture, use, or sale throughout the United States including Florida of Watson's Generic Product. By actively inducing submission of the ANDAs, Watson Pharmaceuticals and/or Watson Pharma committed an act of indirect infringement with respect to the '094 patent under 35 U.S.C. § 271(b).

146. 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 '094 patent will infringe the '094 patent.

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

147. Biovail incorporates paragraphs 1-146.

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

149. 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.

150. Upon information and belief, Watson intends, soon after the FDA has approved either ANDA No. 91-500 or 20-0835, 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.

151. 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 '094 patent.

152. 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 '094 patent.

153. Watson's actions, including without limitation the filing of ANDA Nos. 91-500 and 20-0835, exhibit a refusal to change the course of its action despite Biovail's patent rights.

154. 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 '094 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '094 patent.

155. 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 Product before expiration of the '094 patent by Watson, will infringe the '094 patent.

### **INJUNCTIVE RELIEF**

156. 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**

Because Watson has submitted multiple Paragraph IV certifications for bupropion hydrobromide, including certifications submitted after Biovail's earlier complaint (Case No. 10-20526-CIV-KING), Biovail respectfully prays for the following relief:

- a. An order consolidating Biovail's earlier complaint (Case No. 10-20526-CIV-KING) with this action.
- b. A judgment that Watson has infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA Nos. 91-500 and 20-0835 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.
- c. A judgment that Watson has infringed the '935 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA Nos. 91-500 and 20-0835 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.
- d. A judgment that Watson has infringed the '019 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA Nos. 91-500 and 20-0835 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.
- e. A judgment that Watson has infringed the '823 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA Nos. 91-500 and 20-0835 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.
- f. A judgment that Watson has infringed the '992 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA Nos. 91-500 and 20-0835 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.

g. A judgment that Watson has infringed the '094 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA Nos. 91-500 and 20-0835 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 '094 patent.

h. 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.

i. 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.

j. 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.

k. 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.

l. 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.

m. A declaration issued under 28 U.S.C. § 2201 that Watson 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 Watson's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '094 patent.

n. An order issued under 35 U.S.C. § 271(e)(4)(A) that the earliest effective approval date of either ANDA No. 91-500 or 20-0835, if any, shall be no earlier than the date of expiration of any patent-in-suit Watson is found to infringe, including any extensions.

o. 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.

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

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

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

s. 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.

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

Dated: April 16, 2010

By: \_\_\_\_\_

**KOZYAK TROPIN &  
THROCKMORTION**

Harley S. Tropin  
Gail A. McQuilkin  
2525 Ponce de Leon, 9th floor  
Telephone: 305-372-1800  
Fax: 305-372-3508  
Email: hst@kttlaw.com  
Email: gam@kttlaw.com

**HOWREY LLP**

Theresa M. Gillis  
601 Lexington Avenue, Floor 54  
New York, NY 10022-4629  
Telephone: (212) 896-6500  
Fax: (212) 896-6501  
Email: gillist@howrey.com

**HOWREY LLP**

Thomas W. Jenkins Jr.  
321 North Clark St.  
Suite 3400  
Chicago, IL 60654  
Telephone: (312) 595-1239  
Fax: (312) 595-2250  
Email: jenkest@howrey.com

**Attorneys for Plaintiff Biovail Laboratories  
International SRL**

| [#312022](#)