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Shire LLC and Shire Development LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SHIRE LLC et al., Plaintiffs, v. WATSON LABORATORIES, INC. et al., Defendants.	Civ. No. 2:12-cv-00083-SRC-CLW

AMENDED COMPLAINT

Plaintiffs Shire LLC and Shire Development LLC (collectively "Shire"), by its undersigned attorneys, for its Amended Complaint against defendant Watson Laboratories, Inc. ("Watson") and defendants Johnson Matthey Pharmaceutical Materials and Johnson Matthey

Inc. (collectively, "Johnson Matthey") (Watson and Johnson Matthey hereinafter collectively, "Defendants") herein, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 7,105,486 ("the '486 patent") (attached as Exhibit A hereto); United States Patent No. 7,223,735 ("the '735 patent") (attached as Exhibit B hereto); and United States Patent No. 7,700,561 ("the '561 patent") (attached as Exhibit C hereto).

THE PARTIES

2. Plaintiff Shire LLC is a corporation organized and existing under the laws of the State of Kentucky, having a place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

3. Plaintiff Shire Development LLC is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 725 Chesterbrook Boulevard, Wayne, Pennsylvania 19087.

4. Upon information and belief, Watson Laboratories, Inc. is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business in this District at 311 Bonnie Circle, Corona, California 92880.

5. Upon information and belief, Johnson Matthey Pharmaceutical Materials (also known as Johnson Matthey Inc. - Pharmaceutical Materials and/or Johnson Matthey Pharmaceutical Materials - USA) is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 2003 Nolte Drive, West Deptford, New Jersey 08066.

6. Upon information and belief, Johnson Matthey Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a place of business at 435 Devon Park Drive, Suite 600, Wayne, Pennsylvania 19087.

7. Upon information and belief, Johnson Matthey Pharmaceutical Materials is a wholly owned subsidiary of Johnson Matthey Inc.

8. Upon information and belief, Johnson Matthey Pharmaceutical Materials acts at the direction of, under the control of, and for the direct benefit of Johnson Matthey Inc. and is controlled and/or dominated by Johnson Matthey Inc.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Watson because, inter alia, of its continuous and systematic contacts with this judicial district. Upon information and belief, Watson derives substantial revenue from articles used and consumed in this judicial district. Upon information and belief, Watson markets products through distributors with retail branch locations in this judicial district.

11. This Court has personal jurisdiction over Johnson Matthey Pharmaceutical Materials. Johnson Matthey Pharmaceutical Materials has submitted to personal jurisdiction in this Court because, inter alia, it resides and is doing business in New Jersey.

12. This Court has personal jurisdiction over Johnson Matthey Inc. because, inter alia, it is doing business in New Jersey and has continuous and systematic contacts with this judicial district, including through its wholly-owned subsidiary Johnson Matthey Pharmaceutical Materials.

13. Upon information and belief, Johnson Matthey manufactures, uses, markets, sells, and/or distributes pharmaceutical materials and services, including active pharmaceutical ingredients, in this judicial district.

14. Upon information and belief, this Court has specific personal jurisdiction over Johnson Matthey because, inter alia, it purposely registered the Johnson Matthey Pharmaceutical Materials facility in West Deptford, New Jersey, with the federal Drug Enforcement Agency ("DEA") as a manufacturer of lisdexamfetamine dimesylate active pharmaceutical ingredient ("API") for sale to Johnson Matthey's customer(s), which upon information and belief, as Johnson Matthey's Drug Master File ("DMF") for lisdexamfetamine dimesylate is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, includes Watson and as such is purposely manufacturing, using, offering for sale, selling, and supporting its customer(s)' Abbreviated New Drug Applications ("ANDA") for generic lisdexamfetamine dimesylate capsules, including Watson's ANDA No. 202818.

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

FACTS AS TO ALL COUNTS

16. Shire Development LLC is the current owner of New Drug Application ("NDA") No. 021977, which was approved by the FDA for the manufacture and sale of Vyvanse®. Vyvanse® is the trade name for lisdexamfetamine dimesylate, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg capsules for oral administration and is approved for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD").

17. Pursuant to 21 U.S.C. § 355(b)(1), the '486 patent, the '735 patent, and the '561 patent ("the Patents-in-Suit") are listed in FDA's publication titled "Approved Drug

Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering the Vyvanse® product.

18. Shire LLC has been assigned, and currently owns, the rights to each of the Patents-in-Suit.

19. The '486 patent, titled "Abuse-Resistant Amphetamine Compounds," was duly and legally issued on September 12, 2006. The '486 patent is generally directed to methods of treatment using L-lysine-d-amphetamine.

20. The '735 patent, titled "Abuse Resistant Lysine Amphetamine Compounds," was duly and legally issued on May 29, 2007. The '735 patent is generally directed to pharmaceutical compositions comprising L-lysine-d-amphetamine.

21. The '561 patent, titled "Abuse-Resistant Amphetamine Prodrugs" was duly and legally issued on April 20, 2010. The '561 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

22. Watson prepared, submitted, and filed Abbreviated New Drug Application ("ANDA") No. 202818 ("the Watson ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic lisdexamfetamine dimesylate capsules, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg, for oral administration ("the Watson Proposed Product").

23. Upon information and belief, according to the FDA's website, Johnson Matthey submitted a Type II DMF for lisdexamfetamine dimesylate API, No. 22442 ("Johnson Matthey's DMF"), to the FDA on or about January 27, 2009.

24. Upon information and belief, Johnson Matthey makes, uses, sells, offers for sale and/or imports lisdexamfetamine dimesylate API and, upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, Johnson Matthey makes, uses, sells, offers for sale and/or imports the lisdexamfetamine dimesylate API in the Watson Proposed Product.

25. Upon information and belief, pursuant to 21 C.F.R. § 314.420, Johnson Matthey is authorizing the FDA to reference and review its lisdexamfetamine dimesylate API DMF No. 22442 in support of the Watson ANDA and provided Watson with written authorization to submit to the FDA in the Watson ANDA.

26. Upon information and belief, Johnson Matthey registered the Johnson Matthey Pharmaceutical Materials facility in West Deptford, New Jersey, with the DEA as a manufacturer of lisdexamfetamine dimesylate API.

27. Upon information and belief, Johnson Matthey manufactures its lisdexamfetamine dimesylate API in West Deptford, New Jersey.

28. Upon information and belief, Johnson Matthey is a prime mover in the chain of events leading to infringement.

29. Watson sent a letter to Shire LLC, Shire Development Inc., Shire Pharmaceuticals Inc., and Shire US Inc. purporting to provide notification that the Watson ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") with regard to the '486 patent, the '735 patent, and the '561 patent ("the Watson Notice Letter").

30. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed

statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

31. The Watson Notice Letter does not assert non-infringement for each and every claim of each and every patent for which Watson has made a paragraph IV certification.

32. The Watson Notice Letter does not provide a full and detailed explanation of Watson's factual and legal basis of invalidity and/or unenforceability for each and every claim of each and every patent for which Watson has made a paragraph IV certification.

33. The Watson Notice Letter does not address United States Patent No. 7,655,630 ("the '630 patent"); United States Patent No. 7,659,253 ("the '253 patent"); U.S. Patent No. 7,659,254 ("the '254 patent"); United States Patent No. 7,662,787 ("the '787 patent"); United States Patent No. 7,671,030 ("the '030 patent"); United States Patent No. 7,671,031 ("the '031 patent"); United States Patent No. 7,674,774 ("the '774 patent"); United States Patent No. 7,678,770 ("the '770 patent"); United States Patent No. 7,678,771 ("the '771 patent"); United States Patent No. 7,687,466 ("the '466 patent"); United States Patent No. 7,687,467 ("the '467 patent"); United States Patent No. 7,718,619 ("the '619 patent"); and United States Patent No. 7,723,305 ("the '305 patent"), each also listed in the Orange Book for Vyvanse®.

34. On information and belief, Watson made certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("a paragraph III certification") for the '630 patent, the '253 patent, the '254 patent, the '787 patent, the '030 patent, the '031 patent, the '774 patent, the '770 patent, the '771 patent, the '466 patent, the '467 patent, the '619 patent, and the '305 patent.

35. On information and belief, Watson does not seek approval of the Watson ANDA before the expiration of the '630 patent, the '253 patent, the '254 patent, the '787 patent, the '030 patent, the '031 patent, the '774 patent, the '770 patent, the '771 patent, the '466 patent, the '467 patent, the '619 patent, and the '305 patent.

36. On information and belief, Watson does not seek approval of the Watson ANDA before the expiration of United States Patent No. 7,662,788 ("the '788 patent"), and United States Patent No. 7,713,936 ("the '936 patent").

37. On January 16, 2012 (D.I. 57), Watson represented that it would make additional paragraph IV certifications "as soon as practicable." (D.I. 95.)

38. As of the filing of this Amended Complaint Watson has not made paragraph IV certifications to the '630 patent, the '253 patent, the '254 patent, the '787 patent, the '030 patent, the '031 patent, the '774 patent, the '770 patent, the '771 patent, the '466 patent, the '467 patent, the '619 patent, the '305 patent, the '788 patent, and/or the '936 patent.

FIRST COUNT
(Infringement of the '486 Patent by Defendants)

39. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

40. Upon information and belief, Watson seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Watson Proposed Product.

41. Upon information and belief, Watson included a paragraph IV certification to the '486 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Watson Proposed Product before the expiration of the '486 patent.

42. Upon information and belief, Watson will commercially manufacture, sell, offer for sale, and/or import the Watson Proposed Product upon, or in anticipation of, FDA approval.

43. Upon information and belief, as of the dates of the Watson Notice Letter, Watson was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

44. The inclusion of a paragraph IV certification to the '486 patent in ANDA No. 202818 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Watson Proposed Product before the expiration of the '486 patent is an act of infringement by Watson of one or more claims of the '486 patent under 35 U.S.C. § 271(e)(2)(A) indirectly, including by inducement and/or contributory infringement.

45. Upon information and belief, Watson's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Watson Proposed Product that is the subject of ANDA No. 202818 will infringe one or more claims of the '486 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

46. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine

dimesylate API in the Watson Proposed Product is manufactured and supplied by Johnson Matthey.

47. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Watson ANDA for the purpose of supporting the Watson ANDA is an act of infringement of one or more claims of the '486 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

48. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Watson Proposed Product.

49. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Watson Proposed Product that is the subject of ANDA No. 202818 will infringe one or more claims of the '486 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

50. Upon information and belief, Defendants are aware of the existence of the '486 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '486 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

51. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Infringement of the '735 Patent by Defendants)

52. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

53. Upon information and belief, Watson seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Watson Proposed Product.

54. Upon information and belief, Watson included a paragraph IV certification to the '735 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Watson Proposed Product before the expiration of the '735 patent.

55. Upon information and belief, Watson will commercially manufacture, sell, offer for sale, and/or import the Watson Proposed Product upon, or in anticipation of, FDA approval.

56. Upon information and belief, as of the date of the Watson Notice Letter, Watson was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

57. The inclusion of a paragraph IV certification to the '735 patent in ANDA No. 202818 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Watson Proposed Product before the expiration of the '735 patent is an act of infringement by Watson of one or more claims of the '735 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

58. Upon information and belief, Watson's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Watson Proposed Product that is the subject of ANDA No. 202818 will infringe one or more claims of the '735 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

59. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Watson Proposed Product is manufactured and supplied by Johnson Matthey.

60. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Watson ANDA for the purpose of supporting the Watson ANDA is an act of infringement of one or more claims of the '735 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

61. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Watson Proposed Product.

62. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Watson Proposed Product that is the subject of ANDA No. 202818 will infringe one or more claims of the '735 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

63. Upon information and belief, Defendants are aware of the existence of the '735 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '735 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

64. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

THIRD COUNT
(Infringement of the '561 Patent by Defendants)

65. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

66. Upon information and belief, Watson seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Watson Proposed Product.

67. Upon information and belief, Watson included a paragraph IV certification to the '561 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Watson Proposed Product before the expiration of the '561 patent.

68. Upon information and belief, Watson will commercially manufacture, sell, offer for sale, and/or import the Watson Proposed Product upon, or in anticipation of, FDA approval.

69. Upon information and belief, as of the date of the Watson Notice Letter, Watson was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

70. The inclusion of a paragraph IV certification to the '561 patent in ANDA No. 202818 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Watson Proposed Product before the expiration of the '561 patent is an act of infringement by Watson of one or more claims of the '561 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

71. Upon information and belief, Watson's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Watson Proposed Product

that is the subject of ANDA No. 202818 will infringe one or more claims of the '561 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

72. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Watson Proposed Product is manufactured and supplied by Johnson Matthey.

73. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Watson ANDA for the purpose of supporting the Watson ANDA is an act of infringement of one or more claims of the '561 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

74. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Watson Proposed Product.

75. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Watson Proposed Product that is the subject of ANDA No. 202818 will infringe one or more claims of the '561 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

76. Upon information and belief, Defendants are aware of the existence of the '561 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '561 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

77. The acts of infringement set forth above will cause Shire irreparable

harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

i. A judgment declaring that the '486 patent is valid and enforceable;

ii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202818 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 was an act of infringement of the '486 patent by Defendants indirectly, including by inducement and/or contributory infringement;

iii. A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 and/or DMF No. 22442 prior to the expiration of the '486 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

iv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202818 shall be no earlier than the date on which the '486 patent expires including any regulatory extensions;

v. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from

engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 and/or DMF No. 22442 until the expiration of the '486 patent including any regulatory extensions;

vi. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202818 and/or DMF No. 22442 that infringes the '486 patent;

vii. A judgment declaring that infringement of the '486 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202818 and/or DMF No. 22442 that infringes the '486 patent;

viii. A judgment declaring that the '735 patent is valid and enforceable;

ix. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202818 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 was an act of infringement of the '735 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

x. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 and/or DMF No. 22442 prior to the expiration of the '735 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202818 shall be no earlier than the date on which the '735 patent expires including any regulatory extensions;

xii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 and/or DMF No. 22442 until the expiration of the '735 patent including any regulatory extensions;

xiii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202818 and/or DMF No. 22442 that infringes the '735 patent;

xiv. A judgment declaring that infringement of the '735 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202818 and/or DMF No. 22442 that infringes the '735 patent;

xv. A judgment declaring that the '561 patent is valid and enforceable;

xvi. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202818 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 was an act of infringement of the '561 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 and/or DMF No. 22442 prior to the expiration of the '561 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xviii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202818 shall be no earlier than the date on which the '561 patent expires including any regulatory extensions;

xix. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202818 and/or DMF No. 22442 until the expiration of the '561 patent including any regulatory extensions;

xx. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202818 and/or DMF No. 22442 that infringes the '561 patent;

xxi. A judgment declaring that infringement of the '561 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202818 and/or DMF No. 22442 that infringes the '561 patent;

xxii. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Shire its attorneys' fees and costs;

xxiii. Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

Dated: August 8, 2012

s/ Michael R. Griffinger
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