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

10 CV 1798

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

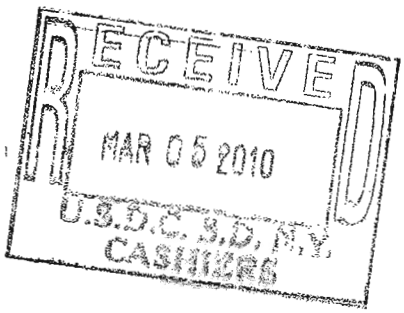
Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC. and
TEVA PHARMACEUTICAL INDUSTRIES
LIMITED,

Defendants.

Case No.:



COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Gilead Sciences, Inc. ("Gilead") and Emory University ("Emory") (collectively, "Plaintiffs") for their Complaint against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva"), 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 Teva Pharmacuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454.

5. On information and belief, defendant Teva Pharmaceutical Industries, Ltd. ("Teva Industries") is an Israeli corporation having its principal place of business at 5 Basel St., P.O. Box 3190, Petach Tikva 49131, Israel.

6. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Industries, and these two companies have common officers and directors.

7. Upon information and belief, the acts of Teva USA complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, assistance of, and at least in part the benefit of, Teva Industries.

Jurisdiction and Venue

8. 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).

9. On information and belief, this Court has personal jurisdiction over Teva USA and Teva Industries.

10. On information and belief, Teva USA derives substantial revenue from selling various products and doing business throughout the United States, including in New York and this District.

11. On information and belief, Teva USA is registered to do business with the New York State Division of Corporations, and Corporate Creations Network Inc., 15 North Mill Street, Nyack, New York 10960 is authorized to accept service on behalf of Teva USA.

12. On information and belief, Teva Industries manufactures bulk pharmaceuticals and pharmaceutical products that are sold, including sold by Teva USA, throughout the United States, including 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. 21-752 which relates to tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate. On August 2, 2004, the United States Food and Drug Administration ("FDA") approved the use of the tablets described in NDA No. 21-752 for the treatment of HIV-1 infection in adults. These tablets are prescribed and sold in the United States under the trademark Truvada®.

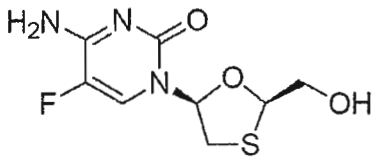
15. Gilead is the holder of NDA No. 21-937 which relates to tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate. On July 12, 2006, the FDA approved the use of the tablets described in NDA No. 21-937 for the treatment of HIV-1 infection in adults. These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

16. United States Patent No. 5,814,639 ("the '639 Patent," copy attached as Exhibit A), entitled "Method for the synthesis, compositions and use of 2'-Deoxy-5-Fluoro-3'-Thiacytidine and related compounds," was duly and legally issued by the United States Patent

and Trademark Office on September 29, 1998. The '639 Patent claims relate to, *inter alia*, emtricitabine (one of the active ingredients in Truvada® and Atripla®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Truvada® and Atripla®.

17. United States Patent No. 5,914,331 ("the '331 Patent," copy attached as Exhibit B), 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 June 22, 1999. The '331 Patent claims relate to, *inter alia*, emtricitabine (one of the active ingredients in Truvada® and Atripla®), and is listed in the FDA Orange Book for Truvada® and 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 Truvada® and Atripla® labels is "5-fluoro-1-(2*R*,5*S*)-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine."

20. The named inventors on the '639 and '331 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 '639 and '331 Patents to Emory.

22. Pursuant to an agreement entered into between Gilead and Emory, Gilead has substantial rights in the '639 and '331 Patents, including but not limited to, rights associated with being a licensee of the '639 and '331 Patents, and the right to sue for infringement of the '639 and '331 Patents.

COUNT 1
Infringement of U.S. Patent No. 5,814,639 (ANDA No. 90-894)

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

24. On information and belief, Teva submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 90-894, to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate.

25. On information and belief, ANDA No. 90-894 seeks approval to manufacture, use, sell and import emtricitabine for the purpose of treating HIV infection in adults.

26. By letter dated January 28, 2010 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "January 28, 2010 Truvada® Notice Letter"), Teva notified Plaintiffs that it had submitted ANDA No. 90-894 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '639 Patent.

27. In its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiffs that, as a part of ANDA No. 90-894, 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 '639 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 '639 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this 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 factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

28. Teva alleged in its January 28, 2010 Truvada® Notice Letter that Claims 1 and 2 of the '639 Patent are invalid.

29. By filing ANDA No. 90-894 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 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate before the '639 Patent's expiration, Teva has committed an act of infringement of the '639 Patent under 35 U.S.C. § 271(e)(2).

30. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 90-894 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '639 Patent.

31. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 90-894 will infringe , induce infringement, or contributorily infringe one or more claims of the '639 Patent.

COUNT 2
Infringement of U.S. Patent No. 5,914,331 (ANDA No. 90-894)

32. Plaintiffs repeat and reallege paragraphs 1-22, 24 and 25 above as if set forth herein.

33. By letter dated January 28, 2010 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "January 28, 2010 Truvada® Notice Letter"), Teva notified Plaintiffs that it had submitted ANDA No. 90-894 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '331 Patent.

34. In its January 28, 2010 Notice Letter, Teva notified Plaintiffs that, as a part of its ANDA No. 90-894, it had filed a Paragraph IV certification with respect to the '331 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 '331 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this 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 factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

35. Teva alleged in its January 28, 2010 Truvada® Notice Letter that Claims 1-2 and 4-6 of the '331 Patent are invalid and that Claims 3 and 7 of the '331 Patent would not be infringed by the commercial manufacture, use, sale and importation of its proposed product that is the subject of ANDA No. 90-894.

36. By filing ANDA No. 90-894 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 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate before the '331 Patent's expiration, Teva has committed an act of infringement of the '331 Patent under 35 U.S.C. § 271(e)(2).

37. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 90-894 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '331 Patent.

38. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for which Teva seeks approval in ANDA No. 90-894 will infringe, induce infringement, or contributorily infringe one or more claims of the '331 Patent.

COUNT 3
Infringement of U.S. Patent No. 5,814,639 (ANDA No. 91-215)

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

40. On information and belief, Teva submitted or caused to be submitted an ANDA, specifically ANDA No. 91-215, to the FDA seeking approval to engage in the commercial manufacture, use and sale of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate.

41. On information and belief, ANDA No. 91-215 seeks approval to manufacture, use and sell emtricitabine for the purpose of treating HIV infection in adults.

42. By letter dated January 28, 2010 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "January 28, 2010 Atripla® Notice Letter"), Teva notified Plaintiffs that it had submitted

ANDA No. 91-215 to the FDA seeking approval to engage in the commercial manufacture, use and sale of tablets containing 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '639 Patent.

43. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiffs that, as a part of ANDA No. 91-215, it had filed a Paragraph IV certification with respect to the '639 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 '639 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this 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 factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

44. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1 and 2 of the '639 Patent were invalid.

45. By filing ANDA No. 91-215 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use and/or sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, before the '639 Patent's expiration, Teva has committed an act of infringement of the '639 Patent under 35 U.S.C. § 271(e)(2).

46. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-215 was filed and when the Paragraph IV certification was made.

Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '639 Patent.

47. On information and belief, the commercial manufacture, use and/or sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use of which Teva seeks approval in ANDA No. 91-215 will infringe , induce infringement, or contributorily infringe one or more claims of the '639 Patent.

COUNT 4
Infringement of U.S. Patent No. 5,914,331 (ANDA No. 91-215)

48. Plaintiffs repeat and reallege paragraphs 1-22, 40 and 41 above as if set forth herein.

49. By letter dated January 28, 2010 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "January 28, 2010 Atripla® Notice Letter"), Teva notified Plaintiffs that it had submitted ANDA No. 91-215 to the FDA seeking approval to engage in the commercial manufacture, use and sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '331 Patent.

50. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiffs that, as a part of its ANDA No. 91-215, it had filed a Paragraph IV certification with respect to the '331 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 '331 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this 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 factual statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules

and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

51. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1-2 and 4-6 of the '331 Patent are invalid and that Claims 3 and 7 of the '331 Patent would not be infringed by the commercial manufacture, use, and sale of its proposed product that is the subject of ANDA No. 91-215.

52. By filing ANDA No. 91-215 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use and/or sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, before the '331 Patent's expiration, Teva has committed an act of infringement of the '331 Patent under 35 U.S.C. § 271(e)(2).

53. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-215 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '331 Patent.

54. On information and belief, the commercial manufacture, use and/or sale of tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for which Teva seeks approval in ANDA No. 91-215 will infringe, induce infringement, or contributorily infringe one or more claims of the '331 Patent.

55. 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 Teva's ANDA No. 90-894 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 '639 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 Teva's ANDA No. 90-894 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 '331 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(c) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-215 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 '639 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(d) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-215 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 '331 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(e) A judgment declaring that the '639 Patent remains valid, enforceable and has been infringed by Teva;

(f) A judgment declaring that the '331 Patent remains valid, enforceable and has been infringed by Teva;

(g) A permanent injunction against any infringement of the '639 Patent by Teva, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(h) A permanent injunction against any infringement of the '331 Patent by Teva, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(i) A judgment that this is an exceptional case, and that Plaintiffs are entitled to an award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(j) To the extent that Teva has committed any acts with respect to the subject matter claimed in the '639 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) To the extent that Teva has committed any acts with respect to the subject matter claimed in the '331 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;

(l) Costs and expenses in this action; and

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

March 5, 2010

Respectfully submitted,

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