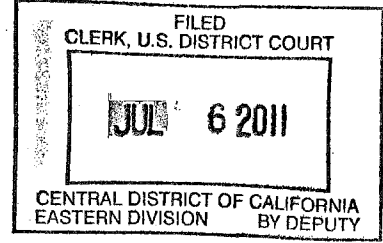


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13 Attorneys for Plaintiffs  
 SHIRE LLC and SHIRE DEVELOPMENT INC.

14  
 15 UNITED STATES DISTRICT COURT  
 16 CENTRAL DISTRICT OF CALIFORNIA  
 17 EASTERN DIVISION

18 SHIRE LLC and SHIRE  
 19 DEVELOPMENT INC.,

CV 11 Case No. 05565

AHM (DTBX)

20 Plaintiffs,

) COMPLAINT FOR PATENT  
 ) INFRINGEMENT  
 )

21 vs.

22 WATSON LABORATORIES, INC.,

23 Defendant.  
 24  
 25  
 26  
 27  
 28

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 LAWYERS  
 LOS ANGELES, CALIFORNIA

1 Plaintiffs Shire LLC and Shire Development Inc. (collectively "Shire"), by  
2 their undersigned attorneys, for their Complaint against defendant Watson  
3 Laboratories, Inc. ("Watson") herein, allege as follows:

4 **JURISDICTION AND VENUE**

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

7 2. This Court has personal jurisdiction over Watson. Watson has submitted  
8 to personal jurisdiction in this Court because, *inter alia*, it resides, and is doing  
9 business in this District.

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

12 **NATURE OF THE ACTION**

13 4. This is an action for patent infringement arising under the patent laws of  
14 the United States, Title 35, United States Code, involving United States Patent No.  
15 7,105,486 ("the '486 patent") (attached as Exhibit A hereto); United States Patent No.  
16 7,223,735 ("the '735 patent") (attached as Exhibit B hereto); and United States Patent  
17 No. 7,700,561 ("the '561 patent") (attached as Exhibit C hereto).

18 **THE PARTIES**

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

22 6. Plaintiff Shire Development Inc. is a corporation organized and existing  
23 under the laws of the State of Delaware, having a place of business at 725  
24 Chesterbrook Boulevard, Wayne, Pennsylvania 19087.

25 7. Upon information and belief, Watson Laboratories, Inc. is a corporation  
26 organized and existing under the laws of the State of Nevada, having its principal  
27 place of business in this District at 311 Bonnie Circle, Corona, California 92880.  
28

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**FACTS AS TO ALL COUNTS**

1  
2 8. Shire Development Inc. is the owner of New Drug Application (“NDA”)  
3 No. 021977, which was approved by the FDA for the manufacture and sale of  
4 Vyvanse®. Vyvanse® is the trade name for lisdexamfetamine dimesylate, 20 mg, 30  
5 mg, 40 mg, 50 mg, 60 mg, and 70 mg capsules for oral administration and is approved  
6 for the treatment of Attention Deficit Hyperactivity Disorder (“ADHD”).

7 9. Pursuant to 21 U.S.C. § 355(b)(1), the ’486 patent, the ’735 patent, and  
8 the ’561 patent (“the Patents-in-Suit”) are listed in FDA’s publication titled  
9 “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly  
10 known as the “*Orange Book*”) as covering the Vyvanse® product.

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

13 11. The ’486 patent, titled “Abuse-Resistant Amphetamine Compounds,”  
14 was duly and legally issued on September 12, 2006. The ’486 patent is generally  
15 directed to methods of treatment using L-lysine-d-amphetamine

16 12. The ’735 patent, titled “Abuse Resistant Lysine Amphetamine  
17 Compounds,” was duly and legally issued on May 29, 2007. The ’735 patent is  
18 generally directed to pharmaceutical compositions comprising L-lysine-d-  
19 amphetamine.

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

23 14. Watson prepared, submitted, and filed Abbreviated New Drug  
24 Application (“ANDA”) No. 202818 (“the Watson ANDA”) to the FDA under § 505(j)  
25 of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (codified at 21 U.S.C. §  
26 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for  
27 sale and/or importation of generic lisdexamfetamine dimesylate capsules, 20 mg, 30  
28 mg, 40 mg, 50 mg, 60 mg, and 70 mg, for oral administration (“the Watson Proposed

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1 Product”).

2 15. Watson sent a letter to Shire LLC, Shire Development Inc., Shire  
3 Pharmaceuticals Inc., and Shire US Inc. purporting to provide notification that the  
4 Watson ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a  
5 “paragraph IV certification”) with regard to the ’486 patent, the ’735 patent, and the  
6 ’561 patent (“the Watson Notice Letter”).

7 16. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent  
8 holder of the filing of an ANDA containing a paragraph IV certification “include a  
9 detailed statement of the factual and legal basis of the opinion of the applicant that the  
10 patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(6)  
11 requires a paragraph IV notification to include “[a] detailed statement of the factual  
12 and legal basis of applicant’s opinion that the patent is not valid, unenforceable, or  
13 will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a  
14 patent alleged not to be infringed, a full and detailed explanation of why the claim is  
15 not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or  
16 unenforceable, a full and detailed explanation of the grounds supporting the  
17 allegation.” 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

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

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

25 19. The Watson Notice Letter does not address United States Patent No.  
26 7,655,630 (“the ’630 patent”); United States Patent No. 7,659,253 (“the ’253 patent”);  
27 U.S. Patent No. 7,659,254 (“the ’254 patent”); United States Patent No. 7,662,787  
28 (“the ’787 patent”); United States Patent No. 7,671,030 (“the ’030 patent”); United

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1 States Patent No. 7,671,031 (“the ’031 patent”); United States Patent No. 7,674,774  
2 (“the ’774 patent”); United States Patent No. 7,678,770 (“the ’770 patent”); United  
3 States Patent No. 7,678,771 (“the ’771 patent”); United States Patent No. 7,687,466  
4 (“the ’466 patent”); United States Patent No. 7,687,467 (“the ’467 patent”); United  
5 States Patent No. 7,718,619 (“the ’619 patent”); and United States Patent No.  
6 7,723,305 (“the ’305 patent”), each also listed in the Orange Book for Vyvanse®.

7 20. On information and belief, Watson made certifications under 21 U.S.C. §  
8 355(j)(2)(A)(vii)(III) (“a paragraph III certification”) for the ’630 patent, the ’253  
9 patent, the ’254 patent, the ’787 patent, the ’030 patent, the ’031 patent, the ’774  
10 patent, the ’770 patent, the ’771 patent, the ’466 patent, the ’467 patent, the ’619  
11 patent, and the ’305 patent.

12 21. On information and belief, Watson does not seek approval of the Watson  
13 ANDA before the expiration of the ’630 patent, the ’253 patent, the ’254 patent, the  
14 ’787 patent, the ’030 patent, the ’031 patent, the ’774 patent, the ’770 patent, the ’771  
15 patent, the ’466 patent, the ’467 patent, the ’619 patent, and the ’305 patent.

16 22. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), the Watson Notice Letter  
17 contained an Offer of Confidential Access to the Watson ANDA. Shire requested a  
18 copy of the Watson ANDA and samples of the Watson Proposed Product from  
19 Watson. Watson has not produced the Watson ANDA or any samples of Watson  
20 Proposed Product.

21 **FIRST COUNT**

22 **(Infringement of the ’486 Patent by Watson)**

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

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

27 25. Upon information and belief, Watson included a paragraph IV  
28 certification to the ’486 patent to obtain approval to engage in the commercial

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1 manufacture, use, sale, offer for sale and/or importation of the Watson Proposed  
2 Product before the expiration of the '486 patent.

3 26. Upon information and belief, Watson will commercially manufacture,  
4 sell, offer for sale, and/or import the Watson Proposed Product upon FDA approval.

5 27. Upon information and belief, as of the date of the Watson Notice Letter,  
6 Watson was aware of the statutory provisions and regulations set forth in 21 U.S.C. §  
7 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

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

14 29. Upon information and belief, Watson's commercial manufacture, use,  
15 sale, offer for sale and/or importation into the United States of the Watson Proposed  
16 Product that is the subject of ANDA No. 202818 will infringe one or more claims of  
17 the '486 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. §  
18 271(c).

19 30. Upon information and belief, Watson is aware of the existence of the  
20 '486 patent and acted without a reasonable basis for believing that it would not be  
21 liable for infringement of the '486 patent, thus rendering this case "exceptional" under  
22 35 U.S.C. § 285.

23 31. The acts of infringement set forth above will cause Shire irreparable  
24 harm for which it has no adequate remedy at law, unless Watson is preliminarily and  
25 permanently enjoined by this Court.

26 **SECOND COUNT**

27 **(Infringement of the '735 Patent by Watson)**

28 32. Shire repeats and realleges each of the foregoing paragraphs as if fully



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1 set forth herein.

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

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

8 35. Upon information and belief, Watson will commercially manufacture,  
9 sell, offer for sale, and/or import the Watson Proposed Product upon FDA approval.

10 36. Upon information and belief, as of the date of the Watson Notice Letter,  
11 Watson was aware of the statutory provisions and regulations set forth in 21 U.S.C. §  
12 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

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

19 38. Upon information and belief, Watson's commercial manufacture, use,  
20 sale, offer for sale and/or importation into the United States of the Watson Proposed  
21 Product that is the subject of ANDA No. 202818 will infringe one or more claims of  
22 the '735 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. §  
23 271(c).

24 39. Upon information and belief, Watson is aware of the existence of the  
25 '735 patent and acted without a reasonable basis for believing that it would not be  
26 liable for infringement of the '735 patent, thus rendering this case "exceptional" under  
27 35 U.S.C. § 285.

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

1 harm for which it has no adequate remedy at law, unless Watson is preliminarily and  
2 permanently enjoined by this Court.

3 **THIRD COUNT**

4 **(Infringement of the '561 Patent by Watson)**

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

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

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

13 44. Upon information and belief, Watson will commercially manufacture,  
14 sell, offer for sale, and/or import the Watson Proposed Product upon FDA approval.

15 45. Upon information and belief, as of the date of the Watson Notice Letter,  
16 Watson was aware of the statutory provisions and regulations set forth in 21 U.S.C. §  
17 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

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

24 47. Upon information and belief, Watson's commercial manufacture, use,  
25 sale, offer for sale and/or importation into the United States of the Watson Proposed  
26 Product that is the subject of ANDA No. 202818 will infringe one or more claims of  
27 the '561 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. §  
28 271(c).

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1 48. Upon information and belief, Watson is aware of the existence of the  
2 '561 patent and acted without a reasonable basis for believing that it would not be  
3 liable for infringement of the '561 patent, thus rendering this case "exceptional" under  
4 35 U.S.C. § 285.

5 49. The acts of infringement set forth above will cause Shire irreparable  
6 harm for which it has no adequate remedy at law, unless Watson is preliminarily and  
7 permanently enjoined by this Court.

8 **PRAYER FOR RELIEF**

9 WHEREFORE, Plaintiffs respectfully request the following relief:

- 10 1. A judgment declaring that the '486 patent is valid and enforceable;
- 11 2. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the  
12 submission to the FDA and filing of ANDA No. 202818 with a paragraph IV  
13 certification to obtain approval for the commercial manufacture, use, sale, offer for  
14 sale and/or importation in the United States of the product that is the subject of  
15 ANDA No. 202818 was an act of infringement of the '486 patent by Watson directly  
16 and/or indirectly, including by inducement and/or contributory infringement;
- 17 3. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. §  
18 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for  
19 sale and/or importation in the United States of the product that is the subject of  
20 ANDA No. 202818 prior to the expiration of the '486 patent, including any regulatory  
21 extensions, will constitute an act of infringement by Watson directly and/or indirectly,  
22 including by inducement and/or contributory infringement;
- 23 4. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of  
24 any approval of the product that is the subject of ANDA No. 202818 shall be no  
25 earlier than the date on which the '486 patent expires including any regulatory  
26 extensions;
- 27 5. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and  
28 permanently enjoining Watson and their officers, agents, servants, employees and

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1 attorneys, and those persons in active concert or participation or privity with them or  
2 any of them, from engaging in the commercial manufacture, use, sale, offer to sale  
3 and/or importation in the United States of the product that is the subject of ANDA No.  
4 202818 until the expiration of the '486 patent including any regulatory extensions;

5 6. A judgment awarding Shire damages or other monetary relief, pursuant  
6 to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Watson commercially manufactures, uses,  
7 sells, offers to sell and/or imports any product that is the subject of ANDA No.  
8 202818 that infringes the '486 patent;

9 7. A judgment declaring that infringement of the '486 patent is willful if  
10 Watson commercially manufactures, uses, sells, offers to sell and/or imports any  
11 product that is the subject of ANDA No. 202818 that infringes the '486 patent;

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

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

19 10. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. §  
20 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for  
21 sale and/or importation in the United States of the product that is the subject of  
22 ANDA No. 202818 prior to the expiration of the '735 patent, including any regulatory  
23 extensions, will constitute an act of infringement by Watson directly and/or indirectly,  
24 including by inducement and/or contributory infringement;

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

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1 12. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and  
2 permanently enjoining Watson and their officers, agents, servants, employees and  
3 attorneys, and those persons in active concert or participation or privity with them or  
4 any of them, from engaging in the commercial manufacture, use, sale, offer to sale  
5 and/or importation in the United States of the product that is the subject of ANDA No.  
6 202818 until the expiration of the '735 patent including any regulatory extensions;

7 13. A judgment awarding Shire damages or other monetary relief, pursuant  
8 to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Watson commercially manufactures, uses,  
9 sells, offers to sell and/or imports any product that is the subject of ANDA No.  
10 202818 that infringes the '735 patent;

11 14. A judgment declaring that infringement of the '735 patent is willful if  
12 Watson commercially manufactures, uses, sells, offers to sell and/or imports any  
13 product that is the subject of ANDA No. 202818 that infringes the '735 patent;

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

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

21 17. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. §  
22 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for  
23 sale and/or importation in the United States of the product that is the subject of  
24 ANDA No. 202818 prior to the expiration of the '561 patent, including any regulatory  
25 extensions, will constitute an act of infringement by Watson directly and/or indirectly,  
26 including by inducement and/or contributory infringement;

27 18. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of  
28 any approval of the product that is the subject of ANDA No. 202818 shall be no

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1 earlier than the date on which the '561 patent expires including any regulatory  
2 extensions;

3 19. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and  
4 permanently enjoining Watson and their officers, agents, servants, employees and  
5 attorneys, and those persons in active concert or participation or privity with them or  
6 any of them, from engaging in the commercial manufacture, use, sale, offer to sale  
7 and/or importation in the United States of the product that is the subject of ANDA No.  
8 202818 until the expiration of the '561 patent including any regulatory extensions;

9 20. A judgment awarding Shire damages or other monetary relief, pursuant  
10 to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Watson commercially manufactures, uses,  
11 sells, offers to sell and/or imports any product that is the subject of ANDA No.  
12 202818 that infringes the '561 patent;

13 21. A judgment declaring that infringement of the '561 patent is willful if  
14 Watson commercially manufactures, uses, sells, offers to sell and/or imports any  
15 product that is the subject of ANDA No. 202818 that infringes the '561 patent;

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

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

19 DATED: July 6, 2011

HENNIGAN DORMAN LLP  
FROMMER LAWRENCE & HAUG LLP

22  
23 By:   
Mieke K. Malmberg

24 Attorneys for Plaintiffs SHIRE LLC and  
25 SHIRE DEVELOPMENT INC.