

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE LLC, SHIRE DEVELOPMENT LLC)	
AND SUPERNUS PHARMACEUTICALS,)	
INC.,)	
)	
Plaintiffs,)	
)	
v.)	
)	C.A. No. _____
RANBAXY LABORATORIES LTD.,)	
RANBAXY INC. AND OHM)	
LABORATORIES INC.,)	
)	
Defendant.)	

COMPLAINT

Plaintiffs Shire LLC (“Shire”), Shire Development LLC (“Shire Development”), and Supernus Pharmaceuticals, Inc. (“Supernus”) (collectively “Plaintiffs”) by their undersigned attorneys, for their Complaint against Defendants Ranbaxy Laboratories Ltd., Ranbaxy Inc., and Ohm Laboratories Inc. (collectively “Defendants” or “Ranbaxy”) 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. 6,287,599 (“the ’599 patent”) and 6,811,794 (“the ’794 patent”) (attached as Exhibits A and B 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 Shire Development 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.

4. 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.

5. Upon information and belief, Ranbaxy Laboratories Ltd. is a company organized and existing under the laws of India, having its corporate headquarters at Research & Development Centre, Sarhaul, Sector 18, Gurgaon, Haryana, India.

6. Upon information and believe, Ranbaxy Laboratories Ltd. is in the business of, among other things, developing, manufacturing , packaging, and selling generic pharmaceutical products for the United States market, including the state of Delaware.

7. Upon information and belief, Ranbaxy Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 600 College Road East, Suite 2100, Princeton, NJ 08540.

8. Upon information and belief, Ranbaxy Inc. is in the business of, among other things, marketing and selling generic pharmaceutical products in the United States market, including the state of Delaware.

9. Upon information and belief, Ranbaxy Inc. is a wholly owned subsidiary of Ranbaxy Laboratories Ltd. Upon information and belief, Ranbaxy Inc. acts at the direction of, under the control of, and for the direct benefit of Ranbaxy Laboratories Ltd. and is controlled and/or dominated by Ranbaxy Laboratories Ltd.

10. Upon information and belief, Ranbaxy Inc. is an agent, affiliate, or subsidiary of Ranbaxy Laboratories Ltd., including for Abbreviated New Drug Application No. 205689 (“the Ranbaxy ANDA” or “Ranbaxy’s ANDA”).

11. Upon information and belief, Ranbaxy Inc. is authorized to accept service of process for Ranbaxy Laboratories Ltd. in the United States.

12. Upon information and belief, Ranbaxy Laboratories Inc. serves as Ranbaxy Laboratories Ltd.'s United States distributor and/or sells and offers for sale Ranbaxy Laboratories Ltd.'s drug products throughout the United States, including in the state of Delaware.

13. Upon information and belief, Ohm Laboratories Inc. is a company organized and existing under the laws of the state of New Jersey, having a principal place of business at 14 Terminal Road, New Brunswick, NY 08901.

14. Upon information and belief, Ohm Laboratories Inc. is a wholly owned subsidiary of Ranbaxy Laboratories Ltd. Upon information and belief, Ohm Laboratories Inc. acts at the direction of, under the control of, and for the direct benefit of Ranbaxy Laboratories Ltd. and is controlled and/or dominated by Ranbaxy Laboratories Ltd.

15. Upon information and belief, Ohm Laboratories Inc. manufactures, packages, and/or tests drug products for Ranbaxy Laboratories Ltd. for sale throughout the United States, include the state of Delaware.

JURISDICTION AND VENUE

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

17. This Court has personal jurisdiction over Defendants Ranbaxy.

18. Upon information and belief, Ranbaxy Laboratories Ltd. is subject to personal jurisdiction in the District of Delaware because it markets and sells generic drugs throughout the United States and in the state of Delaware and is the ANDA holder in this case.

19. Upon information and belief, Ranbaxy Laboratories Ltd. is the applicant for Ranbaxy's ANDA No. 205689 which was filed with the U.S. Food and Drug Administration

(“FDA”) under § 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (codified at 21 U.S.C. § 355(j)) seeking approval to manufacture, use, sell, offer for sale, and/or import a 1, 2, 3, and 4 mg Guanfacine Hydrochloride Extended-Release Oral Tablets (“Ranbaxy’s ANDA Products”) for the treatment of Attention Deficit Hyperactivity Disorder (“ADHD”) in the United States, including in the state of Delaware.

20. Upon information and belief, Ranbaxy Laboratories Ltd. resides and is doing business within this judicial district through its subsidiaries, Ranbaxy Inc. and Ohm Laboratories Inc.

21. Upon information and belief, Ranbaxy Laboratories Ltd. (itself or through its wholly-owned subsidiaries Ranbaxy Inc. and Ohm Laboratories Inc.) receives revenue from the sales and marketing of branded and generic drug products in the state of Delaware.

22. Upon information and belief, Ranbaxy Laboratories Ltd. (itself or through its wholly-owned subsidiaries Ranbaxy Inc. and Ohm Laboratories Inc.) intends to market and sell Ranbaxy’s ANDA Products in the state of Delaware.

23. Upon information and belief, Ranbaxy Inc. is a Delaware corporation with a registered agent in Delaware.

24. Upon information and believe, Ohm Laboratories Inc. is a New Jersey corporation.

25. Upon information and belief, Ranbaxy Inc. purposefully avails itself of the laws of the state of Delaware such that it should reasonably anticipate being haled into court in the state of Delaware. For example, upon information and belief, Ranbaxy Inc., alone and on behalf of its parent Ranbaxy Laboratories Ltd., markets and sells generic drug products throughout the United States and in the state of Delaware.

26. Upon information and belief, Ohm Laboratories Inc. purposefully avails itself of the laws of the state of Delaware such that it should reasonably anticipate being haled into court

in the state of Delaware. For example, upon information and belief, Ohm Laboratories Inc., alone and on behalf of its parent Ranbaxy Laboratories Ltd., manufactures generic drug products to be sold throughout the United States and in the state of Delaware.

27. Upon information and belief, Ranbaxy Inc. operated as an instrumentality for the preparation and submission of Ranbaxy's ANDA, which seeks approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Ranbaxy's ANDA Products.

28. Upon information and belief, Ranbaxy has a continuous and systematic business presence within this judicial district and/or substantial events giving rise to acts of infringement that have occurred and/or will occur within this judicial district including its preparation of and/or contribution to the submission and/or filing of Ranbaxy's ANDA seeking approval to sell or offer to sell Ranbaxy's ANDA Products in the United States including in the state of Delaware.

29. Upon information and belief, Ranbaxy's business includes developing, manufacturing, distributing, and/or selling generic drug products for sale and use throughout the United States including for sale and use in the state of Delaware.

30. Upon information and belief, Ranbaxy has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction and/or by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 525 F. Supp. 2d 680 (D. Del. 2007).

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

FACTS COMMON TO ALL COUNTS

32. Shire Development 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.

33. The '599 patent is entitled "Sustained release pharmaceutical dosage forms with minimized pH dependent dissolution profiles" and was duly and legally issued on September 11, 2001.

34. The '794 patent is also entitled "Sustained release pharmaceutical dosage forms with minimized pH dependent dissolution profiles" and was duly and legally issued on November 2, 2004.

35. 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[®].

36. Upon information and belief, Ranbaxy filed its ANDA with the FDA under § 505(j) of the FDCA seeking approval to engage in the 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 before the expiration of the '599 and '794 patents.

37. Upon information and belief, Ranbaxy sent Shire a letter ("Ranbaxy's Notice Letter") purporting to include a notice of certification for the '599 and '794 patents under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. 505(j)(2)(B)(ii) of the FDCA regarding Ranbaxy's ANDA Products. This letter was received by Shire on May 13, 2014.

FIRST COUNT

(Infringement of the '599 patent by Ranbaxy)

38. Plaintiffs repeat and incorporate by reference each paragraph above.

39. 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, Ron-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.

40. Upon information and belief, Ranbaxy seeks FDA approval for the manufacture and/or distribution of Ranbaxy’s ANDA Products.

41. Upon information and belief, Ranbaxy’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 Ranbaxy’s ANDA Products before the expiration of the ’599 patent.

42. Upon information and belief, Ranbaxy will commercially manufacture, sell, offer for sale, and/or import Ranbaxy’s ANDA Products immediately upon FDA approval.

43. Upon information and belief, as of the date of Ranbaxy’s Notice Letters, Ranbaxy 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).

44. The submission and filing of Ranbaxy’s ANDA 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 Ranbaxy’s ANDA Products before the expiration of the ’599 patent is an act of infringement of one or more claims of the ’599 patent under 35 U.S.C. § 271(e)(2)(A).

45. Ranbaxy’s commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Ranbaxy’s ANDA Products that are the subject of Ranbaxy’s ANDA will infringe one or more claims of the ’599 patent.

46. Upon information and belief, as of the date of Ranbaxy’s Notice Letters, Ranbaxy was aware of the existence of the ’599 patent and acted without 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.

SECOND COUNT

(Infringement of the '794 patent by Ranbaxy)

47. Plaintiffs repeat and incorporate by reference each paragraph above.

48. 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, Ron-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.

49. Upon information and belief, Ranbaxy seeks FDA approval for the manufacture and/or distribution of Ranbaxy's ANDA Products.

50. Upon information and belief, Ranbaxy'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 Ranbaxy's ANDA Products before the expiration of the '794 patent.

51. Upon information and belief, Ranbaxy will commercially manufacture, sell, offer for sale, and/or import Ranbaxy's ANDA Products immediately upon FDA approval.

52. Upon information and belief, as of the date of Ranbaxy's Notice Letters, Ranbaxy 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).

53. The submission and filing of Ranbaxy's ANDA 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 Ranbaxy's ANDA Products before

the expiration of the '794 patent is an act of infringement by Ranbaxy before the expiration of the '794 patent is an act of infringement by Ranbaxy of one or more claims of the '794 patent under 35 U.S.C. § 271(e)(2)(A).

54. Ranbaxy's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Ranbaxy's ANDA Products that are the subject of Ranbaxy's ANDA will infringe one or more claims of the '794 patent.

55. Upon information and belief, as of the date of Ranbaxy's Notice Letters, Ranbaxy was aware of the existence of the '794 patent and acted without 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.

THIRD COUNT

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

56. Plaintiffs repeat and incorporate by reference each paragraph above.

57. Ranbaxy Inc. and Ohm Laboratories Inc. are jointly and severally liable for Ranbaxy Laboratories Ltd.'s infringement of one or more claims of the '599 patent.

58. Upon information and belief, Ranbaxy Laboratories Ltd. knowingly induced and/or will induce Ranbaxy Inc. and Ohm Laboratories Inc. to infringe and/or contributed and/or will contribute to Ranbaxy Laboratories Ltd.'s infringement of one or more claims of the '599 patent.

59. Upon information and belief, Ranbaxy Laboratories Ltd. has, continues to, and will actively induce, encourage, aid, or abet Ranbaxy Inc.'s and Ohm Laboratories Inc.'s infringement of the '599 patent with knowledge that it is in contravention of the rights of Plaintiffs.

60. Upon information and believe, Ranbaxy Inc. and Ohm Laboratories Inc. are wholly owned subsidiaries of Ranbaxy Laboratories Ltd. Upon information and belief, Ranbaxy

Inc. serves as Ranbaxy Laboratories Ltd.'s United States marketer and distributor and sells and offers for sale Ranbaxy Laboratories Ltd.'s drug products throughout the United States including Delaware. Ranbaxy's ANDA indicates that Ranbaxy Inc. is the United States agent for Ranbaxy Laboratories Ltd. with respect to Ranbaxy's ANDA. Ranbaxy's ANDA also indicates that Ohm Laboratories Inc. is the manufacturer of Ranbaxy's ANDA Products.

61. Upon information and belief, Ranbaxy Laboratories Ltd. actively induced, encouraged, aided, and/or abetted Ranbaxy Inc.'s and Ohm Laboratories Inc.'s participation and/or preparation and/or submission and/or filing of Ranbaxy's ANDA.

62. Ranbaxy Laboratories Ltd. will induce and/or contribute to Ranbaxy Inc.'s and Ohm Laboratories Inc.'s infringement of the '599 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c) by virtue of commercial use, sale, offer for sale, manufacture, and/or importation of Ranbaxy's ANDA Products.

63. Upon information and belief, Ranbaxy (all three Ranbaxy defendants, individually and collectively) will induce and/or contribute to infringement by third parties of the '599 patent under 35 U.S.C. § 271 by virtue of their inducement, encouragement, aiding, and/or abetting of the use, sale, or offer for sale of Ranbaxy's ANDA Products.

64. Upon information and belief, Ranbaxy Laboratories Ltd. has, continues to, and will actively induce, encourage, aid, or abet Ranbaxy Inc.'s and Ohm Laboratories Inc.'s infringement of the '599 patent with knowledge that it is in contravention of the rights of Plaintiffs.

65. Upon information and belief, as of the date of Ranbaxy's Notice Letter, Ranbaxy Laboratories Ltd. 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 Ranbaxy Inc.'s and Ohm Laboratories Inc.'s infringement, thus rendering this case "exceptional" under 35 U.S.C. § 285.

66. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which neither has adequate remedy at law, unless Ranbaxy is preliminarily and permanently enjoined by this Court.

FOURTH COUNT

(Induced and/or Contributory Infringement of the '794 Patent.)

67. Plaintiffs repeat and incorporate by reference each paragraph above.

68. Ranbaxy Inc. and Ohm Laboratories Inc. are jointly and severally liable for Ranbaxy Laboratories Ltd.'s infringement of one or more claims of the '794 patent.

69. Upon information and belief, Ranbaxy Laboratories Ltd. knowingly induced and/or will induce Ranbaxy Inc. and Ohm Laboratories Inc. to infringe and/or contributed and/or will contribute to Ranbaxy Laboratories Ltd.'s infringement of one or more claims of the '794 patent.

70. Upon information and belief, Ranbaxy Laboratories Ltd. has, continues to, and will actively induce, encourage, aid, or abet Ranbaxy Inc.'s and Ohm Laboratories Inc.'s infringement of the '794 patent with knowledge that it is in contravention of the rights of Plaintiffs.

71. Upon information and believe, Ranbaxy Inc. and Ohm Laboratories Inc. are wholly owned subsidiaries of Ranbaxy Laboratories Ltd. Upon information and belief, Ranbaxy Inc. serves as Ranbaxy Laboratories Ltd.'s United States marketer and distributor and sells and offers for sale Ranbaxy Laboratories Ltd.'s drug products throughout the United States including Delaware. Ranbaxy's ANDA indicates that Ranbaxy Inc. is the United States agent for Ranbaxy Laboratories Ltd. with respect to Ranbaxy's ANDA. Ranbaxy's ANDA also indicates that Ohm Laboratories Inc. is the manufacturer of Ranbaxy's ANDA Products.

72. Upon information and belief, Ranbaxy Laboratories Ltd. actively induced, encouraged, aided, and/or abetted Ranbaxy Inc.'s and Ohm Laboratories Inc.'s participation and/or preparation and/or submission and/or filing of Ranbaxy's ANDA.

73. Ranbaxy Laboratories Ltd. will induce and/or contribute to Ranbaxy Inc.'s and Ohm Laboratories Inc.'s infringement of the '794 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c) by virtue of commercial use, sale, offer for sale, manufacture, and/or importation of Ranbaxy's Proposed Products.

74. Upon information and belief, Ranbaxy (all three Ranbaxy defendants, individually and collectively) will induce and/or contribute to infringement by third parties of the '794 patent under 35 U.S.C. § 271 by virtue of their inducement, encouragement, aiding, and/or abetting of the use, sale, or offer for sale of Ranbaxy's ANDA Products.

75. Upon information and belief, Ranbaxy Laboratories Ltd. has, continues to, and will actively induce, encourage, aid, or abet Ranbaxy Inc.'s and Ohm Laboratories Inc.'s infringement of the '794 patent with knowledge that it is in contravention of the rights of Plaintiffs.

76. Upon information and belief, as of the date of Ranbaxy's Notice Letter, Ranbaxy Laboratories Ltd. 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 Ranbaxy Inc.'s and Ohm Laboratories Inc.'s infringement, thus rendering this case "exceptional" under 35 U.S.C. § 285.

77. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which neither has adequate remedy at law, unless Ranbaxy is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

- (a) A judgment declaring that the '599 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 Ranbaxy's ANDA 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 Ranbaxy's ANDA prior to the expiration of the '599 patent was an act of infringement;
- (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 Ranbaxy's ANDA prior to the expiration of the '599 patent will constitute an act of infringement of the '599 patent by Ranbaxy Laboratories Ltd., Ranbaxy Inc., and Ohm Laboratories Inc., individually and collectively;
- (d) 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 Ranbaxy's ANDA shall be no earlier than the date on which the '599 patent expires;
- (e) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Ranbaxy, 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 of the product that is the subject of Ranbaxy's ANDA in the United States until the expiration of the '599 patent;
- (f) A judgment awarding Plaintiffs damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Ranbaxy commercially manufactures, uses, sells, offers to sell and/or imports any products that are the subject of Ranbaxy's ANDA prior to the expiration of the '599 patent;

(g) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Ranbaxy Laboratories Ltd. would induce and/or contribute to Ranbaxy Inc.'s and Ohm Laboratories Inc.'s and/or other third parties infringement of the '599 patent based on the commercial manufacture, use, sale, offer for sale and/or importation into the United States of any products that are the subject of Ranbaxy's ANDA prior to the expiration of the '599 patent.

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

(i) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission and filing of Ranbaxy's ANDA 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 Ranbaxy's ANDA prior to the expiration of the '794 patent was an act of infringement;

(j) 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 Ranbaxy's ANDA prior to the expiration of the '794 patent will constitute an act of infringement of the '794 patent by Ranbaxy Laboratories Ltd., Ranbaxy Inc., and Ohm Laboratories Inc., individually and collectively;

(k) 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 Ranbaxy's ANDA shall be no earlier than the date on which the '794 patent expires;

(l) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Ranbaxy, 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 of the products that are the subject of Ranbaxy's ANDA in the United States until the expiration of the '794 patent;

(m) A judgment awarding Plaintiffs damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Ranbaxy commercially manufactures, uses, sells, offers to sell and/or imports any products that are the subject of Ranbaxy’s ANDA prior to the expiration of the ’794 patent;

(n) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Ranbaxy Laboratories Ltd. would induce and/or contribute to Ranbaxy Inc.’s and Ohm Laboratories Inc.’s and/or other third parties infringement of the ’794 patent based on the commercial manufacture, use, sale, offer for sale and/or importation into the United States products that are the subject of Ranbaxy’s ANDA prior to the expiration of the ’794 patent.

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Of Counsel

Edgar H. Haug
Jason A. Lief
Erin A. Lawrence
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

Jack B. Blumenfeld (#1014)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
dfahnestock@mnat.com

Attorney for Plaintiffs

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8345258