IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No.: _____

SHIRE LLC, SUPERNUS PHARMACEUTICALS, INC., SHIRE DEVELOPMENT INC., SHIRE INTERNATIONAL LICENSING B.V., AMY F.T. ARNSTEN, PH.D., PASKO RAKIC, M.D., and ROBERT D. HUNT, M.D., Plaintiffs, v. SANDOZ INC. Defendant.	)

COMPLAINT

Plaintiffs Shire LLC, Supernus Pharmaceuticals, Inc. ("Supernus"), Shire Development Inc., Shire International Licensing B.V., Amy F.T. Arnsten, Ph.D. ("Dr. Arnsten"), Pasko Rakic, M.D. ("Dr. Rakic"), and Robert D. Hunt, M.D. ("Dr. Hunt") (collectively "Plaintiffs"), by their attorneys, for their Complaint against defendant Sandoz Inc. ("Sandoz") 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 Nos. 5,854,290 ("the '290 patent"), 6,287,599 ("the '599 patent") and 6,811,794 ("the '794 patent") (attached as Exhibits 1, 2, and 3 respectively hereto) (collectively "the patents-in-suit").

THE PARTIES

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

3. Plaintiff Supernus is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

4. 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.

5. Plaintiff Shire International Licensing B.V. 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.

6. Plaintiff Dr. Arnsten is an individual with a principal place of business at Yale University School of Medicine, 333 Cedar Street, New Haven, Connecticut 06510.

7. Plaintiff 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. Plaintiff Dr. Hunt is an individual with a principal place of business at Center for Attention and Hyperactive Disorders, 2129 Belcourt Avenue, Nashville, Tennessee 37212.

9. Upon information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Colorado, having its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over Sandoz. Sandoz has submitted to personal jurisdiction in this Court because, *inter alia*, it is a resident and citizen of the State of Colorado and has availed itself of the rights and benefits of the laws of Colorado by virtue of incorporating in Colorado, and engaging in systematic and continuous contacts with the State of Colorado.

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. 022037, which was approved by the FDA for the manufacture and sale of guanfacine hydrochloride extended release tablets, Eq. 1 mg Base, Eq. 2 mg Base, Eq. 3 mg Base, and Eq. 4 mg Base, which is marketed under the name of Intuniv®. Intuniv® is indicated for the treatment of Attention Deficit Hyperactivity Disorder.

14. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering Intuniv®.

15. Sandoz prepared and submitted Abbreviated New Drug Application ("ANDA") No. 202568 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 guanfacine hydrochloride extended release tablets, 4 mg.

16. By a letter dated March 14, 2011 Sandoz provided a Notification and Certification, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B) (a "paragraph IV" certification), with respect to its intention to manufacture a 4 mg product only. That certification resulted in the related lawsuit: Shire LLC v. Sandoz, Inc., Civ. Action No. 1:11-cv-01110 PAB-KMT.

17. On information and belief, Sandoz amended ANDA No. 202568 ("Sandoz's Amended ANDA") to seek approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic guanfacine hydrochloride extended release tablets in 1 mg, 2 mg, and 3 mg strengths ("Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products").

18. Sandoz sent Notifications, dated November 22, 2011, purportedly pursuant to § 505(j)(2)(B)(ii) of the FDCA, regarding Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products ("Sandoz's Notice Letters").

19. Plaintiffs, through their attorneys Frommer Lawrence & Haug LLP, requested that Sandoz provide confidential access to Sandoz's Amended ANDA regarding the 1 mg, 2 mg, and 3 mg products, but Sandoz did not grant such access and also did not provide detailed formulation or other information that would aid Plaintiffs' pre-suit investigation.

20. Plaintiffs believe that infringement of valid patent claims exists, but must resort to the judicial process to fully assess Sandoz's potential defenses to Plaintiffs' claims since Plaintiffs were denied access to Sandoz's Amended ANDA and were given extremely limited information in the November 22, 2011 Notice Letters. See, e.g., 21 U.S.C. § 355(j)(2)(B)(iv)(II); 21 C.F.R. § 314.95(c)(6) (requiring a detailed statement).

FIRST COUNT
(Infringement of the '290 Patent by Sandoz)

21. Shire LLC, Shire International Licensing B.V., Dr. Arnsten, Dr. Rakic and Dr. Hunt repeat and re-allege paragraphs 1-20 above as if fully set forth herein.

22. The '290 patent, entitled "Use of guanfacine in the treatment of behavioral

disorders," was duly and legally issued on December 29, 1998 to Yale University, upon assignment from Dr. Arnsten and Dr. Goldman-Rakic, and to Dr. Hunt. Yale University later assigned its rights in the '290 patent back to Dr. Arnsten and Dr. Goldman-Rakic. Dr. Rakic (the spouse of Dr. Goldman-Rakic) succeeded to the interest of Dr. Goldman-Rakic upon Dr. Goldman-Rakic's death. Dr. Arnsten, Dr. Goldman-Rakic and Dr. Hunt granted Shire International Licensing B.V. an exclusive license under the '290 patent with respect to, *inter alia*, drug products containing the active ingredient guanfacine and its derivatives. Shire LLC is exclusively distributing Intuniv® in the United States.

23. Upon information and belief, Sandoz seeks FDA approval for the manufacture and/or distribution of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products.

24. Upon information and belief, Sandoz's Amended ANDA includes paragraph IV certifications to the '290 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products before the expiration of the '290 patent.

25. Upon information and belief, Sandoz will commercially manufacture, sell, offer for sale, and/or import Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products immediately upon FDA approval.

26. Upon information and belief, as of the date of Sandoz's Notice Letters, Sandoz 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).

27. The submission and filing of Sandoz's Amended ANDA with paragraph IV certifications to the '290 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products before the expiration of the '290 patent is an act of infringement by

Sandoz of one or more claims of the '290 patent under 35 U.S.C. § 271(e)(2)(A).

28. Upon information and belief, the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products that are the subject of Sandoz's Amended ANDA will infringe one or more claims of the '290 patent. However, Sandoz has failed to provide information necessary for Plaintiffs to fully determine the issue. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Sandoz infringes one or more claims of the '290 patent.

29. Upon information and belief, the sale and/or offer for sale of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products by Sandoz would induce and/or contribute to third-party infringement of one or more claims of the '290 patent under 35 U.S.C. § 271(b) and/or (c) and Sandoz would be the prime mover in the chain of events leading to that infringement.

30. Upon information and belief, as of the date of Sandoz's Notice Letters, Sandoz was aware of the existence of the '290 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '290 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

31. The acts of infringement set forth above will cause Shire LLC, Shire International Licensing B.V., Dr. Arnsten, Dr. Rakic and Dr. Hunt irreparable harm for which none have adequate remedy at law, unless Sandoz is preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Infringement of the '599 Patent by Sandoz)

32. Shire LLC and Supernus repeat and re-allege paragraphs 1-31 above as if fully set forth herein.

33. The '599 patent, entitled "Sustained release pharmaceutical dosage forms with minimized pH dependent dissolution profiles," was duly and legally issued on September 11, 2001 to Shire Laboratories, Inc. ("Shire Labs") upon assignment from Beth A. Burnside, Rong-Kun Chang and Xiaodi Guo. Supernus became the owner of the '599 patent upon assignment from Shire Labs. Supernus granted Shire LLC an exclusive license under the '599 patent with respect to, *inter alia*, drug products containing the active ingredient guanfacine, or salts thereof.

34. Upon information and belief, Sandoz seeks FDA approval for the manufacture and/or distribution of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products.

35. Upon information and belief, Sandoz's Amended ANDA includes paragraph IV certifications to the '599 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products before the expiration of the '599 patent.

36. Upon information and belief, Sandoz will commercially manufacture, sell, offer for sale, and/or import Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products immediately upon FDA approval.

37. Upon information and belief, as of the date of Sandoz's Notice Letters, Sandoz 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).

38. The submission and filing of Sandoz's Amended ANDA with paragraph IV certifications to the '599 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products before the expiration of the '599 patent is an act of infringement by Sandoz of one or more claims of the '599 patent under 35 U.S.C. § 271(e)(2)(A).

39. Upon information and belief, Sandoz's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products that are the subject of Sandoz's Amended ANDA will infringe one or more claims of the '599 patent. However, Sandoz has failed to provide information necessary for Shire LLC and Supernus to fully determine the issue. In the absence of such information, Shire LLC and Supernus must resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Sandoz infringes one or more claims of the '599 patent.

40. Upon information and belief, as of the date of Sandoz's Notice Letters, Sandoz was aware of the existence of the '599 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '599 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

41. The acts of infringement set forth above will cause Shire LLC and Supernus irreparable harm for which neither has adequate remedy at law, unless Sandoz is preliminarily and permanently enjoined by this Court.

THIRD COUNT
(Infringement of the '794 Patent by Sandoz)

42. Shire LLC and Supernus repeat and re-allege paragraphs 1-41 above as if fully set forth herein.

43. The '794 patent, entitled "Sustained release pharmaceutical dosage forms with minimized pH dependent dissolution profiles," was duly and legally issued on November 2, 2004 to Shire Labs upon assignment from Beth A. Burnside, Rong-Kun Chang and Xiaodi Guo. Supernus became the owner of the '794 patent upon assignment from Shire Labs. Supernus granted Shire LLC an exclusive license under the '794 patent with respect to, *inter alia*, drug products containing the active ingredient guanfacine or salts thereof.

44. Upon information and belief, Sandoz seeks FDA approval for the manufacture and/or distribution of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products.

45. Upon information and belief, Sandoz's Amended ANDA includes paragraph IV certifications to the '794 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products before the expiration of the '794 patent.

46. Upon information and belief, Sandoz will commercially manufacture, sell, offer for sale, and/or import Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products immediately upon FDA approval.

47. Upon information and belief, as of the date of Sandoz's Notice Letters, Sandoz 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).

48. The submission and filing of Sandoz's Amended ANDA with paragraph IV certifications to the '794 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products before the expiration of the '794 patent is an act of infringement by Sandoz of one or more claims of the '794 patent under 35 U.S.C. § 271(e)(2)(A).

49. Upon information and belief, Sandoz's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products that are the subject of Sandoz's Amended ANDA will infringe one or more claims of the '794 patent. However, Sandoz has failed to provide information necessary for Shire LLC and Supernus to fully determine the issue. In the absence of such information, Shire LLC and Supernus must resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to

present to the Court evidence that Sandoz infringes one or more claims of the '794 patent.

50. Upon information and belief, the sale or offer for sale of Sandoz's 1 mg, 2 mg, and 3 mg Proposed Products by Sandoz would induce and/or contribute to third-party infringement of one or more claims of the '794 patent under 35 U.S.C. § 271(b) and/or (c) and Sandoz would be the prime mover in the chain of events leading to that infringement.

51. Upon information and belief, as of the date of Sandoz's Notice Letters, Sandoz was aware of the existence of the '794 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '794 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

52. The acts of infringement set forth above will cause Shire LLC and Supernus irreparable harm for which neither has adequate remedy at law, unless Sandoz is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the '290 patent is valid and enforceable;

(b) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission and filing of Sandoz's Amended ANDA with paragraph IV certifications to the FDA to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of Sandoz's Amended ANDA, prior to the expiration of the '290 patent, was an act of infringement of the '290 patent by Sandoz;

(c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A) and/or 35 U.S.C. § 271(a), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of Sandoz's Amended ANDA, prior to the expiration of the '290 patent, will constitute an act of infringement of the '290 patent by Sandoz;

(d) 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 products that are the subject of Sandoz's Amended ANDA by Sandoz would induce and/or contribute to third-party infringement of the '290 patent;

(e) An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the products that are the subject of Sandoz's Amended ANDA shall be no earlier than the date on which the '290 patent expires;

(f) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Sandoz, its 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, offering to sell and/or importation in the United States of the products that are the subject of Sandoz's Amended ANDA until the expiration of the '290 patent;

(g) A judgment awarding Shire LLC and Shire International Licensing B.V. damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Sandoz commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of Sandoz's Amended ANDA prior to the expiration of the '290 patent;

(h) A judgment declaring that Sandoz's infringement of the '290 patent based on Sandoz's Amended ANDA is willful if Sandoz commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of Sandoz's Amended ANDA prior to the expiration of the '290 patent;

(i) A judgment declaring that the '599 patent is valid and enforceable;

(j) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission and filing of Sandoz's Amended ANDA with paragraph IV certifications to the FDA

to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of Sandoz's Amended ANDA, prior to the expiration of the '599 patent, was an act of infringement of the '599 patent by Sandoz;

(k) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A) and/or 35 U.S.C. § 271(a), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of Sandoz's Amended ANDA, prior to the expiration of the '599 patent, will constitute an act of infringement of the '599 patent by Sandoz;

(l) An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the products that are the subject of Sandoz's Amended ANDA shall be no earlier than the date on which the '599 patent expires;

(m) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Sandoz, its 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, offering to sell and/or importation in the United States of the products that are the subject of Sandoz's Amended ANDA until the expiration of the '599 patent;

(n) A judgment awarding Shire LLC damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Sandoz commercially manufactures, uses, sells, offers to sell and/or imports any products that are the subject of Sandoz's Amended ANDA prior to the expiration of the '599 patent;

(o) A judgment declaring that Sandoz's infringement of the '599 patent based on Sandoz's Amended ANDA is willful if Sandoz commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of Sandoz's Amended ANDA prior to the expiration of the '599 patent;

(p) A judgment declaring that the '794 patent is valid and enforceable;

(q) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission and filing of Sandoz's Amended ANDA with paragraph IV certifications to the FDA to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of Sandoz's Amended ANDA, prior to the expiration of the '794 patent, was an act of infringement of the '794 patent by Sandoz;

(r) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A) and/or 35 U.S.C. § 271(a), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of Sandoz's Amended ANDA, prior to the expiration of the '794 patent, will constitute an act of infringement of the '794 patent by Sandoz;

(s) 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 products that are the subject of Sandoz's Amended ANDA by Sandoz would induce and/or contribute to third-party infringement of the '794 patent;

(t) An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the products that are the subject of Sandoz's Amended ANDA shall be no earlier than the date on which the '794 patent expires;

(u) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Sandoz, its 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, offering to sell and/or importation in the United States of the products that are the subject of Sandoz's Amended ANDA until the expiration of the '794 patent;

(v) A judgment awarding Shire LLC damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Sandoz commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of Sandoz's Amended ANDA prior to the expiration of the '794 patent;

(w) A judgment declaring that Sandoz's infringement of the '794 patent based on Sandoz's Amended ANDA is willful if Sandoz commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of Sandoz's Amended ANDA prior to the expiration of the '794 patent;

(x) A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Shire LLC and Shire International Licensing B.V. their attorneys' fees and costs;

(y) **Suc**h other and further relief as this Court may deem just and proper.

Dated: January 6, 2012

Respectfully submitted,

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