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

08 CIV 10838

GILEAD SCIENCES, INC.,

Plaintiff,

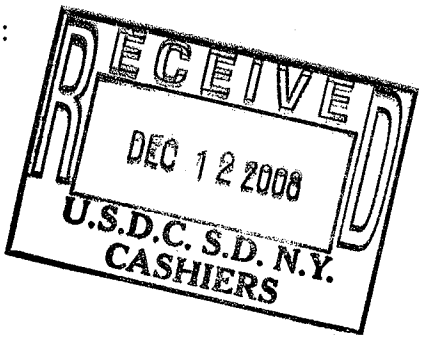
v.

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

Defendants.

JUDGE SULLIVAN

Civil Action No.:



COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Gilead Sciences, Inc. ("Gilead") for its complaint against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva"), 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 Teva Pharmaceuticals 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.

4. 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.

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

6. 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

7. 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).

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

9. 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.

10. 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.

11. 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.

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

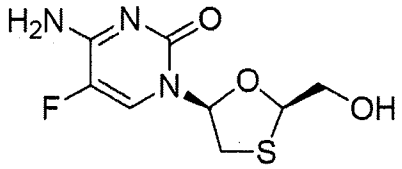
Claim for Relief -- Patent Infringement

13. 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®.

14. 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 two active ingredients in Truvada®), and is listed in the FDA Orange Book for Truvada®.

15. 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 two active ingredients in Truvada®), and is listed in the FDA Orange Book for Truvada®.

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



17. Emtricitabine can be referred to by any of several chemical names. The chemical name given to emtricitabine in the Truvada® 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 "(–)-ß-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane" and "ß-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."

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

19. Dennis C. Liotta, Raymond F. Schinazi, and Woo-Baeg Choi assigned the '245 and '396 Patents to Emory University ("Emory").

20. 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

21. Gilead repeats and realleges paragraphs 1-20 above as if set forth herein.

22. 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.

23. On information and belief, ANDA 90-894 seeks approval to manufacture, use, sell and import emtricitabine for the purpose of treating HIV infection in adults.

24. By letter dated November 3, 2008 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "November 3, 2008 Notice Letter"), Teva notified Gilead 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 '245 Patent.

25. In its November 3, 2008 Notice Letter, Teva notified Gilead 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 '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 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."

26. Teva alleged in its November 3, 2008 Notice Letter that Claims 1-8 and 17-19 of the '245 Patent are invalid and that Claims 9-16 and 20-22 of the '245 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.

27. By filing ANDA 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 '245 Patent's expiration, Teva has committed an act of infringement of the '245 Patent under 35 U.S.C. § 271(e)(2).

28. 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 '245 Patent.

29. 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 and/or contributorily infringe one or more claims of the '245 Patent.

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

30. Gilead realleges paragraphs 1-20 and 22 above as if set forth herein.

31. On information and belief, ANDA 90-894 seeks approval to manufacture, use, sell and import emtricitabine.

32. By letter dated November 3, 2008 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "November 3, 2008 Notice Letter"), Teva notified Gilead 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 '396 Patent.

33. In its November 3, 2008 Notice Letter, Teva notified Gilead that, as a part of its 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 '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 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."

34. Teva USA alleged in its November 3, 2008 Notice Letter that Claims 1-7 and 11-28 of the '396 Patent are invalid and that Claims 8-10 of the '396 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.

35. By filing ANDA 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 '396 Patent's expiration, Teva has committed an act of infringement of the '396 Patent under 35 U.S.C. § 271(e)(2).

36. 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 '396 Patent.

37. 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 one or more claims of the '396 Patent.

38. This case is an exceptional one, and Gilead is entitled to 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 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 '245 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 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 '396 Patent or any later date of exclusivity to which Gilead is or becomes entitled;

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

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

(e) A permanent injunction against any infringement of the '245 Patent by Teva, 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 Teva, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

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

(h) To the extent that Teva 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;

(i) To the extent that Teva 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.

(j) Costs and expenses in this action; and

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

December 12, 2008

Respectfully submitted,

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