11 CV 2340

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JUDGE BATTS

SHIRE LLC,

Plaintiff,

v.

WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC.–FLORIDA,
WATSON PHARMA, INC.,
ANDRX CORPORATION, and
ANDRX PHARMACEUTICALS, L.L.C.,

Defendants.

Civ. Action No.:_____

COMPLAINT FOR PATENT INFRINGEMENT AND BREACH OF CONTRACT

Plaintiff Shire LLC ("Shire"), by its attorneys, for its Complaint against Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals"), Watson Laboratories, Inc.-Florida ("Watson Florida"), Watson Pharma, Inc. ("Watson Pharma"), Andrx Corporation ("Andrx"), and Andrx Pharmaceuticals, L.L.C. ("Andrx Pharmaceuticals") (collectively, "Watson" or "Defendants") alleges as follows:

Nature of the Action

1. This is a patent infringement and breach of contract case in which the Defendants are attempting to deprive Plaintiff Shire of the benefit of a license agreement that the parties executed as part of a settlement years ago. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and New York state law for breach of contract, breach of the implied covenant of good faith and

fair dealing, and repudiation of contract. Shire seeks injunctive relief, declaratory relief that the patents it is asserting are infringed, and attorneys' fees.

The Parties

2. Plaintiff Shire is a limited liability company organized and existing under the laws of the State of Kentucky and having its principal place of business at 9200 Brookfield Ct., Suite 108, Florence, KY 41042.

3. Defendant Watson Pharmaceuticals is a corporation organized and existing under the laws of the State of Nevada and having its principal place of business at 311 Bonnie Circle, Corona, California 92880. Watson Pharmaceuticals manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, alone or through its subsidiaries. Upon information and belief, Watson Pharmaceuticals operates, conducts, and transacts business in New York and contracts to supply goods and services in New York, and owns properties and conducts business at the following locations in New York: Carmel, New York (manufacturing); Copiague, New York (manufacturing, research and development); and Grand Island, New York (sales and marketing, administration). Watson Pharmaceuticals has a Code of Conduct, through which it dictates the conduct for "all of its directly or indirectly controlled subsidiaries and divisions worldwide and their respective officers, directors and employees." Watson Pharmaceuticals files financial statements on behalf of its subsidiaries in its consolidated financial statements submitted to the Securities and Exchange Commission, and Watson Pharmaceuticals generally otherwise represents, and directs the policies of, its subsidiaries in financial, regulatory, legal, and public relations matters.

4. Defendant Watson Pharma is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 360 Mt. Kemble

Avenue, Morristown, NJ 07960. Watson Pharma is registered in New York as a foreign business corporation. Watson Pharma is also registered as a Pharmacy Establishment in the State of New York by the New York Department of Education, Office of the Professions (Registration Nos. 025849 and 026378). The Registrations are active and are valid through August 31, 2012. Upon information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals whose operations, personnel, and business overlap and are intertwined with Watson Pharmaceuticals' operations, personnel, and business, and which is subject to domination and control by Watson Pharmaceuticals. Upon information and belief, Watson Pharmaceuticals maintains Watson Pharma as its subsidiary in the U.S. to serve no other business purpose or goal except to act solely as a sales and marketing agent of Watson Pharmaceuticals and its manufacturing subsidiaries, including Watson Florida. Upon information and belief, Watson Pharma and Watson Pharmaceuticals have a director and at least one officer in common.

5. Defendant Watson Florida is a corporation organized and existing under the laws of the State of Florida and having its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Watson Florida was formerly known as Andrx Pharmaceuticals, Inc. before it was acquired by Watson Pharmaceuticals in 2006. Watson Florida is registered as a Pharmacy Establishment by the New York State Department of Education, Office of the Professions (Registration Nos. 028681 and 028729). The Registrations have an active status and are valid through October 31, 2013 and December 31, 2013, respectively. Registration No. 028719 lists a street address of 4955 Orange Drive, Davie, FL 33314. Upon information and belief, Watson Florida is a wholly-owned subsidiary of Andrx, which in turn is a wholly-owned subsidiary of Watson Pharmaceuticals. Upon information and belief, Watson Florida's operations, personnel, and business are overlapping and intertwined with Watson

Pharmaceuticals' operations, personnel, and business, and Watson Florida is subject to domination and control by Watson Pharmaceuticals. At least five officers of Watson Florida, including the President and Chief Executive Officer, are also officers of Watson Pharmaceuticals, and personnel of Watson Pharmaceuticals act on behalf of, and make decisions for, Watson Florida, and Watson Pharmaceuticals can and has represented and bound Watson Florida in contractual matters. Upon information and belief, Watson Florida operates, conducts, and transacts business in New York and sells generic pharmaceutical products in New York alone, or through Watson Pharmaceuticals and/or other Watson entities and agents, including Watson Pharma.

6. Defendant Andrx is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Watson Pharmaceuticals acquired Andrx in November 2006, and Andrx is now a wholly-owned subsidiary of Watson Pharmaceuticals, whose operations, personnel, and business are overlapping and intertwined with Watson Pharmaceuticals' operations, personnel, and business, and which is subject to domination and control by Watson Pharmaceuticals. Upon information and belief, Andrx operates, conducts, and transacts business in New York and contracts to supply generic pharmaceutical products in New York alone, or through Watson Pharmaceuticals and/or other Watson entities and agents.

7. Upon information and belief, Andrx Pharmaceuticals is a limited liability company organized and existing under the laws of the State of Delaware, and having its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Andrx Pharmaceuticals is a wholly-owned subsidiary of Andrx, and indirectly, of Watson Pharmaceuticals. Upon information and belief, Andrx Pharmaceuticals manufactures numerous

generic drugs for sale and use throughout the United States, including in this judicial district, alone or through other Watson entities.

8. Upon information and belief, the Defendants named in this complaint conduct themselves as part of a unified operation, and have collaborated, cooperated, directed, and/or participated in the acts complained of herein, knowing that these actions would lead to and cause infringement of the patents at issue in this lawsuit, and would lead to and cause a breach of the license agreement at issue in this lawsuit.

Jurisdiction and Venue

9. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271 and 21 U.S.C. § 355, and for declaratory relief under the laws of the United States, 28 U.S.C. §§ 2201-02. This is also a civil action for breach of contract, breach of implied covenant of good faith and fair dealing, and repudiation of contract arising under the laws of the State of New York relating to the breach by Watson of a 2007 License Agreement. All of these claims present the same fundamental question: whether Watson is infringing three patents owned and asserted by Shire in this case – United States Patent Nos. 6,913,768, RE 42,096, and RE 41,148. A copy of each patent is attached as Exhibit A, B, and C respectively.

10. The claims asserting patent infringement will be collectively referred to herein as "the Patent Infringement Claims." This Court has subject matter jurisdiction over the Patent Infringement Claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. The claims relating to the 2007 License Agreement will be collectively referred to herein as "the License Claims." This Court has subject matter jurisdiction over the License Claims pursuant to 28 U.S.C. § 1367 because resolution of the License Claims is bound

up in, and intertwined with, the question of whether the patents asserted by Shire in this litigation are infringed. Because that question is central to both the License Claims and the Patent Infringement Claims, the License Claims form part of the same case or controversy as the Patent Infringement Claims.

12. This Court also has subject matter jurisdiction over the License Claims pursuant to 28 U.S.C. §§ 1331 and 1338(a), because resolution of those claims presents a federal question and requires resolution of a substantial question of patent law, *i.e.*, whether the patents asserted by Shire in this case have been infringed.

13. This Court also has subject matter jurisdiction over the License Claims pursuant to 28 U.S.C. § 1332 because the parties in this case are completely diverse and the amount in controversy exceeds $75,000, exclusive of interest and costs. If the Defendants are permitted to move forward with selling their proposed generic product, in violation of the License Agreement and in infringement of Shire's patents, Shire will experience financial losses well in excess of $75,000. Such losses would include a diminution in value of the Shire patents at issue in this lawsuit.

14. This Court has personal jurisdiction over all of the Defendants because Watson Pharmaceuticals, on behalf of itself and its affiliates, including the other Defendants, expressly consented to personal jurisdiction in this Court for any disputes arising out of or in connection with the License Agreement.

15. In addition to the fact that the Defendants have consented to jurisdiction in this Court, this Court has general personal jurisdiction over Watson Pharmaceuticals because, among other reasons, it is doing business in New York by owning and operating facilities in New York that are engaged in manufacturing and research and development of generic

pharmaceuticals. In addition, upon information and belief, Watson Pharmaceuticals maintains phone listings and permanent employees in New York.

16. In addition to the fact that the Defendants have consented to jurisdiction in this Court, this Court has general personal jurisdiction over Watson Pharma because it is doing business in New York by registering as a foreign business corporation and as a pharmacy establishment, and by soliciting business in New York and making significant sales of Watson's generic products to customers in New York, including products manufactured by Watson Florida.

17. In addition to the fact that the Defendants have consented to jurisdiction in this Court, this Court has general personal jurisdiction over Watson Florida because, upon information and belief, Watson Florida is registered in New York as a pharmacy establishment and operates, conducts, and transacts business in New York and sells generic pharmaceutical products in New York alone, or through Watson Pharmaceuticals and/or other Watson entities and agents, including Watson Pharma. Additionally or alternatively, this Court has general personal jurisdiction over Watson Florida because the contacts of Watson Pharmaceuticals can be imputed to Watson Florida, given that Watson Pharmaceuticals is the ultimate parent of Watson Florida, putting the two entities under common ownership; the operations, business, and personnel of these entities are intertwined, as demonstrated by the fact that Watson Pharmaceuticals and Watson Florida share at least five common officers; and Watson Pharmaceuticals exercises domination and control over Watson Florida's operational policies and business. Additionally or alternatively, this Court has general personal jurisdiction over Watson Florida because the contacts of Watson Pharma can be imputed to Watson Florida, given that Watson Pharmaceuticals is the ultimate parent of both Watson Florida and Watson Pharma,

putting the two entities under common ownership, and that the operations, business, and personnel of these entities are intertwined, as demonstrated by, *inter alia*, the fact that Watson Pharma and Watson Florida share at least one common officer or director.

18. In addition to the fact that the Defendants have consented to personal jurisdiction in this Court, this Court has general personal jurisdiction over Andrx and Andrx Pharmaceuticals because, on information and belief, they operate, conduct, and transact business in New York and contract to supply goods and services in New York alone, or through Watson Pharmaceuticals and/or other Watson entities and agents, including Watson Pharma. Additionally or alternatively, the contacts of Watson Pharmaceuticals can be imputed to Andrx and Andrx Pharmaceuticals because the operations, business, and personnel of these entities are overlapping with Watson Pharmaceuticals' operations, business, and personnel, and Watson Pharmaceuticals exercises domination and control over Andrx and Andrx Pharmaceuticals.

19. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

Factual Background

Shire's Patents and Approved ADDERALL XR® Drug

20. Shire, through a corporate affiliate, makes and sells ADDERALL XR®, a widely used drug that helps to control symptoms of Attention Deficit Hyperactivity Disorder ("ADHD"). ADHD is a condition that makes it difficult for adults and children to focus their attention, control their actions, and remain still.

21. Shire owns three patents that cover ADDERALL XR®. These are U.S. Patent Nos. 6,913,768 ("the '768 patent"), RE 42,096 ("the '096 patent"), and RE 41,148 ("the '148 patent"). Shire is asserting each of these patents in this case.

22. The '768 patent, entitled "Sustained Release Delivery of Amphetamine Salts," issued from the U.S. Patent and Trademark Office on July 5, 2005. *See* Ex. A. This patent was later assigned to Shire on or about December 15, 2006, following a merger of Shire LLC with Shire Laboratories, Inc.

23. The '096 patent, entitled "Oral Pulsed Drug Delivery System," is a reissue of U.S. Patent. No. 6,322,819 ("the '819 patent"), which issued on November 27, 2001. *See* Ex. B. The '096 patent discloses and claims, *inter alia,* a pharmaceutical composition for delivery of one or more pharmaceutically active amphetamine salts. Claims 2, 5, 11, and 13-24 of the '096 patent are identical to claims in the '819 patent. Claims 1, 3, 4, 6-10, and 12 of the '096 patent are narrower than their counterpart claims in the '819 patent.

24. The '148 patent, entitled "Oral Pulsed Drug Delivery System," is a reissue of U.S. Patent No. 6,605,300 ("the '300 patent"), which issued on August 12, 2003. *See* Ex. C. The '148 patent discloses and claims, *inter alia,* a pharmaceutical preparation for the delivery of mixed amphetamine salts. Claims 1-9 and 15-18 of the '148 patent are identical to claims in the '300 patent. Claims 10-14 of the '148 patent are narrower than their counterpart claims in the '300 patent.

25. Shire's affiliate, Shire Development Inc., holds New Drug Application ("NDA") No. 21-303, under which the United States Food and Drug Administration ("FDA") has given Shire approval to make and sell ADDERALL XR® for the treatment of ADHD. The FDA has listed the '819, '300, '148, and '096 patents in the Orange Book – a publication formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – under the listing for NDA No. 21-303 because those patents cover ADDERALL XR®.

Prior Shire-Watson Adderall Patent Litigation ("Watson I")

26. Four years before the filing of this lawsuit, Shire and Watson were involved in patent litigation involving the same ADDERALL XR® product as this case, and involving much of the same intellectual property as this case. That prior litigation will be referred to herein as "Watson I."

27. The Watson I litigation came about after Watson (through its predecessor affiliates Andrx and Andrx Pharmaceuticals) submitted Abbreviated New Drug Application ("ANDA") No. 78-436 to the FDA, seeking approval to make and sell a generic version of ADDERALL XR® before the expiration of Shire's ADDERALL XR® patents.

28. As part of that ANDA filing, Watson provided a certification to the FDA that, in Watson's view, the claims of the '819 and '300 patents covering ADDERALL XR® were purportedly invalid, unenforceable, and/or would not be infringed.

29. By letter dated September 28, 2006, Watson gave notice of such certification to Shire, and informed Shire that it was seeking approval to engage in the commercial manufacture, use and sale of a product bioequivalent to ADDERALL XR® prior to the expiration of the '819 and '300 patents.

30. On or about November 9, 2006, Shire sued Watson Pharmaceuticals, Andrx, and Andrx Pharmaceuticals in the United States District Court for the District of New Jersey for infringement of the '819 and '300 patents. *See* Compl., *Shire Labs. Inc. v. Andrx Pharms., LLC*, No. 2:06-cv-05394-KSH-PS (D.N.J.). Under 35 U.S.C. § 271(e)(2)(A), Watson's submission of the ANDA, and certification that the patents covering ADDERALL XR® were purportedly invalid, unenforceable, and/or not infringed, constituted an act of patent infringement, giving rise to the suit by Shire in Watson I.

31. On or about August 22, 2007, the Watson I litigation was transferred to the United States District Court for the Southern District of Florida. *Shire Labs., Inc. v. Andrx Pharms., LLC*, No. 07-22201-CIV-COOKE (S.D. Fla.). Thereafter, on November 15, 2007, Shire filed a Second Amended Complaint, adding infringement of the '768 patent to its causes of action.

32. On or about November 2007, Shire and Watson settled the Watson I litigation. They did so by entering into a License Agreement and a Settlement Agreement. Watson Pharmaceuticals entered into the Settlement and License Agreements on behalf of itself and its Affiliates. *See supra* ¶ 15. Thomas Russillo executed the Settlement Agreement and License Agreement in his role as Executive Vice President and President, U.S. Generics Division for Watson Pharmaceuticals. Upon information and belief, Mr. Russillo is currently an officer or director of Watson Florida.

33. The parties also consented to the entry of Judgment and Order of Permanent Injunction ("Permanent Injunction"), which is attached as Exhibit D. The License Agreement, Settlement Agreement, and Permanent Injunction are collectively referred to herein as the "Settlement Documents."

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Watson Files New ANDA No. 202618 for ADDERALL XR®

41. Upon information and belief, in late 2010 Watson submitted a new ANDA ("ANDA No. 202618"), seeking – as it did in its previously submitted ANDA No. 78-436 that

prompted the Watson I litigation – to obtain approval to make a generic equivalent of ADDERALL XR®. In submitting its new ANDA, Watson did what it warranted it would not do in the Settlement Documents it previously executed.

42.

43. In addition, on or about March 2, 2011, Watson again violated its prior agreement and commitments from the Watson I settlement by sending Shire a Notification of Certification of Invalidity and/or Noninfringement for U.S. Patent No. RE 42,096 ("the '096 patent"). In that notice, Watson asserted that Shire's '096 patent "is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, sale, offer for sale or importation of the drug products" described in Watson's ANDA No. 202618. This was in violation of Watson' prior agreement because the '096 patent contains 15 claims from the '819 patent, *all of which Watson previously agreed were valid and enforceable* as part of the Watson I settlement.

44.

Dispute Resolution Process

45. On or about March 8, 2011, Shire sent Watson a letter requesting a meeting on March 22, 2011 to discuss Watson's filing of ANDA No. 202618 and whether such filing breached the License Agreement between Shire and Watson.

46. On March 22, 2011, representatives of Shire and Watson met by telephone to discuss the dispute. Amy Hulina, in-house counsel for Watson Pharmaceuticals, represented the Defendants on the call. Upon information and belief, Ms. Hulina represented that Watson did not believe that filing ANDA No. 202618 breached the License Agreement or Settlement Agreement. Shire asked Watson to withdraw ANDA No. 202618, but the parties were unable to resolve the dispute during the call.

47. On March 31, 2011, Shire sent Watson a letter stating Shire's willingness to make additional efforts to resolve the dispute by holding a conference call or meeting between the Presidents of Shire and Watson. Shire asked Watson to confirm by the close of business on

April 1, 2011 whether Watson wished to schedule such a call or meeting by April 4, 2011. Shire informed Watson that if Watson did not respond, Shire would conclude that such a call or meeting would be futile. As of the close of business on April 4, 2011, Watson had not responded to Shire's letter.

COUNT I

(Patent Infringement of the '096 Patent)

48. Shire re-alleges paragraphs 1 through 47 above as fully set forth therein.

49. Upon information and belief, Defendants have collaborated in the submission of ANDA No. 202618, and continue to collaborate in seeking approval of ANDA No. 202618 from the FDA.

50. Defendants have infringed the '096 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 202618 with a Paragraph IV certification and seeking FDA approval of ANDA No. 202618 prior to the expiration of the '096 patent. Moreover, the Defendants would be liable jointly and severally as infringers under 35 U.S.C. §§ 271(a) and/or (g).

51. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of ANDA No. 202618 would actively induce and contribute to infringement of the '096 patent, and the Defendants jointly and severally would be liable as infringers under 35 U.S.C. §§ 271(b) and/or (c).

52. Defendants had actual and constructive notice of the '096 patent prior to filing a baseless paragraph IV certification that contended without adequate basis that the patent was invalid and non-infringed by Defendants' proposed generic ADDERALL XR® equivalent.

Defendants' conduct in certifying invalidity and non-infringement with respect to the '096 patent has been, and continues to be, willful.

53. Shire will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '096 patent. Shire does not have an adequate remedy at law and, considering the balance of hardships between Shire and Defendants, a remedy at equity is warranted. Further, the public interest would not be disserved by a permanent injunction.

COUNT II

(Patent Infringement of the '148 Patent)

54. Shire re-alleges paragraphs 1 through 53 above as fully set forth therein.

55. Upon information and belief, Defendants have collaborated in the submission of ANDA No. 202618, and continue to collaborate in seeking approval of ANDA No. 202618 from the FDA.

56. Defendants have infringed the '148 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 202618 with a Paragraph IV certification and seeking FDA approval of ANDA No. 202618 prior to the expiration of the '148 patent. Moreover, Defendants would be liable jointly and severally as infringers under 35 U.S.C. §§ 271(a) and/or (g).

57. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of ANDA No. 202618 would actively induce and contribute to infringement of the '148 patent, and Defendants jointly and severally would be liable as infringers under 35 U.S.C. §§ 271(b) and/or (c).

58. Defendants had actual notice of the '148 patent, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

59. Shire will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '148 patent. Shire does not have an adequate remedy at law and, considering the balance of hardships between Shire and Defendants, a remedy at equity is warranted. Further, the public interest would not be disserved by a permanent injunction.

COUNT III

(Patent Infringement of the '768 Patent)

60. Shire re-alleges paragraphs 1 through 59 above as fully set forth therein.

61. Upon information and belief, Defendants have collaborated in the submission of ANDA No. 202618, and continue to collaborate in seeking approval of ANDA No. 202618 from the FDA.

62. Defendants have infringed the '768 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 202618 with a Paragraph IV certification and seeking FDA approval of ANDA No. 202618 prior to the expiration of the '768 patent. Moreover, Defendants would be liable jointly and severally as infringers under 35 U.S.C. §§ 271(a) and/or (g).

63. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of ANDA No. 202618 would actively induce and contribute to infringement of the '768 patent, and the Defendants jointly and severally would be liable as infringers under 35 U.S.C. §§ 271(b) and/or (c).

64. Defendants had actual notice of the '768 patent, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

65. Shire will be irreparably harmed if Defendants is not enjoined from infringing or actively inducing or contributing to infringement of the '768 patent. Shire does not have an adequate remedy at law and, considering the balance of hardships between Shire and Defendants, a remedy at equity is warranted. Further, the public interest would not be disserved by a permanent injunction.

COUNT IV
(Breach of Contract)

66. Shire re-alleges paragraph 1 through 65 above as fully set forth therein.

67. Upon information and belief, Defendants withdrew ANDA No. 78-436 and submitted ANDA No. 202618 seeking approval for a generic equivalent of ADDERALL XR®. ANDA No. 202618 is a new ANDA and is not an amendment or supplement to ANDA No. 78-436.

68. The subject product of ANDA No. 202618 is a Generic Equivalent and Therapeutic Equivalent to ADDERALL XR® and infringes the '768, '148, and '096 patents.

69. On information and belief, in connection with the submission of ANDA No. 202618, Watson Pharmaceuticals' President and Chief Executive Officer, Paul M. Bisaro, touted and promoted as a new formulation the Generic Equivalent of ADDERALL XR® that is the subject of ANDA No. 202618.

70. Upon information and belief, Defendants have used the tradename "ADDERALL XR" and the ADDERALL XR® labeling in ANDA No. 202618.

71. Upon information and belief, Defendants have contracted with a third party to conduct bioequivalence studies on the subject product of ANDA No. 202618 and have included the results of those studies in the submitted ANDA No. 202618.

72.

73. Based on the facts alleged in paragraphs 1 through 72, Defendants' submission of ANDA No. 202618 breaches at least Sections 3.2(a), 3.2(b), and 11.1 of the License Agreement.

74. Defendants' breach of the License Agreement damages Shire because Defendants seek to introduce into the marketplace an unauthorized generic equivalent of ADDERALL XR® that infringes Shire's valid and enforceable intellectual property and damages the value of the ADDERALL XR® brand. Defendants' breach also damages Shire by requiring Shire to devote time and money to litigating a matter that it previously resolved by executing the Settlement Documents over three years ago.

75. Shire will be irreparably harmed if the Defendants are not enjoined from manufacturing or marketing the subject product of ANDA No. 202618. Shire does not have an adequate remedy at law and, considering the balance of hardships between Shire and Defendants, a remedy at equity is warranted. Further, the public interest would not be disserved by a permanent injunction.

COUNT V

(Breach of Implied Covenant of Good Faith and Fair Dealing)

76. Shire re-alleges paragraph 1 through 75 above as fully set forth therein.

77. In the alternative to Count IV, and based on the facts alleged in paragraph 1 through 76, Watson has breached its covenant of good faith and fair dealing.

78. Shire will be irreparably harmed if Defendants are not enjoined from manufacturing or marketing the subject product of ANDA No. 202618. Shire does not have an adequate remedy at law and, considering the balance of hardships between Shire and Defendants, a remedy at equity is warranted. Further, the public interest would not be disserved by a permanent injunction.

COUNT VI

(Repudiation of Contract)

79. Shire re-alleges paragraph 1 through 78 above as fully set forth therein.

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82. Defendants have represented to Shire that it will not withdraw ANDA No. 202618, and instead will continue to seek FDA approval for a generic equivalent of ADDERALL XR® under ANDA No. 202618.

83. Based on these facts, Defendants have repudiated the License Agreement and its obligations thereunder.

84. Shire will be irreparably harmed if the Defendants are not enjoined from manufacturing or selling the subject product of ANDA No. 202618. Shire does not have an adequate remedy at law and, considering the balance of hardships between Shire and Defendants, a remedy at equity is warranted. Further, the public interest would not be disserved by a permanent injunction.

Prayer for Relief

WHEREFORE, Shire seeks the following relief:

A. A judgment that Defendants have infringed the '096, '148 and '768 patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment providing that the effective date of any FDA approval of the ANDA No. 202618 be not earlier than the latest expiration date of the '096, '148 and '768 patents, including any extensions or regulatory exclusivities appended thereto;

C. A judgment declaring that the making, using, selling, offering to sell, or importing of the products for which approval is sought in ANDA No. 202618 would constitute infringement of the '096, '148 and '768 patents, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(a), (b), (c) and/or (g);

D. A judgment permanently enjoining Defendants, and their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from making, using selling, or offering to sell in the United States, or importing into the United States, the products for which approval is sought in ANDA No. 202618, or any product that infringes or induces or contributes to the infringement of the '096, '148

and '768 patents, until the expiration of those patents, including any extensions or regulatory exclusivities appended thereto;

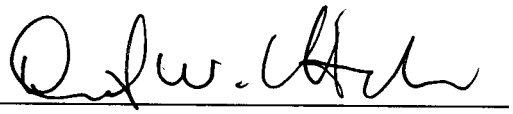
E. Entry of an order directing Defendants to withdraw ANDA No. 202618;

F. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

G. Costs and expenses in this action; and

H. Such further and other relief as this Court determines to be just and proper.

COVINGTON & BURLING LLP

By: 

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