IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

GILEAD SCIENCES, INC., Plaintiff, v. LUPIN LIMITED, Defendant.	Civil Action No.: 2:14-cv-796

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Gilead Sciences, Inc. ("Gilead") for its complaint against Lupin Ltd. ("Lupin"), hereby alleges as follows:

Nature of Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code.

The Parties

2. Gilead is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. On information and belief, defendant Lupin is an Indian corporation having its principal place of business at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India.

Jurisdiction and Venue

4. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

5. On information and belief, this Court has personal jurisdiction over Lupin.

6. On information and belief, Lupin, itself or through one of its wholly-owned subsidiaries, derives substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in Texas and this District.

7. On information and belief, Lupin, itself or through one of its wholly-owned subsidiaries, manufactures pharmaceutical drug products that are sold and used throughout the United States, including in Texas and this District.

8. On information and belief, Lupin, itself or through one of its wholly-owned subsidiaries, has sale representatives focused on the sale of pharmaceutical drug products in Texas and this District.

9. On information and belief, residents of the State of Texas purchase pharmaceutical drug products from Lupin in the State of Texas.

10. On information and belief, Lupin, itself or through one of its wholly-owned subsidiaries, has authorized distributors in the State of Texas to distribute Lupin's pharmaceutical drug products throughout the State of Texas.

11. On information and belief, Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 20-5590, discussed below, indicates Lupin's intention to engage in the commercial manufacture, use, sale and/or importation of products that will compete directly with Gilead's Atripla® product, which is currently being sold throughout the United States,

including in Texas and this District. On information and belief, Lupin will sell the tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate for the use for which Lupin seeks approval in ANDA No. 20-5590, if approved, throughout the United States, including in Texas and this District.

12. On information and belief, Lupin has previously consented to personal jurisdiction in this District.

13. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), (d), and 28 U.S.C. § 1400(b).

Background

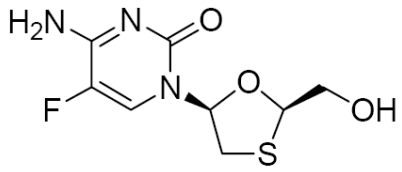
14. Gilead is the holder of New Drug Application ("NDA") No. 21-937 which relates to tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate. On July 12, 2006, the United States Food and Drug Administration ("FDA") approved the use of the tablets described in NDA No. 21-937 for the treatment of HIV-1 infection in adults. These tablets are prescribed and sold in the United States under the trademark Atripla®.

15. United States Patent No. 8,592,397 ("the '397 Patent," copy attached as Exhibit A), entitled "Compositions and Methods for Combination Antiviral Therapy," was duly and legally issued by the United States Patent and Trademark Office on November 26, 2013. The '397 Patent claims, *inter alia*, a chemically stable pharmaceutical combination tablet containing emtricitabine, tenofovir disoproxil fumarate (two of the active ingredients in Atripla®), and certain excipients, and methods for treating HIV infection in humans with the emtricitabine and tenofovir disoproxil fumarate combination (with certain listed excipients). The

'397 Patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Atripla®.

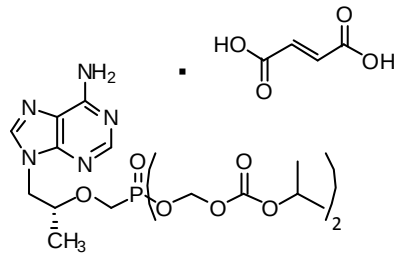
16. United States Patent No. 8,716,264 ("the '264 Patent," copy attached as Exhibit B), entitled "Compositions and Methods for Combination Antiviral Therapy," was duly and legally issued by the United States Patent and Trademark Office on May 6, 2014. The '264 Patent claims, *inter alia*, a chemically stable pharmaceutical combination tablet containing emtricitabine and tenofovir disoproxil fumarate (two of the active ingredients in Atripla®) and methods for treating HIV infection in humans with the emtricitabine and tenofovir disoproxil fumarate combination. The '264 Patent is also listed in the FDA Orange Book for Atripla®.

17. Emtricitabine is a compound that has a molecular formula of $C_8H_{10}FN_3O_3S$, and which has the following chemical structure:



18. Emtricitabine can be referred to by any of several chemical names. The chemical name given to emtricitabine in the Atripla® label is "5-fluoro-1-(2*R*,5*S*)-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine." Chemical names recited for emtricitabine in the '397 and '264 Patents are: "(2R, 5S, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine, Emtriva™, (-)-cis FTC)," "β-L-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane," "(2R,5S)-5-fluoro-1-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine," and "4-amino-5-fluoro-1-(2-hydroxymethyl-[1,3]-(2R,5S)-oxathiolan-5-yl)-1H-pyrimidin-2-one."

19. Tenofovir disoproxil fumarate is a compound that has a molecular formula of $C_{19}H_{30}N_5O_{10}P \cdot C_4H_4O_4$, and which has the following chemical structure:



TDF

20. Tenofovir disoproxil fumarate can be referred to by any of several chemical names. The chemical name given to tenofovir disoproxil fumarate in the Atripla® label is "9-[(*R*)-2[[bis[[(isopropoxycarbonyl)oxy]-methoxy]phosphinyl]methoxy]propyl]adenine fumarate (1:1)." Chemical names recited for tenofovir disoproxil fumarate in the '397 and '264 Patents are: "[2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate, tenofovir DF, TDF, Viread®)," and "2,4,6,8-tetraoxa-5-phosphanonanedioic acid, 5-[[(1R)-2-(6-amino-9H-purin-9-yl)-1-methylethoxy]methyl]-, bis(1-methylethyl)ester, 5-oxide, (2E)-2-butenedioate."

21. The named inventors of the '397 and '264 Patents are Terrence C. Dahl, Mark M. Menning, and Reza Oliyai.

22. Terrence C. Dahl, Mark M. Menning, and Reza Oliyai assigned the '397 and '264 Patents to Gilead.

COUNT 1
Infringement of U.S. Patent No. 8,592,397

23. Gilead repeats and realleges paragraphs 1-22 above as if set forth herein.

24. On information and belief, Lupin submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 20-5590, to the FDA

seeking approval to engage in the commercial manufacture, use, sale, and/or importation of tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate for the purpose of treating HIV infection.

25. By letter dated June 13, 2014 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "June 13, 2014 Notice Letter"), Lupin notified Gilead that it had submitted ANDA No. 20-5590 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '397 Patent.

26. In its June 13, 2014 Notice Letter, Lupin notified Gilead that, as a part of ANDA No. 20-5590, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '397 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '397 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include, "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

27. Lupin alleged in its June 13, 2014 Notice Letter that Claims 1-26 of the '397 Patent are invalid and Claims 7-13, 15-18, and 23 of the '397 Patent would not be infringed by the commercial manufacture, use, sale, and/or importation of its proposed product that is the subject of ANDA No. 20-5590.

28. The June 13, 2014 Notice Letter does not allege non-infringement of Claims 1-6, 14, 19-22, and 24-26 of the '397 Patent other than solely stating that the '397 Patent is invalid.

29. The June 13, 2014 Notice Letter does not provide the full and detailed statement of Lupin's factual and legal basis to support its non-infringement and invalidity allegations as to the '397 Patent.

30. Accordingly, the June 13, 2014 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

31. By filing ANDA No. 20-5590 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale, and/or importation of tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate before the '397 Patent's expiration, Lupin has committed an act of infringement of the '397 Patent under 35 U.S.C. § 271(e)(2).

32. Lupin's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '397 Patent.

33. Lupin's submission of ANDA No. 20-5590 and service of the June 13, 2014 Notice Letter indicates a refusal to change its current course of action.

34. On information and belief, the commercial manufacture, use, sale, and/or importation of tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate for which Lupin seeks approval in ANDA No. 20-5590, if approved, will infringe one or more claims of the '397 Patent.

35. On information and belief, the tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate for the use for which Lupin seeks approval in ANDA No. 20-5590, if approved, will be administered to human patients in an effective amount for treating HIV infection. This administration will infringe one or more claims of the '397 Patent. On information and belief, this administration will occur at Lupin's active behest and with its intent, knowledge, and encouragement. On information and belief, Lupin will actively encourage, aid, and abet this administration with knowledge that it is in contravention of Gilead's rights under the '397 Patent. Further, by filing ANDA No. 20-5590 with a Paragraph IV certification, Lupin admits that it has knowledge of the '397 Patent.

36. The June 13, 2014 Notice Letter does not allege and does not address unenforceability of any claims of the '397 Patent. By not addressing unenforceability of any claims of the '397 Patent in its June 13, 2014 Notice Letter, Lupin admits that all of the claims of the '397 Patent are enforceable.

COUNT 2
Infringement of U.S. Patent No. 8,716,264

37. Gilead repeats and realleges paragraphs 1-22 above as if set forth herein.

38. On information and belief, Lupin submitted or caused to be submitted an ANDA, specifically ANDA No. 20-5590, to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of tablets containing the combination of

600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate for the purpose of treating HIV infection.

39. In its June 13, 2014 Notice Letter, Lupin notified Gilead that it had submitted ANDA No. 20-5590 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '264 Patent.

40. In its June 13, 2014 Notice Letter, Lupin notified Gilead that, as a part of ANDA No. 20-5590, it had filed a Paragraph IV certification with respect to the '264 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '264 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include, "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

41. Lupin alleged in its June 13, 2014 Notice Letter that Claims 1-38 of the '264 Patent are invalid and Claims 18-24, 28-29, 31, and 33-38 of the '264 Patent would not be infringed by the commercial manufacture, use, sale, and/or importation of its proposed product that is the subject of ANDA No. 20-5590.

42. The June 13, 2014 Notice Letter does not allege non-infringement of Claims 1-17, 25-27, 30, and 32 of the ’264 Patent other than solely stating that the ’264 Patent is invalid.

43. The June 13, 2014 Notice Letter does not provide the full and detailed statement of Lupin’s factual and legal basis to support its non-infringement and invalidity allegations as to the ’264 Patent.

44. Accordingly, the June 13, 2014 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

45. By filing ANDA No. 20-5590 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale, and/or importation of tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate before the ’264 Patent’s expiration, Lupin has committed an act of infringement of the ’264 Patent under 35 U.S.C. § 271(e)(2).

46. Lupin’s ANDA and Paragraph IV certification is a wholly unjustified infringement of the ’264 Patent.

47. Lupin’s submission of ANDA No. 20-5590 and service of the June 13, 2014 Notice Letter indicates a refusal to change its current course of action.

48. On information and belief, the commercial manufacture, use, sale, and/or importation of tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate for which Lupin seeks approval in ANDA No. 20-5590, if approved, will infringe one or more claims of the ’264 Patent.

49. On information and belief, the tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir disoproxil fumarate for the use for which Lupin seeks approval in ANDA No. 20-5590, if approved, will be administered to human patients in an effective amount for treating HIV infection. This administration will infringe one or more claims of the '264 Patent. On information and belief, this administration will occur at Lupin's active behest and with its intent, knowledge, and encouragement. On information and belief, Lupin will actively encourage, aid, and abet this administration with knowledge that it is in contravention of Gilead's rights under the '264 Patent. Further, by filing ANDA No. 20-5590 with a Paragraph IV certification, Lupin admits that it has knowledge of the '264 Patent.

50. The June 13, 2014 Notice Letter does not allege and does not address unenforceability of any claims of the '264 Patent. By not addressing unenforceability of any claims of the '264 Patent in its June 13, 2014 Notice Letter, Lupin admits that all of the claims of the '264 Patent are enforceable.

* * *

51. Gilead seeks a determination that this case is an exceptional one and an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Gilead respectfully requests the following relief:

(a) A judgment declaring that the effective date of any approval of Lupin's ANDA No. 20-5590 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '397 Patent or any later date of exclusivity to which Gilead is or becomes entitled;

(b) A judgment declaring that the effective date of any approval of Lupin's ANDA No. 20-5590 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '264 Patent or any later date of exclusivity to which Gilead is or becomes entitled;

(c) A judgment declaring that the '397 Patent remains valid, enforceable, and that one or more claims have been infringed by Lupin;

(d) A judgment declaring that the '264 Patent remains valid, enforceable, and that one or more claims have been infringed by Lupin;

(e) A permanent injunction against any infringement of the '397 Patent by Lupin, their officers, agents, attorneys, and employees, and those acting in privity or contract with them;

(f) A permanent injunction against any infringement of the '264 Patent by Lupin, their officers, agents, attorneys, and employees, and those acting in privity or contract with them;

(g) A judgment that Lupin's conduct is exceptional in this case;

(h) An award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(i) To the extent that Lupin has committed any acts with respect to the subject matter claimed in the '397 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(j) To the extent that Lupin has committed any acts with respect to the subject matter claimed in the '264 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(k) Costs and expenses in this action; and

(r) Such other relief as this Court may deem proper.

July 24, 2014

Respectfully submitted,

/s/ David Bassett by permission Wesley Hill
David Bassett (Lead Attorney) (*pro hac vice forthcoming*)
David Manspeizer (*pro hac vice forthcoming*)
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Tel: 212-230-8800
Fax: 212-230-8888

Vinita Ferrera (*pro hac vice forthcoming*)
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel: 617-526-6000
Fax: 617-526-5000

Nicholas M. Cannella (*pro hac vice forthcoming*)
Peter Shapiro (*pro hac vice forthcoming*)
Christopher P. Borello (*pro hac vice forthcoming*)
FITZPATRICK, CELLA, HARPER
& SCINTO
1290 Avenue of the Americas
New York, NY 10104
Tel: 212-218-2100
Fax: 212-218-2200

Colleen Tracy (*pro hac vice forthcoming*)
MAYER BROWN LLP
1675 Broadway
New York, NY 10019
Tel: 212-506-2122
Fax: 212-849-5336

T. John Ward
Texas State Bar No. 2084800

E-mail: tjw@wsfirm.com
J. Wesley Hill
Texas State Bar No. 24032294
E-mail: wh@wsfirm.com
WARD & SMITH LAW FIRM
1127 Judson Road, Ste. 220
Longview, Texas 75601
Tel: 903-757-6400
Fax: 903-757-2323

Attorneys for Plaintiff Bristol-Myers Squibb & Gilead Sciences, LLC