

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SHIRE LLC,)
SUPERNUS PHARMACEUTICALS, INC.,)
AMY F.T. ARNSTEN, PH.D.,)
PASKO RAKIC, M.D., and)
ROBERT D. HUNT, M.D.,)

C.A. No. _____

Plaintiffs,)

v.)

ANCHEN PHARMACEUTICALS, INC., and)
ANCHEN INC.,)
Defendants.)

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 undersigned attorneys, for their Complaint against defendants Anchen Pharmaceuticals, Inc. (“Anchen Pharmaceuticals”) and Anchen Inc. (collectively “Defendants” or “Anchen”) 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, Anchen Pharmaceuticals is a corporation organized and existing under the laws of the State of California, with a principal place of business at 9601 Jeronimo Road, Irvine, California 92618. Upon information and belief, Anchen Pharmaceuticals is in the business of developing, manufacturing, marketing, and selling generic drugs throughout the world, including throughout the United States including the State of Delaware.

8. Upon information and belief, Anchen Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 9601 Jeronimo Road, Irvine, California 92618.

9. Upon information and belief, Anchen Pharmaceuticals and Anchen Inc. are closely related entities in the same corporate family that act in concert, including with respect to the collaboration in the development, manufacture, marketing and sale of generic drug

products pursuant to Abbreviated New Drug Applications. Upon information and belief, Anchen Pharmaceuticals and Anchen Inc. share the same principal place of business. Upon information and belief, Anchen Pharmaceuticals and Anchen Inc. have at least one officer and/or director in common.

10. Upon information and belief, Anchen has represented to the United States Patent and Trademark Office that Anchen Pharmaceuticals and Anchen Inc. “constitute a single source to the relevant public, and there is unity of control with respect to the nature and quality of the goods.”

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 Anchen Pharmaceuticals because, *inter alia*, of its continuous and systematic contacts with the State of Delaware. Anchen Pharmaceuticals directly and/or through Anchen Inc., manufactures, markets, and sells drugs throughout the United States, including the State of Delaware, and therefore derives substantial revenue from Delaware drug sales and has availed itself of the privilege of conducting business within the State of Delaware.

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

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

FACTS AS TO ALL COUNTS

15. 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 Shire markets under the name of Intuniv™. Intuniv™ is indicated for the treatment of Attention Deficit Hyperactivity Disorder.

16. 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™.

17. Anchen prepared and submitted Abbreviated New Drug Application (“ANDA”) No. 201408 (“ANDA No. 201408” or “Anchen’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, 1 mg, 2 mg, 3 mg and 4 mg (“Anchen’s Proposed Products”).

18. Anchen Pharmaceuticals sent to Shire Pharmaceuticals, Inc., Supernus, Dr. Arnsten, Dr. Rakic as the successor-in-interest to Dr. Patricia Goldman-Rakic (“Dr. Goldman-Rakic”), and Dr. Hunt notifications, each dated April 23, 2010, purportedly pursuant to § 505(j)(2)(B)(ii) of the FDCA regarding Anchen’s Proposed Products (“Anchen’s Notice Letters”).

19. 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 Anchen Pharmaceuticals and Anchen Inc.)

20. Shire, Dr. Arnsten, Dr. Rakic and Dr. Hunt repeat and re-allege each of foregoing paragraphs as if fully set forth herein.

21. 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.

22. Upon information and belief, Anchen seeks FDA approval for the manufacture and/or distribution of Anchen’s Proposed Products.

23. Upon information and belief, Anchen’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 Anchen’s Proposed Products before the expiration of the '290 patent.

24. Upon information and belief, Anchen Pharmaceuticals and/or Anchen Inc. will commercially manufacture, sell, offer for sale, and/or import Anchen's Proposed Products immediately upon FDA approval.

25. Upon information and belief, as of the date of Anchen's Notice Letters, Anchen Pharmaceuticals and Anchen Inc. were 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).

26. The submission and filing of ANDA No. 201408 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 Anchen's Proposed Products before the expiration of the '290 patent is an act of infringement by Anchen Pharmaceuticals and/or Anchen Inc. of one or more claims of the '290 patent under 35 U.S.C. § 271(e)(2)(A).

27. Upon information and belief, the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Anchen's Proposed Products that are the subject of ANDA No. 201408 will infringe one or more claims of the '290 patent.

28. Upon information and belief, the sale or offer for sale of Anchen's Proposed Products by Anchen Pharmaceuticals and/or Anchen Inc. would induce and/or contribute to third-party infringement of one or more claims of the '290 patent under 35 U.S.C. § 271.

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

30. 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 Anchen Pharmaceuticals and Anchen Inc. are preliminarily and permanently enjoined by this Court.

SECOND COUNT

(Induced and/or Contributory Infringement of the '290 Patent by Anchen Inc.)

31. Shire, Dr. Arnsten, Dr. Rakic and Dr. Hunt repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

32. Anchen Inc. is jointly and severally liable for Anchen Pharmaceuticals' infringement of one or more claims of the '290 patent.

33. Upon information and belief, Anchen Inc. knowingly induced Anchen Pharmaceuticals to infringe and/or contributed to Anchen Pharmaceuticals' infringement of one or more claims of the '290 patent.

34. Upon information and belief, Anchen Inc. actively induced, encouraged, aided, or abetted Anchen Pharmaceuticals' preparation and submission and filing of ANDA No. 201408 with a paragraph IV certification to the '290 patent.

35. Anchen Inc.'s inducement, encouragement, aiding, or abetting of Anchen Pharmaceuticals' preparation, submission and filing of ANDA 201408 with a paragraph IV certification constitutes infringement of the '290 patent under 35 U.S.C. § 271(e)(2)(A). Further, Anchen Inc.'s commercial use, sale, offer for sale and/or importation of Anchen's Proposed Products would induce and/or contribute to Anchen Pharmaceuticals' infringement of the '290 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

36. Upon information and belief, Anchen Inc.'s inducement, encouragement, aiding, or abetting of the sale or offer for sale of Anchen's Proposed Products by Anchen Pharmaceuticals would induce and/or contribute to third-party infringement of one or more

claims of the '290 patent under 35 U.S.C. § 271.

37. Upon information and belief, Anchen Inc. has, continues to, and will actively induce, encourage, aid, or abet Anchen Pharmaceuticals' infringement of the '290 patent with knowledge that it is in contravention of the rights of Shire, Dr. Arnsten, Dr. Rakic and Dr. Hunt.

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

39. 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 Anchen Inc. is preliminarily and permanently enjoined by this Court.

THIRD COUNT

(Infringement of the '599 Patent by Anchen Pharmaceuticals and Anchen Inc.)

40. Shire and Supernus repeat and re-allege each of the foregoing paragraphs 1-19 as if fully set forth herein.

41. 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.

42. Upon information and belief, Anchen seeks FDA approval for the manufacture and/or distribution of Anchen's Proposed Products.

43. Upon information and belief, Anchen'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 Anchen's Proposed Products before the expiration of the '599 patent.

44. Upon information and belief, Anchen Pharmaceuticals and/or Anchen Inc. will commercially manufacture, sell, offer for sale, and/or import Anchen's Proposed Products immediately upon FDA approval.

45. Upon information and belief, as of the date of Anchen's Notice Letters, Anchen Pharmaceuticals and Anchen Inc. were 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).

46. The submission and filing of ANDA No. 201408 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 Anchen's Proposed Products before the expiration of the '599 patent is an act of infringement by Anchen Pharmaceuticals and/or Anchen Inc. of one or more claims of the '599 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, Anchen Pharmaceuticals' and/or Anchen Inc.'s commercial manufacture, use, sale, offer for sale and/or importation into the United States of Anchen's Proposed Products that are the subject of ANDA No. 201408 will infringe one or more claims of the '599 patent.

48. Upon information and belief, as of the date of Anchen's Notice Letters, Anchen Pharmaceuticals and Anchen Inc. were 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.

49. The acts of infringement set forth above will cause Shire and Supernus irreparable harm for which neither has adequate remedy at law, unless Anchen Pharmaceuticals and Anchen Inc. are preliminarily and permanently enjoined by this Court.

FOURTH COUNT

(Induced and/or Contributory Infringement of the '599 Patent by Anchen Inc.)

50. Shire and Supernus repeat and re-allege each of the foregoing paragraphs 1-19 and 40-49 as if fully set forth herein.

51. Anchen Inc. is jointly and severally liable for Anchen Pharmaceuticals' infringement of one or more claims of the '599 patent.

52. Upon information and belief, Anchen Inc. knowingly induced Anchen Pharmaceuticals to infringe and/or contributed to Anchen Pharmaceuticals' infringement of one or more claims of the '599 patent.

53. Upon information and belief, Anchen Inc. actively induced, encouraged, aided, or abetted Anchen Pharmaceuticals' preparation and submission and filing of ANDA No. 201408 with a paragraph IV certification to the '599 patent.

54. Anchen Inc.'s inducement, encouragement, aiding, or abetting of Anchen Pharmaceuticals' preparation, submission and filing of ANDA 201408 with a paragraph IV certification constitutes infringement of the '599 patent under 35 U.S.C. § 271(e)(2)(A). Further, Anchen Inc.'s commercial use, sale, offer for sale and/or importation of Anchen's Proposed Products would induce and/or contribute to Anchen Pharmaceuticals' infringement of the '599 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

55. Upon information and belief, Anchen Inc. has, continues to, and will

actively induce, encourage, aid, or abet Anchen Pharmaceuticals' infringement of the '599 patent with knowledge that it is in contravention of the rights of Shire and Supernus.

56. Upon information and belief, as of the date of Anchen's Notice Letters, Anchen Inc. was aware of the existence of the '599 patent and acted without a reasonable basis for believing that it would not be liable for inducing and/or contributing to Anchen Pharmaceuticals' infringement, thus rendering this case "exceptional" under 35 U.S.C. § 285.

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

FIFTH COUNT

(Infringement of the '794 Patent by Anchen Pharmaceuticals and Anchen Inc.)

58. Shire and Supernus repeat and re-allege each of the foregoing paragraphs 1-19 and 40-57 as if fully set forth herein.

59. 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 Laboratories Inc. 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.

60. Upon information and belief, Anchen seeks FDA approval for the manufacture and/or distribution of Anchen's Proposed Products.

61. Upon information and belief, Anchen'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 Anchen's Proposed Products before the expiration of the '794 patent.

62. Upon information and belief, Anchen Pharmaceuticals and/or Anchen Inc. will commercially manufacture, sell, offer for sale, and/or import Anchen's Proposed Products immediately upon FDA approval.

63. Upon information and belief, as of the date of Anchen's Notice Letters, Anchen Pharmaceuticals and Anchen Inc. were 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).

64. The submission and filing of ANDA No. 201408 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 Anchen's Proposed Products before the expiration of the '794 patent is an act of infringement by Anchen Pharmaceuticals and/or Anchen Inc. of one or more claims of the '794 patent under 35 U.S.C. § 271(e)(2)(A).

65. Upon information and belief, Anchen Pharmaceuticals' and/or Anchen Inc.'s commercial manufacture, use, sale, offer for sale and/or importation into the United States of Anchen's Proposed Products that are the subject of ANDA No. 201408 will infringe one or more claims of the '794 patent.

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

67. The acts of infringement set forth above will cause Shire and Supernus irreparable harm for which neither has adequate remedy at law, unless Anchen Pharmaceuticals and Anchen Inc. are preliminarily and permanently enjoined by this Court.

SIXTH COUNT

(Induced and/or Contributory Infringement of '794 Patent by Anchen Inc.)

68. Shire and Supernus repeat and re-allege each of the foregoing paragraphs 1-19 and 40-67 as if fully set forth herein.

69. Anchen Inc. is jointly and severally liable for Anchen Pharmaceuticals' infringement of one or more claims of the '794 patent.

70. Upon information and belief, Anchen Inc. knowingly induced Anchen Pharmaceuticals to infringe and/or contributed to Anchen Pharmaceuticals' infringement of one or more claims of the '794 patent.

71. Upon information and belief, Anchen Inc. actively induced, encouraged, aided, or abetted Anchen Pharmaceuticals' preparation and submission and filing of ANDA No. 201408 with a paragraph IV certification to the '794 patent.

72. Anchen Inc.'s inducement, encouragement, aiding, or abetting of Anchen Pharmaceuticals' preparation, submission and filing of ANDA 201408 with a paragraph IV certification constitutes infringement of the '794 patent under 35 U.S.C. § 271(e)(2)(A). Further, Anchen Inc.'s commercial use, sale, offer for sale and/or importation of Anchen's Proposed Products would induce and/or contribute to Anchen Pharmaceuticals' infringement of the '794 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

73. Upon information and belief, Anchen Inc. has, continues to, and will actively induce, encourage, aid, or abet Anchen Pharmaceuticals' infringement of the '794 patent with knowledge that it is in contravention of the rights of Shire and Supernus.

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

75. The acts of infringement set forth above will cause Shire and Supernus irreparable harm for which neither has adequate remedy at law, unless Anchen Inc. 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. 201408 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 products that are the subject of ANDA No. 201408 prior to the expiration of the '290 patent was an act of infringement of the '290 patent by Anchen Pharmaceuticals;
- (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 ANDA No. 201408 prior to the expiration of the '290 patent will constitute an act of infringement of the '290 patent by Anchen Pharmaceuticals and Anchen Inc., individually and collectively;
- (d) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Anchen Inc. has and continues to induce and/or contribute to Anchen Pharmaceuticals' infringement of

the '290 patent based on the submission to the FDA of ANDA No. 201408 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 products that are the subject of ANDA No. 201408 prior to the expiration of the '290 patent;

(e) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Anchen Inc. would induce and/or contribute to Anchen Pharmaceuticals' infringement of the '290 patent based on the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201408 prior to the expiration of the '290 patent;

(f) 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 ANDA No. 201408 by Anchen Pharmaceuticals and/or Anchen Inc. would induce and/or contribute to third-party infringement of the '290 patent.

(g) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Anchen Inc.'s inducement, encouragement, aiding, or abetting of Anchen Pharmaceuticals' commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201408 would induce and/or contribute to third-party infringement of the '290 patent;

(h) 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. 201408 shall be no earlier than the date on which the '290 patent expires;

(i) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and

permanently enjoining Anchen Pharmaceuticals, Anchen Inc., 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 products that are the subject of ANDA No. 201408 until the expiration of the '290 patent;

(j) A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Anchen Pharmaceuticals and/or Anchen Inc. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 201408 prior to the expiration of the '290 patent;

(k) A judgment declaring that Anchen Pharmaceuticals' and Anchen Inc.'s infringement of the '290 patent based on ANDA No. 201408 is willful if Anchen Pharmaceuticals and/or Anchen Inc. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 201408 prior to the expiration of the '290 patent;

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

(m) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission and filing of ANDA No. 201408 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 products that are the subject of ANDA No. 201408 prior to the expiration of the '599 patent was an act of infringement of the '599 patent by Anchen Pharmaceuticals;

(n) 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 ANDA No. 201408 prior to the expiration of the '599 patent will constitute an act of infringement of the '599 patent by Anchen Pharmaceuticals and Anchen Inc., individually and collectively;

(o) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Anchen Inc. has and continues to induce and/or contribute to Anchen Pharmaceuticals' infringement of the '599 patent based on the submission to the FDA of ANDA No. 201408 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 products that are the subject of ANDA No. 201408 prior to the expiration of the '599 patent;

(p) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Anchen Inc. would induce and/or contribute to Anchen Pharmaceuticals' infringement of the '599 patent based on the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201408 prior to the expiration of the '599 patent;

(q) 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. 201408 shall be no earlier than the date on which the '599 patent expires;

(r) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Anchen Pharmaceuticals, Anchen Inc., 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. 201408 until the expiration of the '599 patent;

(s) A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Anchen Pharmaceuticals and/or Anchen Inc. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 201408 prior to the expiration of the '599 patent;

(t) A judgment declaring that Anchen Pharmaceuticals' and/or Anchen Inc.'s infringement of the '599 patent based on ANDA No. 201408 is willful if Anchen Pharmaceuticals and/or Anchen Inc. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 201408 prior to the expiration of the '599 patent;

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

(v) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission and filing of ANDA No. 201408 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 products that are the subject of ANDA No. 201408 prior to the expiration of the '794 patent was an act of infringement of the '794 patent by Anchen Pharmaceuticals;

(w) 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 ANDA No. 201408 prior to the expiration of the '794 patent will constitute an act of infringement of the '794 patent by Anchen Pharmaceuticals and Anchen Inc., individually and collectively;

(x) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Anchen Inc. has and continues to induce and/or contribute to Anchen Pharmaceuticals' infringement of

the '794 patent based on the submission to the FDA of ANDA No. 201408, 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 products that are the subject of ANDA No. 201408 prior to the expiration of the '794 patent;

(y) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Anchen Inc. would induce and/or contribute to Anchen Pharmaceuticals' infringement of the '794 patent based on the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201408 prior to the expiration of the '794 patent;

(z) 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. 201408 shall be no earlier than the date on which the '794 patent expires;

(aa) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Anchen Pharmaceuticals, Anchen Inc., 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 products that are the subject of ANDA No. 201408 until the expiration of the '794 patent;

(bb) A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Anchen Pharmaceuticals and/or Anchen Inc. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 201408 prior to the expiration of the '794 patent;

(cc) A judgment declaring that Anchen Pharmaceuticals' and Anchen Inc.'s

infringement of the '794 patent based on ANDA No. 201408 is willful if Anchen Pharmaceuticals and/or Anchen Inc. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 201408 prior to the expiration of the '794 patent;

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

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

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