IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No.: _____

SHIRE LLC,	)
SUPERNUS PHARMACEUTICALS, INC.,	)
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 ("Shire"), Supernus Pharmaceuticals, Inc. ("Supernus"), Amy F.T. Arnsten, Ph.D. ("Dr. Arnsten"), Pasko Rakic, M.D. ("Dr. Rakic"), and Robert D. Hunt, M.D. ("Dr. Hunt"), 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 A, B, and C respectively hereto) (collectively "the patents-in-suit").

THE PARTIES

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

5. 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.

6. 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.

7. 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

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 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 to 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.

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

FACTS AS TO ALL COUNTS

11. 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.

12. 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.

13. Sandoz prepared and submitted Abbreviated New Drug Application ("ANDA") No. 202568 ("Sandoz's 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 guanfacine hydrochloride extended release tablets, 4 mg ("Sandoz's Proposed Product").

14. Sandoz sent notifications, dated March 14, 2011, purportedly pursuant to § 505(j)(2)(B)(ii) of the FDCA regarding Sandoz's Proposed Product ("Sandoz's Notice Letters").

15. 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).

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

16. Shire, Dr. Arnsten, Dr. Rakic and Dr. Hunt repeat and re-allege paragraphs 1-15 above as if fully set forth herein.

17. 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. Dr. Arnsten and Dr. Goldman-Rakic became the owners of the '290 patent upon assignment from Yale University. Dr. Rakic became the owner of the '290 patent as a successor-in-interest to Dr. Goldman-Rakic. Dr. Arnsten, Dr. Goldman-Rakic and Dr. Hunt granted Shire International Licensing BV an exclusive license under the '290 patent with respect to, *inter alia*, drug products containing the active ingredient guanfacine and its derivatives.

18. Upon information and belief, Sandoz seeks FDA approval for the manufacture and/or distribution of Sandoz's Proposed Product.

19. Upon information and belief, Sandoz's ANDA includes a paragraph IV certification to the '290 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Proposed Product before the expiration of the '290 patent.

20. Upon information and belief, Sandoz will commercially manufacture, sell, offer for sale, and/or import Sandoz's Proposed Product immediately upon FDA approval.

21. 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).

22. The submission and filing of ANDA No. 202568 with a paragraph IV certification 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 Proposed Product 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).

23. Upon information and belief, the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Proposed Product that is the subject of ANDA No. 202568 will infringe one or more claims of the '290 patent.

24. Upon information and belief, the sale or offer for sale of Sandoz's Proposed Product 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).

25. 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.

26. The acts of infringement set forth above will cause Shire, 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 Inc.)

27. Shire and Supernus repeat and re-allege paragraphs 1-15 above as if fully set forth herein.

28. 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 an exclusive license under the '599 patent with respect to, *inter alia*, drug products containing the active ingredient guanfacine or salts thereof.

29. Upon information and belief, Sandoz seeks FDA approval for the manufacture and/or distribution of Sandoz's Proposed Product.

30. Upon information and belief, Sandoz's ANDA includes a paragraph IV certification to the '599 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Proposed Product before the expiration of the '599 patent.

31. Upon information and belief, Sandoz will commercially manufacture, sell,

offer for sale, and/or import Sandoz's Proposed Product immediately upon FDA approval.

32. 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).

33. The submission and filing of ANDA No. 202568 with a paragraph IV certification 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 Proposed Product 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).

34. Upon information and belief, Sandoz's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Proposed Product that is the subject of ANDA No. 202568 will infringe one or more claims of the '599 patent.

35. 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.

36. The acts of infringement set forth above will cause Shire 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)

37. Shire and Supernus repeat and re-allege paragraphs 1-15 and 27-36 above as if fully set forth herein.

38. 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 an exclusive license under the '794 patent with respect to, *inter alia*, drug products containing the active ingredient guanfacine or salts thereof.

39. Upon information and belief, Sandoz seeks FDA approval for the manufacture and/or distribution of Sandoz's Proposed Product.

40. Upon information and belief, Sandoz's ANDA includes a paragraph IV certification to the '794 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Proposed Product before the expiration of the '794 patent.

41. Upon information and belief, Sandoz will commercially manufacture, sell, offer for sale, and/or import Sandoz's Proposed Product immediately upon FDA approval.

42. 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).

43. The submission and filing of ANDA No. 202568 with a paragraph IV certification 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 Proposed Product 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).

44. Upon information and belief, Sandoz's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Proposed Product that is the subject of ANDA No. 202568 will infringe one or more claims of the '794 patent.

45. Upon information and belief, the sale or offer for sale of Sandoz's Proposed Product 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).

46. 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.

47. The acts of infringement set forth above will cause Shire 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, Plaintiff respectfully requests 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 ANDA No. 202568 with a paragraph IV certification to the FDA 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. 202568 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 product that is the subject of ANDA No. 202568 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 product that is the subject of ANDA No. 202568 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 product that is the subject of ANDA No. 202568 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, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202568 until the expiration of the '290 patent;

(g) A judgment awarding Shire 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 ANDA No. 202568 prior to the expiration of the '290 patent;

(h) A judgment declaring that Sandoz's infringement of the '290 patent based on ANDA No. 202568 is willful if Sandoz commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202568 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 ANDA No. 202568 with a paragraph IV certification to the FDA 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. 202568 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 product that is the subject of ANDA No. 202568 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 product that is the subject of ANDA No. 202568 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, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202568 until the expiration of the '599 patent;

(n) A judgment awarding Shire 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 ANDA No. 202568 prior to the expiration of the '599 patent;

(o) A judgment declaring that Sandoz's infringement of the '599 patent based on ANDA No. 202568 is willful if Sandoz commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202568 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 ANDA No. 202568 with a paragraph IV certification to the FDA 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. 202568 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 product that is the subject of ANDA No. 202568 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 product that is the subject of ANDA No. 202568 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 product that is the subject of ANDA No. 202568 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, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202568 until the expiration of the '794 patent;

(v) A judgment awarding Shire 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 ANDA No. 202568 prior to the expiration of the '794 patent;

(w) A judgment declaring that Sandoz's infringement of the '794 patent based on ANDA No. 202568 is willful if Sandoz commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202568 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 its attorneys' fees and costs;

(y) Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

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