IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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JUL 16 2014
U.S.D.C. S.D. N.Y.

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

Plaintiffs,

v.

LUPIN LIMITED,

Defendant.

Civil Action No.:

14 CV 5352

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Gilead Sciences, Inc. ("Gilead") and Emory University ("Emory") (collectively, "Plaintiffs") for its complaint against Lupin Ltd. ("Lupin"), hereby allege 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. Emory is a non-profit corporation of the State of Georgia, having an office at 201 Dowman Drive, Atlanta, Georgia 30322.

4. 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

5. 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).

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

7. On information and belief, Lupin, itself of 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 New York and this District.

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

9. 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 New York and this District.

10. On information and belief, residents of the State of New York purchase pharmaceutical drug products from Lupin in the State of New York.

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

12. On information and belief, Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 205590, 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 New York 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. 205590, if approved, throughout the United States, including in New York and this District.

13. On information and belief, Lupin has previously consented to personal jurisdiction in this District and has previously filed declaratory judgment claims in this District.

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

Background

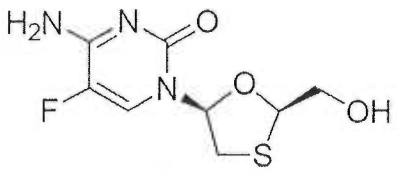
15. Gilead is the holder of New Drug Application ("NDA") No. 21-937 which relates to tablets containing the combination of 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate. On July 12, 2006, the United States Food and Drug Administration ("FDA") approved the use 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®.

16. United States Patent No. 6,642,245 ("the '245 Patent," copy attached as Exhibit A), entitled "Antiviral Activity and Resolution of 2-Hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2003. The '245 Patent claims, *inter alia*, methods for treating HIV

infection in humans with emtricitabine (one of the active ingredients in Atripla®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Atripla®.

17. United States Patent No. 6,703,396 ("the '396 Patent," copy attached as Exhibit B), entitled "Method of Resolution and Antiviral Activity of 1,3-Oxathiolane Nucleoside Enantiomers," was duly and legally issued by the United States Patent and Trademark Office on March 9, 2004. The '396 Patent claims, *inter alia*, emtricitabine (one of the active ingredients in Atripla®), and is listed in the FDA Orange Book for Atripla®.

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



19. 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." Two chemical names recited for emtricitabine in the '245 Patent are "(–)-β-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane" and "β-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane." Two chemical names recited for emtricitabine in the '396 Patent are "(–)-cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one" and "(–)-enantiomer of cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one."

20. The named inventors on the '245 and '396 Patents are Dennis C. Liotta, Raymond F. Schinazi and Woo-Baeg Choi.

21. Dennis C. Liotta, Raymond F. Schinazi and Woo-Baeg Choi assigned the '245 and '396 Patents to Emory.

22. Pursuant to an agreement entered into between Gilead and Emory, Gilead has substantial rights in the '245 and '396 Patents, including but not limited to, rights associated with being a licensee of the '245 and '396 Patents, and the right to sue for infringement of the '245 and '396 Patents.

COUNT 1
Infringement of U.S. Patent No. 6,642,245

23. Plaintiffs repeat and reallege 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. 205590, 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 Plaintiffs that it had submitted ANDA No. 205590 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 '245 Patent.

26. In its June 13, 2014 Notice Letter, Lupin notified Plaintiffs that, as a part of ANDA No. 205590, 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 '245 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 '245 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 1-22 of the '245 Patent are both invalid and would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 205590.

28. 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 '245 Patent.

29. 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.

30. By filing ANDA No. 205590 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 '245 Patent's expiration, Lupin has committed an act of infringement of the '245 Patent under 35 U.S.C. § 271(e)(2).

31. On information and belief, Lupin lacked a good faith basis for alleging invalidity when ANDA No. 205590 was filed and when the Paragraph IV certification was made. Lupin's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '245 Patent.

32. Lupin's submission of ANDA No. 205590 and service of the June 13, 2014 Notice Letter indicates a refusal to change its current course of action.

33. 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. 205590, if approved, will infringe one or more claims of the '245 Patent.

34. 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. 205590, 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 '245 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 Plaintiffs' rights under the '245 Patent. Further, by filing ANDA No. 205590 with a Paragraph IV certification, Lupin admits that it has knowledge of the '245 Patent.

35. The June 13, 2014 Notice Letter does not allege and does not address unenforceability of any claims of the '245 Patent. By not addressing unenforceability of any

claims of the '245 Patent in its June 13, 2014 Notice Letter, Lupin admits that all of the claims of the '245 Patent are enforceable.

COUNT 2
Infringement of U.S. Patent No. 6,703,396

36. Plaintiffs repeat and reallege paragraphs 1-22 above as if set forth herein.

37. On information and belief, Lupin submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 205590, 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.

38. 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 Plaintiffs that it had submitted ANDA No. 205590 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 '396 Patent.

39. In its June 13, 2014 Notice Letter, Lupin notified Plaintiffs that, as a part of its ANDA No. 205590, it had filed a Paragraph IV certification with respect to the '396 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 '396 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."

40. Lupin alleged in its June 13, 2014 Notice Letter that Claims 1-28 of the '396 Patent are both invalid and would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 205590.

41. 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 '396 Patent.

42. 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.

43. By filing ANDA No. 205590 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 '396 Patent's expiration, Lupin has committed an act of infringement of the '396 Patent under 35 U.S.C. § 271(e)(2).

44. On information and belief, Lupin lacked a good faith basis for alleging invalidity when ANDA No. 205590 was filed and when the Paragraph IV certification was made. Lupin's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '396 Patent.

45. Lupin's submission of ANDA No. 205590 and service of the June 13, 2014 Notice Letter indicates a refusal to change its current course of action.

46. 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. 205590, if approved, will infringe one or more claims of the '396 Patent.

47. The June 13, 2014 Notice Letter does not allege and does not address unenforceability of any claims of the '396 Patent. By not addressing unenforceability of any claims of the '396 Patent in its June 13, 2014 Notice Letter, Lupin admits that all of the claims of the '396 Patent are enforceable.

* * *

48. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Lupin's ANDA No. 205590 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 '245 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(b) A judgment declaring that the effective date of any approval of Lupin's ANDA No. 205590 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 '396 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(c) A judgment declaring that the '245 Patent remains valid, enforceable and has been infringed by Lupin;

(d) A judgment declaring that the '396 Patent remains valid, enforceable and has been infringed by Lupin;

(e) A permanent injunction against any infringement of the '245 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 '396 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 '245 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 '396 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 16, 2014

Respectfully submitted,

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