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

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| SHIRE LLC,<br>SUPERNUS PHARMACEUTICALS, INC.,<br>AMY F.T. ARNSTEN, PH.D.,<br>PASKO RAKIC, M.D., and<br>ROBERT D. HUNT, M.D.,<br><br>Plaintiffs,<br><br>v.<br><br>ACTAVIS ELIZABETH LLC and<br>ACTAVIS INC.,<br><br>Defendants. | ) | C.A. No. _____ |

**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 Actavis Elizabeth LLC and Actavis Inc. (collectively "Defendants" or "Actavis") 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, Actavis Elizabeth LLC is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202. Upon information and belief, Actavis Elizabeth LLC 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, Actavis Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07906.

9. Upon information and belief, Actavis Elizabeth LLC is a wholly-owned subsidiary of Actavis Inc. Upon information and belief, Actavis Elizabeth LLC is controlled and/or dominated by Actavis Inc. Upon information and belief, Actavis Elizabeth LLC and

Actavis Inc. have at least one officer and/or director in common.

10. Upon information and belief, Actavis Elizabeth LLC manufactures and distributes generic drugs for sale and use throughout the United States, including at the direction of, under the control of, and for the direct benefit of Actavis Inc. Upon information and belief, Actavis Inc. is in the business of developing generic drugs for sale and use throughout the United States. Upon information and belief, Actavis Elizabeth LLC acts as an agent for Actavis Inc. for purposes of regulatory submissions to the U.S. Food and Drug Administration ("FDA") seeking approval for generic drugs.

## 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 Actavis Elizabeth LLC. Actavis Elizabeth LLC 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.

13. This Court has personal jurisdiction over Actavis Inc. Actavis 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. Actavis prepared and submitted Abbreviated New Drug Application ("ANDA") No. 200881 ("ANDA No. 20-0881" or "Actavis'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 ("Actavis's Proposed Products").

18. Actavis sent to Shire Pharmaceuticals Inc., Supernus, Dr. Arnsten, Dr. Patricia S. Goldman-Rakic ("Dr. Goldman-Rakic") c/o Dr. Rakic, Dr. Rakic and Dr. Hunt notifications, each dated April 2, 2010, purportedly pursuant to § 505(j)(2)(B)(ii) of the FDCA regarding Actavis's Proposed Products ("Actavis'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 Actavis Elizabeth LLC and Actavis 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-Rakin 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, Actavis seeks FDA approval for the manufacture and/or distribution of Actavis's Proposed Products.

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

24. Upon information and belief, Actavis Elizabeth LLC and/or Actavis Inc.

will commercially manufacture, sell, offer for sale, and/or import Actavis's Proposed Products immediately upon FDA approval.

25. Upon information and belief, as of the date of Actavis's Notice Letters, Actavis Elizabeth LLC and Actavis 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. 200881 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 Actavis's Proposed Products before the expiration of the '290 patent is an act of infringement by Actavis Elizabeth LLC 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 Actavis's Proposed Products that are the subject of ANDA No. 20-0881 will infringe one or more claims of the '290 patent.

28. Upon information and belief, the sale or offer for sale of Actavis's Proposed Products by Actavis Elizabeth LLC and/or Actavis 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 Actavis's Notice Letters, Actavis Elizabeth LLC and Actavis 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 Actavis Elizabeth LLC and Actavis Inc. are preliminarily and permanently enjoined by this

Court.

**SECOND COUNT**

(Induced and/or Contributory Infringement of the ’290 Patent by Actavis 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. Actavis Inc. is jointly and severally liable for Actavis Elizabeth LLC’s infringement of one or more claims of the ’290 patent.

33. Upon information and belief, Actavis Inc. knowingly induced Actavis Elizabeth LLC to infringe and/or contributed to Actavis Elizabeth LLC’s infringement of one or more claims of the ’290 patent.

34. Upon information and belief, Actavis Inc. actively induced, encouraged, aided, or abetted Actavis Elizabeth LLC’s preparation and submission and filing of ANDA No. 200881 with a paragraph IV certification to the ’290 patent.

35. Actavis Inc.’s inducement, encouragement, aiding, or abetting of Actavis Elizabeth LLC’s preparation, submission and filing of ANDA 200881 with a paragraph IV certification constitutes infringement of the ’290 patent under 35 U.S.C. § 271(e)(2)(A). Further, Actavis Inc.’s commercial use, sale, offer for sale and/or importation of Actavis’s Proposed Products would induce and/or contribute to Actavis Elizabeth LLC’s 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, Actavis Inc.’s inducement, encouragement, aiding, or abetting of the sale or offer for sale of Actavis’s Proposed Products by Actavis Elizabeth LLC 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, Actavis Inc. has, continues to, and will

actively induce, encourage, aid, or abet Actavis Elizabeth LLC's 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 Actavis's Notice Letters, Actavis 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 Actavis Elizabeth LLC's 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 Actavis Inc. is preliminarily and permanently enjoined by this Court.

**THIRD COUNT**

(Infringement of the '599 Patent by Actavis Elizabeth LLC and Actavis 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, Actavis seeks FDA approval for the manufacture and/or distribution of Actavis's Proposed Products.

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

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

45. Upon information and belief, as of the date of Actavis's Notice Letters, Actavis Elizabeth LLC and Actavis 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. 200881 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 Actavis's Proposed Products before the expiration of the '599 patent is an act of infringement by Actavis Elizabeth LLC of one or more claims of the '599 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, Actavis Elizabeth LLC's and/or Actavis Inc.'s commercial manufacture, use, sale, offer for sale and/or importation into the United States of Actavis's Proposed Products that are the subject of ANDA No. 200881 will infringe one or more claims of the '599 patent.

48. Upon information and belief, as of the date of Actavis's Notice Letters, Actavis Elizabeth LLC and Actavis 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 Actavis Elizabeth LLC and Actavis Inc. are preliminarily and permanently enjoined by this Court.

**FOURTH COUNT**

(Induced and/or Contributory Infringement of the '599 Patent by Actavis 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. Actavis Inc. is jointly and severally liable for Actavis Elizabeth LLC's infringement of one or more claims of the '599 patent.

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

53. Upon information and belief, Actavis Inc. actively induced, encouraged, aided, or abetted Actavis Elizabeth LLC's preparation and submission and filing of ANDA No. 200881 with a paragraph IV certification to the '599 patent.

54. Actavis Inc.'s inducement, encouragement, aiding, or abetting of Actavis Elizabeth LLC's preparation, submission and filing of ANDA 200881 with a paragraph IV certification constitutes infringement of the '599 patent under 35 U.S.C. § 271(e)(2)(A). Further, Actavis Inc.'s commercial use, sale, offer for sale and/or importation of Actavis's Proposed Products would induce and/or contribute to Actavis Elizabeth LLC's 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, Actavis Inc. has, continues to, and will actively induce, encourage, aid, or abet Actavis Elizabeth LLC's 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 Actavis's Notice Letters, Actavis 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 Actavis Elizabeth LLC's infringement of the '599 patent, 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 Actavis Inc. is preliminarily and permanently enjoined by this Court.

**FIFTH COUNT**

(Infringement of the '794 Patent by Actavis Elizabeth LLC and Actavis 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, Actavis seeks FDA approval for the manufacture and/or distribution of Actavis's Proposed Products.

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

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

63. Upon information and belief, as of the date of Actavis's Notice Letters, Actavis Elizabeth LLC and Actavis 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. 200881 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 Actavis's Proposed Products before the expiration of the '794 patent is an act of infringement by Actavis Elizabeth LLC of one or more claims of the '794 patent under 35 U.S.C. § 271(e)(2)(A).

65. Upon information and belief, Actavis Elizabeth LLC's and/or Actavis Inc.'s commercial manufacture, use, sale, offer for sale and/or importation into the United States of Actavis's Proposed Products that are the subject of ANDA No. 200881 will infringe one or more claims of the '794 patent.

66. Upon information and belief, as of the date of Actavis's Notice Letters, Actavis Elizabeth LLC and Actavis 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 Actavis Elizabeth LLC and Actavis Inc. are preliminarily and permanently enjoined by this Court.

**SIXTH COUNT**

(Induced and/or Contributory Infringement of '794 Patent by Actavis 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. Actavis Inc. is jointly and severally liable for Actavis Elizabeth LLC's infringement of one or more claims of the '794 patent.

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

71. Upon information and belief, Actavis Inc. actively induced, encouraged, aided, or abetted Actavis Elizabeth LLC's preparation and submission and filing of ANDA No. 200881 with a paragraph IV certification to the '794 patent.

72. Actavis Inc.'s inducement, encouragement, aiding, or abetting of Actavis Elizabeth LLC's preparation, submission and filing of ANDA 200881 with a paragraph IV certification constitutes infringement of the '794 patent under 35 U.S.C. § 271(e)(2)(A). Further, Actavis Inc.'s commercial use, sale, offer for sale and/or importation of Actavis's Proposed Products would induce and/or contribute to Actavis Elizabeth LLC's 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, Actavis Inc. has, continues to, and will actively induce, encourage, aid, or abet Actavis Elizabth LLC's 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 Actavis's Notice Letters, Actavis 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 Actavis Elizabeth LLC's 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 Actavis 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. 200881 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. 200881 prior to the expiration of the '290 patent was an act of infringement of the '290 patent by Actavis Elizabeth LLC;

(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. 200881 prior to the expiration of the '290 patent will constitute an act of infringement of the '290 patent by Actavis Elizabeth LLC and Actavis Inc., individually and collectively;

(d) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Actavis Inc. has and continues to induce and/or contribute to Actavis Elizabeth LLC's infringement of the

’290 patent based on the submission to the FDA of ANDA No. 200881 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. 200881 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), Actavis Inc. would induce and/or contribute to Actavis Elizabeth LLC’s 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. 200881 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. 200881 by Actavis Elizabeth LLC and/or Actavis 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), Actavis Inc.’s inducement, encouragement, aiding, or abetting of Actavis Elizabeth LLC’s commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 200881 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. 200881 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 Actavis Elizabeth LLC, Actavis 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. 200881 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 Actavis Elizabeth LLC and/or Actavis Inc. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 200881 prior to the expiration of the ’290 patent;

(k) A judgment declaring that Actavis Elizabeth LLC’s and Actavis Inc.’s infringement of the ’290 patent based on ANDA No. 200881 is willful if Actavis Elizabeth LLC and/or Actavis Inc. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 200881 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. 200881 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. 200881 prior to the expiration of the ’599 patent was an act of infringement of the ’599 patent by Actavis Elizabeth LLC;

(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. 200881 prior to the expiration of the ’599 patent will constitute an act of infringement of the ’599 patent by Actavis Elizabeth

LLC and Actavis Inc., individually and collectively;

(o) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Actavis Inc. has and continues to induce and/or contribute to Actavis Elizabeth LLC's infringement of the '599 patent based on the submission to the FDA of ANDA No. 200881 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. 200881 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), Actavis Inc. would induce and/or contribute to Actavis Elizabeth LLC's 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. 200881 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. 200881 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 Actavis Elizabeth LLC, Actavis 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. 200881 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 Actavis Elizabeth LLC and/or Actavis Inc. commercially

manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 200881 prior to the expiration of the ’599 patent;

(t) A judgment declaring that Actavis Elizabeth LLC’s and/or Actavis Inc.’s infringement of the ’599 patent based on ANDA No. 200881 is willful if Actavis Elizabeth LLC and/or Actavis Inc. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 200881 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. 200881 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. 200881 prior to the expiration of the ’794 patent was an act of infringement of the ’794 patent by Actavis Elizabeth LLC;

(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. 200881 prior to the expiration of the ’794 patent will constitute an act of infringement of the ’794 patent by Actavis Elizabeth LLC and Actavis Inc., individually and collectively;

(x) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Actavis Inc. has and continues to induce and/or contribute to Actavis Elizabeth LLC’s infringement of the ’794 patent based on the submission to the FDA of ANDA No. 200881 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. 200881 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), Actavis Inc. would induce and/or contribute to Actavis Elizabeth LLC’s 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. 200881 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. 200881 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 Actavis Elizabeth LLC, Actavis 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. 200881 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 Actavis Elizabeth LLC and/or Actavis Inc. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 200881 prior to the expiration of the ’794 patent;

(cc) A judgment declaring that Actavis Elizabeth LLC’s and Actavis Inc.’s infringement of the ’794 patent based on ANDA No. 200881 is willful if Actavis Elizabeth LLC and/or Actavis Inc. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 200881 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.

/s/ Francis DiGiovanni

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