IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION Plaintiff, v. LUPIN LTD., LUPIN PHARMACEUTICALS, INC., Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiff Novartis Pharmaceuticals Corporation ("Novartis"), by its undersigned attorneys, brings this action against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin Inc."; collectively "Lupin").

Nature of the Action

1. This is an action for infringement of United States Patent Nos. 6,294,197 (the "'197 patent") and 8,101,599 (the "'599 patent") under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, particularly §271(e)(2), and for a declaratory judgment of infringement of the '599 patent under 28 U.S.C. §2201 and 2202. Copies of the '197 and '599 patents are attached as Exhibits A-B, respectively.

2. This action relates to Defendants' filing Abbreviated New Drug Application ("ANDA") No. 200-797 with the United States Food and Drug Administration ("FDA"), seeking approval to commercially market generic versions of Novartis's EXFORGE HCT® drug product in the United States, including Delaware.

The Parties

3. Plaintiff Novartis is a corporation organized and existing under the laws of Delaware, with a principal place of business at One Hanover Health Plaza, East Hanover, New Jersey 07936.

4. On information and belief, Lupin Ltd. is a company organized and existing under the laws of India, having a principal place of business at B/4 Laxami Towers, Branda Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

5. On information and belief, Lupin Inc. is a corporation organized and existing under the laws of Virginia, having a principal place of business at Harbor Place Tower, 111 South Calvert Street, 21st floor, Baltimore, Maryland 21202.

6. On information and belief, Lupin Ltd. and Lupin Inc., acting in their own individual capacities and/or in privity and/or concert with one another, are in the business of making and selling pharmaceutical products in the United States, including Delaware.

Subject Matter Jurisdiction and Venue

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

8. Venue is proper in the judicial district pursuant to 28 U.S.C. §§ 1391(b, c) and/or 1400(b).

Personal Jurisdiction

9. On information and belief, Lupin Ltd. and Lupin Inc. operate as an integrated, unitary business. For example, in its 2011 Annual Report, Lupin Ltd. identifies Lupin Inc. as a wholly-owned subsidiary and ascribes this subsidiary's activities to "the Company," *i.e.*, Lupin Ltd.

10. The Annual 2011 Report also provides consolidated financial information, treating Lupin Ltd. and its various subsidiaries (including Lupin Inc.) and associates as a "Group," and reports that annual revenues in the US for 2011 exceeded $400 million dollars.

11. Lupin Ltd. maintains a web-site at the uniform resource locator (URL) http://www.lupinworld.com. The web-site's "/businesssegment.htm" page reflects that the company divides its "formulation business" into seven regional markets, including the "USA" and identifies Lupin Inc. as the entity responsible for the U.S. market. The "/contact.htm#formulation" page of the web-site further indicates that Lupin Inc. is Lupin Ltd.'s "American" contact within the company's "Global Pharmaceutical Business."

12. Lupin Inc. also maintains a web-site at the uniform resource locator (URL) http://www.lupinpharmaceuticals.com. According to that web-site's "/mission.htm" page, the company's mission and vision is to "capitalize on the strengths of [its] parent company, Lupin Limited," and be positioned "for growth in the US market."

13. On information and belief, Lupin Ltd. and Lupin Inc., acting in their own individual capacities and/or in privity and/or concert with one another, developed generic copies

of Novartis's EXFORGE HCT® drug product, and seek approval from the FDA to sell the same throughout the United States, including Delaware.

14. On information and belief, Lupin Ltd., with the assistance of Lupin Inc. and/or for the benefit of Lupin Inc. and/or itself, filed an ANDA No. 200-797, and prepared a Paragraph IV Notice letter to Novartis regarding infringement of the '197 patent.

15. Lupin Ltd. and Lupin Inc., acting in their own individual capacities and/or in privity and/or concert with one another, committed the tortious act of patent infringement pursuant to 35 U.S.C. §271(e)(2)(A) that has led to foreseeable harm and injury to Novartis, a Delaware corporation, by filing NDA No. 200-797.

16. On information and belief, Lupin Ltd., in its own individual capacity and/or via those it acts in privity and/or concert with, including Lupin Inc., regularly does and solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware. These facts demonstrate that Lupin Ltd. has continuous and systematic contacts with Delaware.

17. On information and belief, Lupin Ltd., in its own individual capacity and/or via those it acts in privity and/or concert with, including Lupin Inc., conducts business in Delaware.

18. On information and belief, Lupin Ltd., in its own individual capacity and/or via those it acts in privity and/or concert with, including Lupin Inc., derives substantial revenue from sales of pharmaceutical products in Delaware.

19. On information and belief, Lupin Ltd., in its own individual capacity and/or via those it acts in privity and/or concert with, including Lupin Inc., has entered into contracts with and/or purchased goods or services from persons located in Delaware.

20. On information and belief, Lupin Inc., in its own individual capacity and/or via those it acts in privity and/or concert with, regularly does and solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware. These facts demonstrate that Lupin Inc. has continuous and systematic contacts with Delaware.

21. On information and belief, Lupin Inc., in its own individual capacity and/or via those it acts in privity and/or concert with, conducts business in Delaware.

22. On information and belief, Lupin Inc., in its own individual capacity and/or via those it acts in privity and/or concert with, derives substantial revenue from sales of pharmaceutical products in Delaware.

23. On information and belief, Lupin Inc., in its own individual capacity and/or via those it acts in privity and/or concert with, has entered into contracts with and/or purchased goods or services from persons located in Delaware.

24. On information and belief, Lupin Ltd. and Lupin Inc. have each previously submitted to this Court's jurisdiction.

25. On information and belief, both Lupin Ltd. and Lupin Inc. have engaged the services of Delaware law firms to represent them and entered this District to litigate claims and/or counterclaims before this Court.

26. On information and belief, if Lupin Ltd. were not subject to the jurisdiction of the courts of general jurisdiction of the State of Delaware, then it would, likewise, not be subject to the jurisdiction of the courts of general jurisdiction of any other state, thereby rendering it amenable to personal jurisdiction in Delaware based on its aggregate contacts with the United States, as authorized by Federal Rule of Civil Procedure 4(k)(2).

The Patents in Suit

27. The '197 patent was duly and lawfully issued on September 25, 2001 to inventors Robert Wagner, Yoshimitsu Katakuse, Takashi Taike, Fujiki Yamato and Manfred Kohlmeyer. Novartis is the owner by assignment of all rights, title and interest in and to the '197 patent.

28. The '599 patent was duly and lawfully issued on January 24, 2012 to inventors Suraj Shetty and Randy Webb. Novartis is the owner by assignment of all rights, title and interest in and to the '599 patent.

The EXFORGE HCT® Product

29. Novartis holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug and Cosmetic Act (the "FFDCA), 21 U.S.C. §355(a), for film-coated tablets of varying dosage strengths comprising amlodipine besylate (5 or 10 mg), valsartan (160 or 320 mg) and hydrochlorothiazide ("HCT"; 12.5 or 25 mg), which are sold under the trade name EXFORGE HCT®. The claims of the '197 and '599 patents cover, *inter alia*, EXFORGE HCT®, its method of manufacture, and its use.

30. Pursuant to 21 U.S.C. § 355(b) and attendant regulations, the '197 and '599 patents have been listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to EXFORGE HCT®.

Acts Giving Rise To This Action

31. On information and belief, Lupin Ltd. and/or Lupin Inc. review(s) US patents and seek(s) opportunities to challenge those patents.

32. On information and belief, Lupin Ltd. and/or Lupin Inc. reviewed the '197 patent and certain commercial and economic information relating to EXFORGE HCT®, including estimates of the revenues generated by the sale of EXFORGE HCT®, and decided to file an ANDA, seeking approval to market amlodipine besylate/valsartan/HCT tablets in the United States, including Delaware.

33. On information and belief, Lupin Ltd., on its own behalf and/or on behalf of Lupin Inc., submitted ANDA No. 200-797 to the FDA under §505(j) of the FFDCA, 21 U.S.C. §355(j). That ANDA seeks FDA approval, *inter alia*, for the commercial marketing in the United States, including Delaware, of generic forms of EXFORGE HCT® that are of base-equivalent strength (the "Lupin Generic Products"). The ANDA also seeks FDA approval to market the Lupin Generic Products prior to the expiration of the '197 patent.

34. Pursuant to §505(j)(2)(A)(vii)(IV) of the FFDCA, and in ANDA 200-797, Lupin Ltd., on its own behalf and/or on behalf of Lupin Inc., alleged that the claims of the '197 patent would not be infringed by the manufacture, use, offer sale, and/or sale in; and/or importation into the United States, including Delaware, of the Lupin Generic Products.

35. Novartis received written notification of the ANDA and of the §505(j)(2)(A)(vii)(IV) allegations on or about February 3, 2010. The Paragraph IV letter states that Lupin Ltd. has submitted data to the FDA regarding the alleged "bioavailability and bioequivalence" of the Lupin Generic Products and EXFORGE HCT®.

36. The stated purpose of the Paragraph IV letter was to notify Novartis that Lupin Ltd. had filed a certification with the FDA, under 21 C.F.R. §314.95(c)(1) and in conjunction with ANDA 200-797, for approval, *inter alia*, to commercially manufacture and sell generic versions of Novartis's EXFORGE HCT®. The Paragraph IV letter stated that activities associated with the manufacture, use, offer for sale, sale or importation of the Lupin Generic Products would not infringe any valid claim of the '197 patent.

37. The Paragraph IV letter failed to comply with the requirements of §505 (j)(2)(B)(iv)(II) of the FFDCA because, *inter alia*, it contains very limited information about the Lupin Generic Products, their composition, method of manufacture, or methods of use.

38. The '599 patent had not issued at the time Lupin Ltd. submitted the ANDA or certification under §505(j)(2)(A)(vii)(IV) of the FFDCA.

39. On or about January 24, 2012, Novartis listed the '599 patent in the Orange Book and, shortly thereafter, Lupin Ltd. and Lupin Inc. were on notice of the same. The '599 patent was listed within the 30-day grace period provided under 21 C.F.R. §314.94(a)(12)(viii)(C)(1).

40. ANDA No. 200-797 will not be deemed complete and will not be approved unless and until a certification with respect to the '599 patent is provided under §505(j)(2)(A)(vii-viii) of the FFDCA and 21 C.F.R. §314.94(a)(12)(viii)(C)(1). Hence, such a certification will need to

be submitted in order for Lupin Ltd. and/or Lupin Inc. to be granted the right to, *inter alia*, commercially manufacture and sell the Lupin Generic Products in the United States.

41. On information and belief, a Paragraph IV certification will ultimately be submitted with respect to the ’599 patent, contending that no valid claim of the ’599 patent will be infringed by activities associated with the manufacture, use, sale, offer for sale, or importation of the Lupin Generic Products.

42. On information and belief, Lupin Ltd. and/or Lupin Inc. continue(s) to seek and desire approval of ANDA 200-797 from the FDA.

43. On information and belief, Lupin Ltd. and/or Lupin Inc. have/has made, and continue(s) to make substantial preparations to manufacture for; offer for sale, and/or sell in; and/or import into the United States the Lupin Generic Products prior to the expiration of the ’197 and ’599 patents.

44. On information and belief, Lupin Ltd. and/or Lupin Inc. has/have every intention of manufacturing for and/or in; offering for sale, and/or selling in; and/or importing into the United States the Lupin Generic Products prior to the expiration of the ’197 and ’599 patents.

COUNT I

(Infringement of the ’197 Patent under 35 U.S.C. §271(e)(2))

45. Paragraphs 1-44 are incorporated herein as set forth above.

46. By submitting ANDA No. 200-797, Lupin Ltd. and Lupin Inc. committed an act of infringement with respect to the ’197 patent under 35 U.S.C. §271(e)(2)(A).

47. Unless enjoined by this Court, Lupin Ltd. and/or Lupin Inc., upon the approval of ANDA No. 200-797, will infringe the '197 patent under 35 U.S.C. §271 by making, using, offering for sale, and/or selling in; and/or importing into the United States the Lupin Generic Products.

48. Lupin Ltd. and Lupin Inc. had notice of the '197 patent prior to filing ANDA No. 200-797. Any infringement of the '197 has been and will be willful and deliberate.

COUNT II

(Infringement of the '599 Patent under 35 U.S.C. § 271(e)(2))

49. Paragraphs 1-44 are incorporated herein as set forth above.

50. By submitting ANDA No. 200-797, Lupin Ltd. and Lupin Inc. committed an act of infringement with respect to the '599 patent under 35 U.S.C. §271(e)(2)(A).

51. Unless enjoined by this Court, Lupin Ltd. and/or Lupin Inc., upon the approval of ANDA No. 200-797, will infringe the '599 patent under 35 U.S.C. §271 by making, using, offering for sale, and/or selling in; and/or importing into the United States the Lupin Generic Products.

52. Lupin Ltd. and Lupin Inc. had notice of the '599 patent prior to the filing of this lawsuit. Any infringement of the '599 has been and will be willful and deliberate.

COUNT III

(Declaratory Judgment of Infringement of the ’599 Patent)

53. Paragraphs 1-44 are incorporated herein as set forth above.

54. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

55. There is an actual case or controversy such that the Court may entertain Novartis’s request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

56. Lupin Ltd. and/or Lupin Inc. has/have made, and will continue to make, substantial preparation to make, use, offer sale and/or sell in; and/or import into the United States the Lupin Generic Products prior to patent expiry.

57. The actions of Lupin Ltd. and/or Lupin Inc., including the filing of ANDA 200-797 and a Paragraph IV with respect to the ’197 patent, indicate a refusal by either and/or both to change course.

58. Any commercial manufacture, use, offer for sale and/or sale in; and/or importation into the United States of the Lupin Generic Products prior to patent expiry will constitute direct, contributory and/or induced infringement of the ’599 patent.

59. Novartis is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale and/or sale in; and/or importation into the United States of the Lupin Generic

Products prior to patent expiry will constitute direct, contributory and/or induced infringement of the ’599 patent.

Injunctive Relief

60. Novartis will be irreparably harmed by the foregoing infringing activities unless those activities are enjoined by this Court. Novartis does not have an adequate remedy at law.

Prayer for Relief

Novartis respectfully prays for the following relief:

a. A judgment that Lupin Ltd. and Lupin Inc. have infringed one or more claims of the ’197 patent;

b. A judgment that Lupin Ltd. and Lupin Inc. have infringed one or more claims of the ’599 patent;

c. An Order that the effective date of any FDA approval of ANDA No. 200-797 be a date that is not earlier than the expiration of the ’197 patent, or any expiration of exclusivity to which Novartis is or becomes entitled;

d. An Order that the effective date of any FDA approval of ANDA No. 200-797 be a date that is not earlier than the expiration of the ’599 patent, or any expiration of exclusivity to which Novartis is or becomes entitled;

e. Preliminary and permanent injunctions enjoining Lupin Ltd., Lupin Inc., officers, agents, attorneys and employees of the same, and those acting in privity or concert with the same, from making, using, offering for sale, and/or selling in; and/or importing into the

United States the Lupin Generic Products until after the expiration of the ’197 patent, inclusive of any patent term extensions and/or exclusivities to which Novartis is or becomes entitled;

f. Preliminary and permanent injunctions enjoining Lupin Ltd., Lupin Inc., officers, agents, attorneys and employees of the same, and those acting in privity or concert with the same, from making, using, offering for sale, and/or selling in; and/or importing into the United States the Lupin Generic Products until after the expiration of the ’599 patent, inclusive of any patent term extensions and/or exclusivities to which Novartis is or becomes entitled;

g. A declaration that the commercial manufacture use, offer for sale, and/or sale in; and/or importation into the United States of the Lupin Generic Products prior to patent expiry will directly infringe, induce and/or contribute to infringement of the ’197 patent;

h. A declaration that the commercial manufacture, use, offer for sale, and/or sale in; and/or importation into the United States of the Lupin Generic Products prior to patent expiry will directly infringe, induce and/or contribute to infringement of the ’599 patent;

i. If Lupin Ltd., Lupin Inc., or anyone acting in privity or concert with any of them engage(s) in the commercial manufacture, use, sale and/or offer for sale; and/or importation of the Lupin Generic Products prior to the expiration of the ’197 patent, a Judgment awarding damages to Novartis for infringement of the ’197 patent, increased to treble the amount found or assessed, together with interest;

j. If Lupin Ltd., Lupin Inc., or anyone acting in privity or concert with any of them engage(s) in the commercial manufacture, use, sale and/or offer for sale; and/or importation of the Lupin Generic Products prior to the expiration of the ’599 patent, a Judgment

awarding damages to Novartis for infringement of the '599 patent, increased to treble the amount found or assessed, together with interest;

k. A declaration that this case is exceptional, entitling Novartis to recover its reasonable attorney fees pursuant to 35 U.S.C. §§271(e)(4) and 285;

l. Costs and expenses in this action; and

m. Such further relief as this Court may deem just and proper.

Dated: May 14, 2012

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Patrick A. Walker (#5242)
Renaissance Centre
405 North King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
Fax: (302) 984-6399
mkelly@mccarter.com
dsilver@mccarter.com
pwalker@mccarter.com

Attorney for Novartis Pharmaceuticals Corporation

OF COUNSEL:

Scott Familant
Jennifer Gordon
BAKER BOTTS LLP
30 Rockefeller Plaza
New York, NY 10112-4498
Phone: 212.408.2500
Fax: 212.408.2501
scott.familant@bakerbotts.com
jennifer.gordon@bakerbotts.com