IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

SHIRE LLC and
SHIRE DEVELOPMENT INC.

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC. and
MYLAN INC.

Defendants.

CV 11 - 3414

C.A. No. _____

MAUSKOPF, J.
POHORELSKY, M.J.

COMPLAINT

Plaintiffs Shire LLC and Shire Development Inc. (collectively "Shire"), by its undersigned attorneys, for its Complaint against defendants Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively "Mylan") 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. 7,700,561 ("the '561 patent") (attached as Exhibit A 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 Inc. 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, Mylan Pharmaceuticals, Inc. is a corporation

organized and existing under the laws of the State of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

5. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

6. Upon information and belief, Mylan Pharmaceuticals, Inc. is a wholly-owned subsidiary of Mylan Inc.

7. Upon information and belief, Mylan Pharmaceuticals, Inc. acts at the direction of, under the control of, and for the direct benefit of Mylan Inc. and is controlled and/or dominated by Mylan Inc.

JURISDICTION AND VENUE

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

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

10. This Court has personal jurisdiction over Mylan Inc. because, inter alia, of its continuous and systematic contacts with this judicial district. Upon information and belief, Mylan Inc. markets, sells, and/or distributes pharmaceutical products in this judicial district through one or more of its wholly-owned subsidiaries, including Mylan Pharmaceuticals, Inc. Mylan Inc.'s 2008 Annual Report stated, "[Mylan Pharmaceuticals, Inc.] is our primary U.S.

pharmaceutical research, development, manufacturing, marketing and distribution subsidiary."

11. Upon information and belief Mylan Pharmaceuticals, Inc. and Mylan Inc. worked in concert to prepare, submit, and file Abbreviated New Drug Application ("ANDA") No. 202835 ("the Mylan 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 Mylan Proposed Product").

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

FACTS AS TO ALL COUNTS

13. Shire Development Inc. is the 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").

14. Pursuant to 21 U.S.C. § 355(b)(1), the '561 patent ("the Patent-in-Suit") is listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering the Vyvanse® product.

15. Shire LLC has been assigned, and currently owns, the rights to the Patent-in-Suit.

16. 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.

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

18. 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).

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

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

21. The Mylan Notice Letter does not address United States Patent No. 7,105,486 ("the '486 patent"), U.S. Patent No. 7,223,735 ("the '735 patent"), U.S. 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®.

22. On information and belief, Mylan made certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("a paragraph III certification") for the '486 patent, the '735 patent, 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.

23. On information and belief, Mylan does not seek approval of the Mylan ANDA before the expiration of the '486 patent, the '735 patent, 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.

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

FIRST COUNT
(Infringement of the '561 Patent by Mylan)

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

set forth herein.

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

27. Upon information and belief, Mylan 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 Mylan Proposed Product before the expiration of the '561 patent.

28. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon FDA approval.

29. Upon information and belief, as of the date of the Mylan Notice Letter, Mylan 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).

30. The inclusion of a paragraph IV certification to the '561 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '561 patent is an act of infringement by Mylan 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.

31. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 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).

32. Upon information and belief, Mylan is aware of the existence of the '561

patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '561 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following relief:

i. A judgment declaring that the '561 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. 202835 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. 202835 was an act of infringement of the '561 patent by Mylan directly and/or indirectly, including by inducement and/or contributory infringement;

iii. 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. 202835 prior to the expiration of the '561 patent, including any regulatory extensions, will constitute an act of infringement by Mylan 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. 202835 shall be no earlier than the date

on which the '561 patent expires including any regulatory extensions;

v. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Mylan 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. 202835 until the expiration of the '561 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 Mylan commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202835 that infringes the '561 patent;

vii. A judgment declaring that infringement of the '561 patent is willful if Mylan commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202835 that infringes the '561 patent;

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

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

Respectfully submitted,

Sandra Kuzmich /sw

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