Liza M. Walsh, Esq.
Rukhsanah L. Lighari, Esq.
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, New Jersey 07068
Telephone No.: (973) 535-0500

OF COUNSEL:

Brian D. Coggio, Esq.
FISH & RICHARDSON P.C.
601 Lexington Avenue
New York, New York 10022
Telephone No.: (212) 765-5070

W. Chad Shear, Esq.
FISH & RICHARDSON P.C.
222 Delaware Avenue
Wilmington, Delaware 19801
Telephone No.: (302) 652-5070

Attorneys for Plaintiffs

Roche Palo Alto LLC, Gilead Palo Alto, Inc. and Gilead Sciences, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ROCHE PALO ALTO LLC, GILEAD PALO ALTO, INC. and GILEAD SCIENCES, INC.,

Plaintiffs,

v.

LUPIN PHARMACEUTICALS, INC. and LUPIN LTD.,

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiffs, Roche Palo Alto LLC ("Roche") and Gilead Palo Alto, Inc. ("Gilead Palo Alto") and Gilead Sciences, Inc. ("Gilead Sciences") (collectively "Gilead") (Roche and Gilead

collectively "Plaintiffs"), for their Complaint against defendants, Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") and Lupin Ltd. (collectively "Lupin"), to the best of their knowledge, information and belief, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 6,303,607 ("the '607 patent"); 6,479,496 ("the '496 patent"); 6,503,911 ("the '911 patent"); 6,525,057 ("the '057 patent"); 6,562,826 ("the '826 patent"); 6,617,328 ("the '328 patent"); 6,620,814 ("the '814 patent"); 6,852,724 ("the '724 patent") and 6,864,258 ("the '258 patent") (collectively the "patents-in-suit"). Plaintiffs institute this action to enforce their patent rights covering Ranexa® brand ranolazine extended release tablets 500 mg and 1000 mg that are approved in the United States by the U.S. Food and Drug Agency ("FDA") for the treatment of chronic angina. A copy of each of the identified patents is attached to this Complaint as Exhibits A-I, respectively.

PARTIES

2. Roche is a company organized and existing under the laws of the State of Delaware with its principal place of business at 3431 Hillview Avenue, Palo Alto, California 94304-1397, and is the owner of the patents-in-suit, and holds all rights to said patents previously held by Syntex (U.S.A.), Inc., Syntex Corp. and/or Syntex Research Scotland.

3. Gilead Palo Alto, a wholly-owned subsidiary of Gilead Sciences, is a company organized and existing under the laws of the State of Delaware with its principal place of business at 333 Lakeside Drive, Foster City, California 94404, and is the exclusive licensee of the patents-in-suit, and holds all rights to said patents previously held by CV Therapeutics, Inc.

4. Gilead Sciences is a company organized and existing under the laws of the State of Delaware with its principal place of business at 333 Lakeside Drive, Foster City, California 94404, and, as noted above, is the parent company of Gilead Palo Alto.

5. On information and belief, Lupin Ltd. is a company organized under the laws of India with its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra

(E), Mumbai 400 051, India, and filed ANDA No. 201-046 with the FDA covering generic versions of plaintiffs' Ranexa® brand ranolazine drug products.

6. On information and belief, Lupin Pharmaceuticals, a wholly-owned subsidiary of defendant Lupin Ltd., is a company organized and existing under the laws of the Commonwealth of Virginia with its principal place of business at Harborplace Tower, Baltimore, Maryland 21202, and, acting in active concert with Lupin Ltd., filed the aforesaid ANDA No. 201-046 with the FDA.

JURISDICTION AND VENUE

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

8. On information and belief, both Lupin Ltd. and Lupin Pharmaceuticals have submitted to the jurisdiction of the United States District Court for the District of New Jersey in multiple patent litigations, including *Sepracor Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 09-CV-01302 (DMC) (MF), in which Lupin Pharmaceuticals expressly admitted without reservation, that the New Jersey District Court had personal jurisdiction over it. In particular in paragraph 4 of its Answer (Document 32), Lupin Pharmaceuticals stated "Lupin Pharma admits that this Court has personal jurisdiction over it." In addition, both Lupin Ltd. and Lupin Pharmaceuticals have recently submitted to the jurisdiction of the United States District Court for the District of New Jersey by bringing a declaratory judgment lawsuit against Merck, Sharp & Dohme Corp. in February 2010, which was assigned Civil Action No. 10-CV-00683 (JAP)(TJB).

9. On information and belief, Lupin Ltd., directly or through Lupin Pharmaceuticals, is in the business of manufacturing, formulating, marketing and selling generic drug pharmaceutical products that are distributed in New Jersey and throughout the United States, and, therefore, directly or through Lupin Pharmaceuticals, conducts business within this judicial district. On further information and belief Lupin Ltd., directly or through Lupin Pharmaceuticals, and/or through one or more agents or distributors, sells and/or distributes a

substantial volume of its pharmaceutical products in New Jersey and derives significant revenue from these activities in New Jersey. On further information and belief, Lupin Ltd., directly or through Lupin Pharmaceuticals, has twelve (12)authorized distributors for its generic division in the New Jersey, including Cardinal Health, Caremark Pharm Services Inc., CVS Pharmacy Inc., McKesson Corporation and Medco Health Solutions of Willingboro, among others.

10. On information and belief, this Court has personal jurisdiction over Lupin Ltd., directly or through Lupin Pharmaceuticals, by virtue of, among other things: (1) its presence in New Jersey; (2) Lupin Pharmaceuticals' registration to do business in New Jersey , including its appointment of a registered agent in New Jersey for the receipt of service of process; (3) its sales of pharmaceutical drug products in New Jersey; (4) the registration of prescription drug products in the *New Jersey Generic Formulary of the New Jersey Department of Health and Senior Services*; (5) its previous consent to be sued in New Jersey on multiple occasions; (6) its previous availment of the judicial process in New Jersey by bringing a declaratory judgment suit in New Jersey; (7) its systematic and continuous contacts with New Jersey; and (8) its course of conduct that is designed to cause the performance of tortious acts that will ultimately result in foreseeable harm in New Jersey. On information and belief, the accused acts of Lupin Pharmaceuticals were done at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of, Lupin Ltd., and, at least in part, benefit the latter.

11. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals by virtue of, among other things: (1) its presence in New Jersey; (2) its registration to do business in New Jersey including its appointment of a registered agent in New Jersey for the receipt of service of process; (3) its sales of pharmaceutical drug products in New Jersey; (4) its registration of prescription drug products in the *New Jersey Generic Formulary of the New Jersey Department of Health and Senior Services*; (5) its previous consent to be sued in New Jersey on multiple occasions, including its explicit admission, without reservation, that it is subject to personal jurisdiction in New Jersey; (6) its previous availment of the judicial process in New Jersey by bringing a declaratory judgment suit in New Jersey; (7) its systematic and

continuous contacts with New Jersey; and (8) its course of conduct that is designed to cause the performance of tortious acts that will ultimately result in foreseeable harm in New Jersey.

12. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals operate as an integrated business ultimately controlled by Lupin Ltd.

13. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

14. Gilead is the holder of New Drug Application ("NDA") No. 21-256 which relates to tablets containing 500mg or 1000 mg of ranolazine formulated as the Ranexa® brand ranolazine product for the treatment of chronic angina. On January 27, 2006, the FDA approved plaintiffs' Ranexa® brand ranolazine drug products for marketing in the United States pursuant to section 505(b) of the Federal Food, Drug, and Cosmetics Act, ("FFDCA"), 21 U.S.C. § 355(b).

15. On October 16, 2001, the '607 patent, titled "Method for Administering a Sustained Release Ranolazine Formulation" was duly and legally issued by the United States Patent and Trademark Office.

16. On November 12, 2002, the '496 patent, titled "Methods for Treating Angina with Ranolazine" was duly and legally issued by the United States Patent and Trademark Office.

17. On January 7, 2003, the '911 patent, titled "Sustained Release Ranolazine Formulations" was duly and legally issued by the United States Patent and Trademark Office.

18. On February 25, 2003, the '057 patent, titled "Sustained Release Ranolazine Formulations" was duly and legally issued by the United States Patent and Trademark Office.

19. On May 13, 2003, the '826 patent, titled "Sustained Release Ranolazine Formulations" was duly and legally issued by the United States Patent and Trademark Office.

20. On September 9, 2003, the '328 patent, titled "Sustained Release Ranolazine Formulations" was duly and legally issued by the United States Patent and Trademark Office.

21. On September 16, 2003, the '814 patent, titled "Sustained Release Ranolazine Formulations" was duly and legally issued by the United States Patent and Trademark Office.

22. On February 8, 2005, the '724 patent, titled "Sustained Release Ranolazine Formulations" was duly and legally issued by the United States Patent and Trademark Office.

23. On March 8, 2005, the '258 patent, titled "Sustained Release Ranolazine Formulations" was duly and legally issued by the United States Patent and Trademark Office.

24. Roche is the lawful owner by assignment and/or operation of contract and/or law of all rights, title and interest in and to all of the patents-in-suit and Gilead Palo Alto is the exclusive licensee of such patents. Collectively, plaintiffs are in possession of all rights, title and interest in and to all of the patents-in-suit, including all rights to sue and recover for infringement thereof.

STATEMENT OF FACTS COMMON TO ALL COUNTS

25. This action arises because of Lupin's efforts to gain approval from the FDA to market a generic version of plaintiffs' Ranexa® brand ranolazine drug products prior to the expiration of the patent rights covering same.

26. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions with respect to the generic drug approval process were amended in several important respects. One provision requires innovator drug companies to submit patent information to the FDA "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA then lists the patent information in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

27. In compliance with that statutory obligation, plaintiffs submitted patent information to the FDA in connection with NDA No. 20-896 for Ranexa® brand ranolazine drug products, and the FDA has published the same in the Orange Book.

28. The Hatch-Waxman Act further amended the FFDCA to permit generic drug companies to gain approval of generic versions of innovator drugs (also called the "reference drug") by referencing studies performed by the innovator, without having to expend the same

considerable investment in time and resources as the innovator. Thus, generic drug companies are permitted to file what is referred to as an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j). When filing an ANDA, generic drug companies are required to review the patent information that the FDA has listed in the Orange Book for the reference drug and make a statutory certification (commonly called "patent certification") with respect to same.

29. The generic drug company may, *inter alia*, state that it does not seek FDA approval to market its generic drug product prior to patent expiration (a "Paragraph III certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(III). Alternatively, the generic drug company may seek FDA approval to market its generic drug product prior to patent expiration by alleging in its ANDA that one or more patents listed in the Orange Book is "invalid or will not be infringed" (commonly called a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

30. The patents-in-suit are identified in paragraph 1 hereof and are all listed in the Orange Book as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

31. On information and belief, Lupin has filed ANDA No. 201-046 with the FDA seeking approval to market 500 mg and 1000 mg generic versions of plaintiffs' Ranexa® brand ranolazine drug products prior to expiration of the Listed Patents.

32. On or about June 8, 2010, plaintiffs received a letter from Mr. William A. Rakoczy of Rakoczy Molino Mazzochi Siwik LLP, Lupin's outside counsel, purporting to be a notice of Lupin's filing of an ANDA seeking to market generic versions of plaintiffs' Ranexa® brand ranolazine drug products and allegedly containing the Paragraph IV certification required by 21 U.S.C. § 355(j)(2)(B)(i) and (ii) with respect to the patents listed in the Orange Book for Ranexa® ("Paragraph IV Notice").

33. In particular, Lupin's Paragraph IV Notice states that Lupin is seeking FDA approval to market generic versions of plaintiffs' Ranexa® brand ranolazine drug products prior to expiration of the patents listed in the Orange Book for Ranexa®, which include the patents-in-

suit Notwithstanding the United States Patent and Trademark Office's grant of patent protection, in its Paragraph IV Notice, Lupin asserts that all such patents are invalid, unenforceable, or would not be infringed by its proposed generic products.

34. Lupin's efforts to seek FDA approval to market generic copies of plaintiffs' Ranexa® brand ranolazine drug products prior to expiration of the patents-in-suit constitute acts of infringement pursuant to 35 U.S.C. 271(e)(2) and, thus, create a justifiable controversy between the parties with respect to the subject matter of Lupin's ANDA and the patents-in-suit, which have been challenged in Lupin's Paragraph IV Notice.

COUNT ONE

Infringement Of The '607 Patent Under 35 U.S.C. § 271(e)(2)

35. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

36. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with ANDA No. 201-046 alleging that the '607 patent is invalid, unenforceable or will not be infringed by their manufacture, use, or sale of generic versions of plaintiffs' Ranexa® brand ranolazine drug products.

37. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin committed an act of infringement by filing such ANDA with a Paragraph IV certification that seeks FDA marketing approval for Lupin's generic versions of plaintiffs' Ranexa® brand ranolazine drug products prior to expiration of the '607 patent.

38. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law and further that plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an Order of this Court that the effective date of approval for Lupin' s ANDA be a date that is not earlier than the expiration date of the '607 patent.

COUNT TWO

Infringement Of The '607 Patent Under 35 U.S.C. § 271(a), (b) and/or (c)

39. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

40. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States and in New Jersey.

41. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals acted in concert to seek FDA approval to market generic versions of plaintiffs' Ranexa® ranolazine drug products throughout the United States and in New Jersey.

42. On information and belief, Lupin Ltd. actively induced Lupin Pharmaceuticals to jointly submit ANDA No. 201-046 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the generic versions of plaintiffs' Ranexa® ranolazine drug products throughout the United States, including New Jersey, prior to patent expiry. By engaging in a cooperative venture with Lupin Pharmaceuticals to submit such ANDA to obtain FDA approval to engage in the commercial manufacture, use or sale of such products throughout the United States, Lupin Ltd. has committed an act of infringement of the '607 patent under 35 U.S.C. § 271(b).

43. On information and belief, Lupin Pharmaceuticals will be actively involved in the manufacture, offer for sale and sale of the generic copies of plaintiffs' Ranexa® ranolazine drug products. Such conduct will constitute inducement of infringement of the '607 patent under 35 U.S.C. §271(b).

44. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the generic versions of plaintiffs' Ranexa® ranolazine drug products prior to patent expiry will infringe the '607 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

45. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law.

COUNT THREE

Infringement Of The '496 Patent Under 35 U.S.C. § 271(e)(2)

46. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

47. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with ANDA No. 201-046 alleging that the '496 patent is invalid, unenforceable or will not be infringed by their manufacture, use, or sale of generic versions of plaintiffs' Ranexa® brand ranolazine drug products.

48. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin committed an act of infringement by filing such ANDA with a Paragraph IV certification that seeks FDA marketing approval for Lupin's generic versions of plaintiffs' Ranexa® brand ranolazine drug products prior to expiration of the '496 patent.

49. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law and further that plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an Order of this Court that the effective date of approval for Lupin' s ANDA be a date that is not earlier than the expiration date of the '496 patent.

COUNT FOUR

Infringement Of The '496 Patent Under 35 U.S.C. § 271(a), (b) and/or (c)

50. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

51. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute and sell pharmaceutical products (including generic drug products

manufactured and sold pursuant to approved ANDAs) throughout the United States and in New Jersey.

52. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals acted in concert to seek FDA approval to market generic versions of plaintiffs' Ranexa® ranolazine drug products throughout the United States and in New Jersey.

53. On information and belief, Lupin Ltd. actively induced Lupin Pharmaceuticals to jointly submit ANDA No. 201-046 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the generic versions of plaintiffs' Ranexa® ranolazine drug products throughout the United States, including New Jersey, prior to patent expiry. By engaging in a cooperative venture with Lupin Pharmaceuticals to submit such ANDA to obtain FDA approval to engage in the commercial manufacture, use or sale of such products throughout the United States, Lupin Ltd. has committed an act of infringement of the '496 patent under 35 U.S.C. § 271(b).

54. On further information and belief, Lupin Pharmaceuticals will be actively involved in the manufacture, offer for sale and sale of the generic copies of plaintiffs' Ranexa® ranolazine drug products. Such conduct will constitute inducement of infringement of the '496 patent under 35 U.S.C. §271(b).

55. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of plaintiffs' Ranexa® ranolazine drug products prior to patent expiry will infringe the '496 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

56. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law.

COUNT FIVE

Infringement Of The '911 Patent Under 35 U.S.C. § 271(e)(2)

57. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

58. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with

ANDA No. 201-046 alleging that the '911 patent is invalid, unenforceable or will not be infringed by their manufacture, use, or sale of generic versions of plaintiffs' Ranexa® brand ranolazine drug products.

59. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin committed an act of infringement by filing such ANDA with a Paragraph IV certification that seeks FDA marketing approval for Lupin's generic versions of plaintiffs' Ranexa® brand ranolazine drug product prior to expiration of the '496 patent.

60. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law and further that plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Lupin' s ANDA be a date that is not earlier than the expiration date of the '496 patent.

COUNT SIX

Infringement Of The '911 Patent Under 35 U.S.C. § 271(a), (b) and/or (c)

61. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

62. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States and in New Jersey.

63. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals acted in concert to seek approval from the FDA to market generic versions of plaintiffs' Ranexa® ranolazine drug products that are the subject of ANDA No. 201-046 throughout the United States and in New Jersey.

64. On information and belief, Lupin Ltd. actively induced Lupin Pharmaceuticals to jointly submit ANDA No. 201-046 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the generic versions of plaintiffs' Ranexa® ranolazine drug products

throughout the United States, including New Jersey, prior to patent expiry. By engaging in a cooperative venture with Lupin Pharmaceuticals to submit such ANDA to obtain FDA approval to engage in the commercial manufacture, use or sale of such products throughout the United States, Lupin Ltd. has committed an act of infringement of the '911 patent under 35 U.S.C. § 271(b).

65. On further information and belief, Lupin Pharmaceuticals will be actively involved in the manufacture, offer for sale and sale of the generic versions of plaintiffs' Ranexa® ranolazine drug products. Such conduct will constitute inducement of infringement of the '911 patent under 35 U.S.C. §271(b).

66. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of plaintiffs' Ranexa® ranolazine drug products prior to patent expiry will infringe the '911 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

67. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law.

COUNT SEVEN

Infringement Of The '057 Patent Under 35 U.S.C. § 271(e)(2)

68. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

69. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with ANDA No. 201-046 alleging that the '057 patent is invalid, unenforceable or will not be infringed by their manufacture, use, or sale of generic versions of plaintiffs' Ranexa® brand ranolazine drug products covered by Lupin's ANDA.

70. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin committed an act of infringement by filing such ANDA with a Paragraph IV certification that seeks FDA marketing approval for Lupin's generic versions of plaintiffs' Ranexa® brand ranolazine drug products prior to expiration of the '057 patent.

71. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law and further that plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Lupin' s ANDA be a date that is not earlier than the expiration date of the '057 patent.

COUNT EIGHT

Infringement Of The '057 Patent Under 35 U.S.C. § 271(a), (b) and/or (c)

72. Plaintiff Roche alleges paragraphs 1 through 34 above as if set forth again.

73. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States and in New Jersey.

74. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals acted in concert to seek approval from the FDA to market generic versions of plaintiffs' Ranexa® ranolazine drug products that are the subject of ANDA throughout the United States and in New Jersey.

75. On information and belief, Lupin Ltd. actively induced Lupin Pharmaceuticals to jointly submit ANDA No. 201-046 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the generic versions of plaintiffs' Ranexa® ranolazine drug products throughout the United States, including New Jersey, prior to patent expiry. By engaging in a cooperative venture with Lupin Pharmaceuticals to submit such ANDA to obtain FDA approval to engage in the commercial manufacture, use or sale of such products throughout the United States, Lupin Ltd. has committed an act of infringement of the '057 patent under 35 U.S.C. § 271(b).

76. On further information and belief, Lupin Pharmaceuticals will be actively involved in the manufacture, offer for sale and sale of the generic copies of plaintiffs' Ranexa®

ranolazine drug products. Such conduct will constitute inducement of infringement of the '057 patent under 35 U.S.C. §271(b).

77. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of plaintiffs' Ranexa® ranolazine drug products prior to patent expiry will infringe the '057 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

78. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law.

COUNT NINE

Infringement Of The '826 Patent Under 35 U.S.C. § 271(e)(2)

79. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

80. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with ANDA No. 201-046 alleging that the '826 patent is invalid, unenforceable or will not be infringed by their manufacture, use, or sale of generic version of plaintiffs' Ranexa® brand ranolazine drug product.

81. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin committed an act of infringement by filing such ANDA with a Paragraph IV certification that seeks FDA marketing approval for Lupin's generic versions of plaintiffs' Ranexa® brand ranolazine drug products prior to expiration of the '826 patent.

82. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law and further that plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an Order of this Court that the effective date of approval for Lupin' s ANDA be a date that is not earlier than the expiration date of the '826 patent.

COUNT TEN

Infringement Of The '826 Patent Under 35 U.S.C. § 271(a), (b) and/or (c)

83. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

84. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States and in New Jersey.

85. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals acted in concert to seek approval from the FDA to market generic versions of plaintiffs' Ranexa® ranolazine drug products that are the subject of ANDA throughout the United States and in New Jersey.

86. On information and belief, Lupin Ltd. actively induced Lupin Pharmaceuticals to jointly submit ANDA No. 201-046 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the generic versions of plaintiffs' Ranexa® ranolazine drug products throughout the United States, including New Jersey, prior to patent expiry. By engaging in a cooperative venture with Lupin Pharmaceuticals to submit such ANDA to obtain FDA approval to engage in the commercial manufacture, use or sale of such products throughout the United States, Lupin Ltd. has committed an act of infringement of the '826 patent under 35 U.S.C. §271(b).

87. On further information and belief, Lupin Pharmaceuticals will be actively involved in the manufacture, offer for sale and sale of generic versions of plaintiffs' Ranexa® ranolazine drug products. Such conduct will constitute inducement of infringement under 35 U.S.C. § 271(b).

88. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the generic versions of plaintiffs' Ranexa® ranolazine drug products prior to patent expiry will infringe the '826 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

89. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law.

COUNT ELEVEN

Infringement Of The '328 Patent Under 35 U.S.C. § 271(e)(2)

90. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

91. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with ANDA No. 201-046 alleging that the '328 patent is invalid, unenforceable or will not be infringed by their manufacture, use, or sale of generic version of plaintiffs' Ranexa® brand ranolazine drug products.

92. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin committed an act of infringement by filing such ANDA with a Paragraph IV certification that seeks FDA marketing approval for Lupin's generic versions of plaintiffs' Ranexa® brand ranolazine drug products prior to expiration of the '328 patent.

93. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law and further that plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an Order of this Court that the effective date of approval for Lupin' s ANDA be a date that is not earlier than the expiration date of the '328 patent.

COUNT TWELVE

Infringement Of The '328 Patent Under 35 U.S.C. § 271(a), (b) and/or (c)

94. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

95. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute and sell pharmaceutical products (including generic drug products

manufactured and sold pursuant to approved ANDAs) throughout the United States and in New Jersey.

96. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals acted in concert to seek approval from the FDA to market generic versions of plaintiffs' Ranexa® ranolazine drug products that are the subject of ANDA No. 201-046 throughout the United States and in New Jersey.

97. On information and belief, Lupin Ltd. actively induced Lupin Pharmaceuticals to jointly submit ANDA No. 201-046 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the generic versions of plaintiffs' Ranexa® ranolazine drug products throughout the United States, including New Jersey, prior to patent expiry. By engaging in a cooperative venture with Lupin Pharmaceuticals to submit such ANDA to obtain FDA approval to engage in the commercial manufacture, use or sale of such products throughout the United States, Lupin Ltd. has committed an act of infringement of the '328 patent under 35 U.S.C. § 271(b).

98. On further information and belief, Lupin Pharmaceuticals will be actively involved in the manufacture, offer for sale and sale of generic versions of plaintiffs' Ranexa® ranolazine drug products. Such conduct will constitute inducement of infringement of the '328 patent under 35 U.S.C. §271(b).

99. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of plaintiffs' Ranexa® ranolazine drug products prior to patent expiry will infringe the '328 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

100. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law.

COUNT THIRTEEN

Infringement Of The '814 Patent Under 35 U.S.C. § 271(e)(2)

101. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

102. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with ANDA No. 201-046 alleging that the '814 patent is invalid, unenforceable or will not be infringed by their manufacture, use, or sale of generic versions of plaintiffs' Ranexa® brand ranolazine drug products covered by Lupin's ANDA.

103. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin committed an act of infringement by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Lupin's generic versions of plaintiffs' Ranexa® brand ranolazine drug products prior to expiration of the '814 patent.

104. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law and further that plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an Order of this Court that the effective date of approval for Lupin' s ANDA be a date that is not earlier than the expiration date of the '814 patent.

COUNT FOURTEEN

Infringement Of The '814 Patent Under 35 U.S.C. § 271(a), (b) and/or (c)

105. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

106. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States and in New Jersey.

107. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals acted in concert to seek approval from the FDA to market generic versions of plaintiffs' Ranexa® ranolazine drug products that are the subject of ANDA No. 201-046 throughout the United States and in New Jersey.

108. On information and belief, Lupin Ltd. actively induced Lupin Pharmaceuticals to jointly submit ANDA No. 201-046 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the generic copies of plaintiffs' Ranexa® ranolazine drug products throughout the United States, including New Jersey, prior to patent expiry. By engaging in a cooperative venture with Lupin Pharmaceuticals to submit such ANDA to obtain FDA approval to engage in the commercial manufacture, use or sale of such products throughout the United States, Lupin Ltd. has committed an act of infringement of the '814 patent under 35 U.S.C. § 271(b).

109. On further information and belief, Lupin Pharmaceuticals will be actively involved in the manufacture, offer for sale and sale of generic versions of plaintiffs' Ranexa® ranolazine drug products. Such conduct will constitute inducement of infringement of the '814 patent under 35 U.S.C. §271(b).

110. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of plaintiffs' Ranexa® ranolazine drug products prior to patent expiry will infringe the '814 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

111. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law.

COUNT FIFTEEN

Infringement Of The '724 Patent Under 35 U.S.C. § 271(e)(2)

112. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

113. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with ANDA No. 201-046 alleging that the '724 patent is invalid, unenforceable or will not be infringed by their manufacture, use, or sale of generic versions of plaintiffs' Ranexa® brand ranolazine drug products.

114. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin committed an act of infringement by filing such ANDA with a Paragraph IV certification that seeks FDA marketing approval for

Lupin's generic versions of plaintiffs' Ranexa® brand ranolazine drug products prior to expiration of the '724 patent.

115. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law and further that plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an Order of this Court that the effective date of approval for Lupin' s ANDA be a date that is not earlier than the expiration date of the '724 patent.

COUNT SIXTEEN

Infringement Of The '724 Patent Under 35 U.S.C. § 271(a), (b) and/or (c)

116. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

117. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States and in New Jersey.

118. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals acted in concert to seek approval from the FDA to market generic copies of plaintiffs' Ranexa® ranolazine drug products that are the subject of ANDA No. 201-046 throughout the United States and in New Jersey.

119. On information and belief, Lupin Ltd. actively induced Lupin Pharmaceuticals to jointly submit ANDA No. 201-046 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the generic versions of plaintiffs' Ranexa® ranolazine drug products throughout the United States, including New Jersey, prior to patent expiry. By engaging in a cooperative venture with Lupin Pharmaceuticals to submit such ANDA to obtain FDA approval to engage in the commercial manufacture, use or sale of such products throughout the United States, Lupin Ltd. has committed an act of infringement of the '724 patent under 35 U.S.C. § 271(b).

120. On further information and belief, Lupin Pharmaceuticals will be actively involved in the manufacture, offer for sale and sale of generic versions of plaintiffs' Ranexa® ranolazine drug products. Such conduct will constitute inducement of infringement of the '724 patent under 35 U.S.C. §271(b).

121. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of plaintiffs' Ranexa® ranolazine drug products prior to patent expiry will infringe the '724 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

122. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law.

COUNT SEVENTEEN

Infringement Of The '258 Patent Under 35 U.S.C. § 271(e)(2)

123. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein

124. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals, acting jointly, included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with ANDA No. 201-046 alleging that the patents are invalid or will not be infringed by their manufacture, use, or sale of generic versions of plaintiffs' Ranexa® brand ranolazine drug products covered by Lupin's ANDA.

125. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin committed an act of infringement by filing such ANDA with a Paragraph IV certification that seeks FDA marketing approval for Lupin's generic versions of plaintiffs' Ranexa® brand ranolazine drug products prior to expiration of the '258 patent.

126. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law and further that plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an Order of this Court that the effective date of approval for Lupin' s ANDA be a date that is not earlier than the expiration date of the '258 patent.

COUNT EIGHTEEN

Infringement Of The '258 Patent Under 35 U.S.C. § 271(a), (b) and/or (c)

127. Plaintiffs allege paragraphs 1 through 34 above as if set forth herein.

128. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States and in New Jersey.

129. On information and belief, defendants Lupin Ltd. and Lupin Pharmaceuticals acted in concert to seek approval from the FDA to market generic versions of plaintiffs' Ranexa® ranolazine drug products that are the subject of ANDA No. 201-046 throughout the United States and in New Jersey.

130. On information and belief, Lupin Ltd. actively induced Lupin Pharmaceuticals to submit jointly ANDA No. 201-046 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the generic versions of plaintiffs' Ranexa® ranolazine drug products throughout the United States, including New Jersey, prior to patent expiry. By engaging in a cooperative venture with Lupin Pharmaceuticals to submit such ANDA to obtain FDA approval to engage in the commercial manufacture, use or sale of such products throughout the United States, Lupin Ltd. has committed an act of infringement of the '258 patent under 35 U.S.C. § 271(b).

131. On further information and belief, Lupin Pharmaceuticals will be actively involved in the manufacture, offer for sale and sale of generic versions of plaintiffs' Ranexa® ranolazine drug products. Such conduct will constitute inducement of infringement under 35 U.S.C. §271(b).

132. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of plaintiffs' Ranexa® ranolazine drug products prior to patent expiry will infringe the '258 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

133. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless such activities are enjoined by this Court as plaintiffs do not have an adequate remedy at law.

RELIEF SOUGHT

WHEREFORE, Plaintiffs request:

A) A judgment and decree that all patent-in-suits are valid and enforceable;

B) A judgment that Lupin has infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 201-046 with a Paragraph IV certification seeking to market its generic versions of Ranexa® ranolazine drug products prior to the expiration of said patents;

C) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Lupin's ANDA No. 201-046 be a date that is not earlier than the expiration date of the patents-in-suit;

D) A judgment that Lupin Ltd. has infringed the patents-in-suit under 35 U.S.C. § 271(b) by inducing Lupin Pharmaceuticals to submit ANDA No. 201-046 under the FFDCA, and that commercial manufacture, use, offer for sale, sale, and/or importation of its generic version of Ranexa® ranolazine drug products prior to the expiration of the patents-in-suit will constitute acts of infringement of said patents under § 271;

E) A judgment that Lupin would infringe and induce infringement of patents-in-suit upon marketing of its generic version of Ranexa® ranolazine drug products after grant of FDA approval and prior to the expiration of the patents-in-suit;

F) A judgment declaring that if Lupin, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its generic version of Ranexa®

ranolazine drug products prior to the expiration of the patents-in-suit, it will constitute acts of infringement of the said patents under 35 U.S.C. § 271 (a), (b) and/or (c);

G) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Lupin and its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of its generic version of Ranexa® ranolazine drug products and any other product that infringes or induces or contributes to the infringement of the patents-in-suit prior to the expiration of the said patents;

H) A judgment that this is an exceptional case and that plaintiffs are entitled to an award of attorneys fees from Lupin under 35 U.S.C. § 285; and

I) Such other and further relief as the Court may deem just and proper.

Dated: July 14, 2010

CONNELL FOLEY LLP

By: *s/Liza M. Walsh*

Liza M. Walsh, Esq.
Rukhsanah L. Lighari, Esq.
85 Livingston Avenue
Roseland, New Jersey 07068
Telephone No.: (973) 535-0500

OF COUNSEL:

Brian D. Coggio, Esq.
FISH & RICHARDSON P.C.
601 Lexington Avenue
New York, New York 10022
Telephone No.: (212) 765-5070

W. Chad Shear, Esq.
FISH & RICHARDSON P.C.
222 Delaware Avenue
Wilmington, Delaware 19801
Telephone No.: (302) 652-5070

Attorneys for Plaintiffs

Roche Palo Alto LLC, Gilead Palo Alto, Inc. and Gilead Sciences, Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action.

Dated: July 14, 2010

CONNELL FOLEY LLP

By: *s/Liza M. Walsh*

Liza M. Walsh, Esq.
Rukhsanah L. Lighari, Esq.
85 Livingston Avenue
Roseland, New Jersey 07068
Telephone No.: (973) 535-0500

OF COUNSEL:

Brian D. Coggio, Esq.
FISH & RICHARDSON P.C.
601 Lexington Avenue
New York, New York 10022
Telephone No.: (212) 765-5070

W. Chad Shear, Esq.
FISH & RICHARDSON P.C.
222 Delaware Avenue
Wilmington, Delaware 19801
Telephone No.: (302) 652-5070

Attorneys for Plaintiffs

Roche Palo Alto LLC, Gilead Palo Alto, Inc. and Gilead Sciences, Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that declaratory and injunctive relief is sought.

Dated: July 14, 2010

CONNELL FOLEY LLP

By: *s/Liza M. Walsh*

Liza M. Walsh, Esq.
Rukhsanah L. Lighari, Esq.
85 Livingston Avenue
Roseland, New Jersey 07068
Telephone No.: (973) 535-0500

OF COUNSEL:

Brian D. Coggio, Esq.
FISH & RICHARDSON P.C.
601 Lexington Avenue
New York, New York 10022
Telephone No.: (212) 765-5070

W. Chad Shear, Esq.
FISH & RICHARDSON P.C.
222 Delaware Avenue
Wilmington, Delaware 19801
Telephone No.: (302) 652-5070

Attorneys for Plaintiffs

Roche Palo Alto LLC, Gilead Palo Alto, Inc. and Gilead Sciences, Inc.