IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

SHIRE LLC, SUPERNUS PHARMACEUTICALS, INC., SHIRE DEVELOPMENT INC., SHIRE INTERNATIONAL LICENSING B.V., AMY F.T. ARNSTEN, PH.D., ROBERT D. HUNT, M.D., and PASKO RAKIC, M.D., Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	C. A. No. _____

COMPLAINT

Plaintiffs Shire LLC; Supernus Pharmaceuticals, Inc.; Shire Development Inc.; Shire International Licensing B.V.; Amy F.T. Arnsten, Ph.D.; Robert D. Hunt, M.D.; and Pasko Rakic, M.D. (collectively, "Plaintiffs"), for their Complaint against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Defendants" or "Mylan"), hereby allege as follows:

1. Shire LLC ("Shire") is a corporation organized and existing under the laws of the State of Kentucky, having a principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

2. Supernus Pharmaceuticals, Inc. ("Supernus") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

3. Shire Development Inc. ("SDI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 725 Chesterbrook Boulevard, Wayne, Pennsylvania 19087.

4. Shire International Licensing B.V. ("SILBV") is a corporation organized and existing under the laws of The Netherlands, having a principal place of business at Strawinskylaan 847, 1077 XX Amsterdam, The Netherlands.

5. Amy F.T. Arnsten, Ph.D. ("Dr. Arnsten") is an individual with a principal place of business at Yale University School of Medicine, 333 Cedar Street, New Haven, Connecticut 06510.

6. Robert D. Hunt, M.D. ("Dr. Hunt") is an individual with a principal place of business at Center for Attention and Hyperactive Disorders, 2129 Belcourt Avenue, Nashville, Tennessee 37212.

7. Pasko Rakic, M.D. ("Dr. Rakic") is an individual with a principal place of business at Yale University School of Medicine, 333 Cedar Street, New Haven, Connecticut 06510.

8. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharma") is a West Virginia corporation, and a wholly-owned subsidiary and agent of Defendant Mylan Inc. ("Mylan Inc.") having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Defendant Mylan

Pharma manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

9. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Upon information and belief, Defendant Mylan Inc., itself and through its wholly-owned subsidiary and agent Defendant Mylan Pharma, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

10. This is a civil action for infringement of U.S. Patent Nos. 6,287,599 B1 ("the '599 patent"), 6,811,794 B2 ("the '794 patent"), and 5,854,290 ("the '290 patent") (Exhibits A, B, and C, respectively). This action is based upon the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*.

JURISDICTION AND VENUE

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

12. This Court has personal jurisdiction over Defendant Mylan Pharma, by virtue of, *inter alia*, its incorporation under the laws of the State of West Virginia, and because it maintains its principal place of business in the State of West Virginia.

13. Upon information and belief, Defendants Mylan Inc. and Mylan Pharma share common employees, officers, and/or directors.

14. Upon information and belief, Defendants are in the business of developing, manufacturing, marketing, and selling generic drugs. Upon information and belief, Defendant Mylan Inc. conducts its North American operations, in part, through Defendant Mylan

Pharma. Upon information and belief, Defendants collaborate in developing, manufacturing, marketing, and selling generic drugs throughout the United States, including in this judicial district.

15. Upon information and belief, Defendant Mylan Inc., through its own actions and the actions of one or more its subsidiaries, actively engages in the concerted effort to sell generic drugs throughout the United States, including this judicial district.

16. This Court has personal jurisdiction over Defendant Mylan Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of West Virginia, including through its wholly-owned subsidiary and agent Defendant Mylan Pharma, a West Virginia corporation. Furthermore, Defendant Mylan Inc. is registered to do business in the State of West Virginia and has appointed a registered agent for service of process in the State of West Virginia. Defendant Mylan Inc. (formerly known as Mylan Laboratories Inc.) has also previously availed itself of this Court by asserting counterclaims arising under the patent laws of the United States in other civil actions initiated in this jurisdiction. *See, e.g., Shire LLC v. Mylan Pharms. Inc., et al.*, C.A. No. 11-00055-IMK; *Novartis Pharms. Corp. v. Mylan Pharms. Inc., et al.*, C.A. No. 11-00015-IMK; *Alza Corp. v. Mylan Labs. Inc., et al.*, C.A. No. 03-00158-IMK.

17. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

THE PATENTS-IN-SUIT

18. On September 11, 2001, the '599 patent, titled "Sustained Release Pharmaceutical Dosage Forms with Minimized pH Dependent Dissolution Profiles," was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). Supernus is the record owner of the '599 patent. Shire has an exclusive license under the '599 patent with regard to pharmaceutical products containing the active ingredient guanfacine or salts thereof.

19. On November 2, 2004, the '794 patent, titled "Sustained Release Pharmaceutical Dosage Forms with Minimized pH Dependent Dissolution Profiles," was duly and legally issued by the USPTO. Supernus is the record owner of the '794 patent. Shire has an exclusive license under the '794 patent with regard to pharmaceutical products containing the active ingredient guanfacine or salts thereof.

20. On December 29, 1998, the '290 patent, titled "Use of Guanfacine in the Treatment of Behavioral Disorders," was duly and legally issued by the USPTO. Dr. Arnsten, Dr. Hunt, and Dr. Patricia S. Goldman-Rakic are the record owners of the '290 patent. Dr. Rakic is Dr. Patricia S. Goldman-Rakic's lawful heir and successor in interest. SILBV has an exclusive license under the '290 patent.

21. SDI holds New Drug Application ("NDA") No. 022037 for guanfacine hydrochloride extended-release tablets, 1 mg, 2 mg, 3 mg, and 4 mg. Shire markets these tablets in the United States under the trade name "INTUNIV®." The '599 patent, the '794 patent, and the '290 patent are listed in the U.S. Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for INTUNIV®.

ACTS GIVING RISE TO THIS ACTION

22. Upon information and belief, Defendant Mylan Pharma, on behalf of itself and as agent for Defendant Mylan Inc., submitted Abbreviated New Drug Application ("ANDA") No. 202-578 ("Mylan's original ANDA") to the FDA under § 505(j)(1) and (2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Mylan's original ANDA sought FDA approval for the commercial manufacture, use, and sale of 4 mg guanfacine hydrochloride extended-release tablets ("Mylan's 4 mg ANDA Product"). Upon information and belief, Mylan's original ANDA specifically sought FDA approval to

market Mylan's 4 mg ANDA Product prior to the expiration of the '599 patent and the '794 patent.

23. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Defendant Mylan Pharma certified in its original ANDA that the claims of the '599 patent and '794 patent will not be infringed by the manufacture, use, or sale of Mylan's 4 mg ANDA Product. Defendants provided written notification of Mylan's original ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by sending each of Shire Pharmaceuticals Inc., Supernus, and SDI letters bearing the date February 8, 2011.

24. On April 20, 2011, Plaintiffs Shire and Supernus filed suit in this District against Defendants Mylan Inc. and Mylan Pharma for infringement of the '599 patent and the '794 patent, based, *inter alia*, upon Defendant Mylan Pharma's written notification of its filing of Mylan's original ANDA, directed to Mylan's 4 mg ANDA Product, and its accompanying § 505(j)(2)(A)(vii)(IV) certification, directed to the '599 patent and the '794 patent. *See Shire LLC v. Mylan Pharms. Inc., et al.*, C.A. No. 11-00055-IMK.

25. Defendant Mylan Inc. has relied upon its own activities and the activities of its wholly-owned subsidiary and agent Defendant Mylan Pharma in the filing of its original ANDA to affirmatively assert its own declaratory judgment counterclaims in *Shire LLC v. Mylan Pharms. Inc., et al.*, C.A. No. 11-00055-IMK.

26. Upon information and belief, Defendant Mylan Pharma, on behalf of itself and as agent for Defendant Mylan Inc., subsequently submitted an amendment to ANDA No. 202-578 ("Mylan's amended ANDA") to the FDA under § 505(j)(1) and (2)(A) of the Federal Food, Drug, and Cosmetic Act. Upon information and belief, Mylan's amended ANDA seeks FDA approval for the commercial manufacture, use, and sale of three additional dosages (1 mg,

2 mg, and 3 mg) of guanfacine hydrochloride extended-release tablets ("Mylan's 1 mg, 2 mg, and 3 mg ANDA Products"), in addition to Mylan's 4 mg ANDA Product that was the subject of Mylan's original ANDA (collectively, "Mylan's ANDA Products").

27. Upon information and belief, Mylan's amended ANDA specifically seeks FDA approval to market Mylan's ANDA Products prior to the expiration of the '599 patent, the '794 patent, and, additionally, the '290 patent.

28. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Defendant Mylan Pharma certified in its amended ANDA that the claims of the '599 patent, the '794 patent, and, additionally, the '290 patent will not be infringed by the manufacture, use, or sale of Mylan's ANDA Products. Defendants provided written notification of the amendment to Mylan's ANDA No. 202-578 and its accompanying § 505(j)(2)(A)(vii)(IV) certification ("Mylan's Second Notice Letter") by sending each of Shire, Supernus, SDI, Dr. Arnsten, Dr. Hunt, and Dr. Rakic letters bearing the date October 31, 2011.

29. Plaintiffs have commenced this action with forty-five days of receipt of Mylan's Second Notice Letter.

COUNT 1 – INFRINGEMENT OF THE '599 PATENT

30. Plaintiffs reallege Paragraphs 1-29 as if fully set forth herein.

31. Defendant Mylan Pharma's submission of Mylan's amended ANDA to the FDA, on behalf of itself and as agent for Defendant Mylan Inc., constitutes infringement of the '599 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Defendant Mylan Pharma commercially manufactures, uses, offers to sell, sells, or imports Mylan's 1 mg, 2 mg, and 3 mg ANDA Products, or induces or contributes to any such conduct, Defendant Mylan Pharma would further infringe the '599 patent under 35 U.S.C. §271(a), (b), and/or (c).

32. Defendant Mylan Inc. is jointly and severally liable for Defendant Mylan Pharma's infringement of the '599 patent. Upon information and belief, Defendant Mylan Inc. participated in, contributed to, aided, abetted, and/or induced Defendant Mylan Pharma's submission of Mylan's amended ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification to the FDA. Defendant Mylan Inc.'s participation in, contribution to, aiding, abetting, and/or inducement of the submission of Mylan's amended ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification to the FDA constitutes infringement of the '599 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Defendant Mylan Inc. commercially manufactures, uses, offers to sell, sells, or imports Mylan's 1 mg, 2 mg, and 3 mg ANDA Products, or induces or contributes to any such conduct, Defendant Mylan Inc. would further infringe the '599 patent under 35 U.S.C. §271(a), (b), and/or (c).

33. Defendants Mylan Inc. and Mylan Pharma were aware of the existence of the '599 patent prior to filing Mylan's amended ANDA.

34. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 2 – INFRINGEMENT OF THE '794 PATENT

35. Plaintiffs reallege Paragraphs 1-29 as if fully set forth herein.

36. Defendant Mylan Pharma's submission of Mylan's amended ANDA to the FDA, on behalf of itself and as agent for Defendant Mylan Inc., constitutes infringement of the '794 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Defendant Mylan Pharma commercially manufactures, uses, offers to sell, sells, or imports Mylan's 1 mg, 2 mg, and 3 mg ANDA Products, or induces or contributes to any such conduct, Defendant Mylan Pharma would further infringe the '794 patent under 35 U.S.C. §271(a), (b), and/or (c).

37. Defendant Mylan Inc. is jointly and severally liable for Defendant Mylan Pharma's infringement of the '794 patent. Upon information and belief, Defendant Mylan Inc. participated in, contributed to, aided, abetted, and/or induced Defendant Mylan Pharma's submission of Mylan's amended ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification to the FDA. Defendant Mylan Inc.'s participation in, contribution to, aiding, abetting, and/or inducement of the submission of Mylan's amended ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification to the FDA constitutes infringement of the '794 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Defendant Mylan Inc. commercially manufactures, uses, offers to sell, sells, or imports Mylan's 1 mg, 2 mg, and 3 mg ANDA Products, or induces or contributes to any such conduct, Defendant Mylan Inc. would further infringe the '794 patent under 35 U.S.C. §271(a), (b), and/or (c).

38. Defendants Mylan Inc. and Mylan Pharma were aware of the existence of the '794 patent prior to filing Mylan's amended ANDA.

39. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 3 – INFRINGEMENT OF THE '290 PATENT

40. Plaintiffs reallege Paragraphs 1-29 as if fully set forth herein.

41. Defendant Mylan Pharma's submission of Mylan's amended ANDA to the FDA, on behalf of itself and as agent for Defendant Mylan Inc., constitutes infringement of the '290 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Defendant Mylan Pharma commercially manufactures, uses, offers to sell, sells, or imports Mylan's ANDA Products, or induces or contributes to any such conduct, Defendant Mylan Pharma would further infringe the '290 patent under 35 U.S.C. §271(a), (b), and/or (c).

42. Defendant Mylan Inc. is jointly and severally liable for Defendant Mylan Pharma's infringement of the '290 patent. Upon information and belief, Defendant Mylan Inc. participated in, contributed to, aided, abetted, and/or induced Defendant Mylan Pharma's submission of Mylan's amended ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification to the FDA. Defendant Mylan Inc.'s participation in, contribution to, aiding, abetting, and/or inducement of the submission of Mylan's amended ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification to the FDA constitutes infringement of the '290 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Defendant Mylan Inc. commercially manufactures, uses, offers to sell, sells, or imports Mylan's ANDA Products, or induces or contributes to any such conduct, Defendant Mylan Inc. would further infringe the '290 patent under 35 U.S.C. §271(a), (b), and/or (c).

43. Defendants Mylan Inc. and Mylan Pharma were aware of the existence of the '290 patent prior to filing Mylan's amended ANDA.

44. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendants have infringed the '599 patent, the '794 patent, and the '290 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mylan's amended ANDA shall not be earlier than the expiration date of the last to expire of the '599 patent, the '794 patent, or the '290 patent, or any later expiration of any

patent term extension or exclusivity for the '599 patent, the '794 patent, or the '290 patent to which Plaintiffs are or become entitled;

C. That Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from engaging in the commercial manufacture, use, offer to sell, or sale within the United States and its territories, or importation into the United States and its territories, of Mylan's ANDA Products identified in this Complaint, and any other products that infringe the '599 patent, the '794 patent, and the '290 patent prior to the expiration date of the last to expire of the '599 patent, the '794 patent, or the '290 patent, or any later expiration of any patent term extension or exclusivity for the '599 patent, the '794 patent, or the '290 patent to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur in prosecuting this action; and

E. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: December 15, 2011

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/s/ John Porco

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