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

GILEAD SCIENCES, INC.,

Plaintiff,

v.

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

Defendants.

JUN 15 2011
U.S.D.C. S.D. N.Y.
CASHIERS

Case No.: 10-cv-1796 (RJS) (AJP)
ECF Case

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

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

7. On information and belief, defendant Cipla is a corporation organized and existing under the laws of India, having its principal place of business at 289 Bellasis Road Mumbai Central, Mumbai 400 008, Maharashtra, India.

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. On information and belief, this court has personal jurisdiction over Cipla.

14. On information and belief, Cipla manufactures active pharmaceutical ingredients ("API") for generic pharmaceutical products that are sold throughout the United States, including in this District.

15. On information and belief, Cipla derives substantial revenue from selling API that is used in various generic pharmaceutical products sold throughout the United States, including in New York and this District.

16. On information and belief, Cipla submitted Drug Master File ("DMF") No. 020003 to the FDA for the purpose of manufacturing tenofovir disoproxil fumarate for use in the United States, and manufactures and sells tenofovir disoproxil fumarate API to Teva for use in tenofovir disoproxil fumarate drug products.

17. On information and belief, Cipla is subject to personal jurisdiction in New York because, *inter alia*, Cipla designated an agent in New York in filing DMF No. 020003 with

the FDA, and because Cipla's sales of API to generic pharmaceutical companies for incorporation into generic products sold throughout the United States, including New York and this District, contributed to or induced acts of infringement in New York.

18. In the alternative Cipla is subject to jurisdiction in the United States under the principles of general jurisdiction, and specifically in New York pursuant to Fed. R. Civ. P. 4(k)(2). Cipla has contacts with the United States by, *inter alia*, its having filed a DMF with the FDA, its sale of pharmaceutical drug substances to Teva, and its sale of API to generic pharmaceutical companies for incorporation into generic products sold throughout the United States, including New York and this District.

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

Background

20. Gilead is the holder of New Drug Application ("NDA") No. 21-356 which relates to tablets containing 300 mg of tenofovir disoproxil fumarate. On October 26, 2001, the United States Food and Drug Administration ("FDA") approved the use of the tablets described in NDA No. 21-356 for the treatment of HIV-1 infection in adults. These tablets are prescribed in the United States under the trademark Viread®.

21. Gilead is the holder of 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 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®.

22. 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®.

23. United States Patent No. 5,922,695 ("the '695 Patent," copy attached as Exhibit A), entitled "Antiviral Phosphonomethoxy Nucleotide analogs having increased oral bioavailability," was duly and legally issued by the United States Patent and Trademark Office on July 13, 1999. The claims of the '695 Patent cover, *inter alia*, tenofovir disoproxil fumarate (the active ingredient in Viread® and 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 Viread®, Truvada®, and Atripla®.

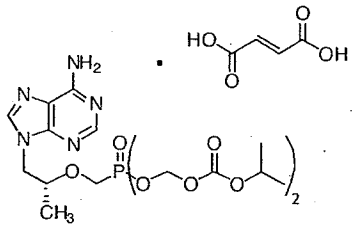
24. United States Patent No. 5,935,946 ("the '946 Patent," copy attached as Exhibit B), entitled "Nucleotide analog composition and synthesis method," was duly and legally issued by the USPTO on August 10, 1999. The claims of the '946 Patent cover, *inter alia*, tenofovir disoproxil fumarate (the active ingredient in Viread® and one of the active ingredients in Truvada® and Atripla®) and its use to treat a patient infected with a virus or who is at risk of

viral infection. The '946 Patent is listed in the FDA Orange Book for Viread®, Truvada®, and Atripla®.

25. United States Patent No. 5,977,089 ("the '089 Patent," copy attached as Exhibit C), entitled "Antiviral Phosphonomethoxy Nucleotide analogs having increased oral bioavailability," was duly and legally issued by the USPTO on November 2, 1999. The claims of the '089 Patent cover, *inter alia*, the oral administration to a patient tenofovir disoproxil fumarate (the active ingredient in Viread® and one of the active ingredients in Truvada® and Atripla®), and is listed in the FDA Orange Book for Viread®, Truvada®, and Atripla®.

26. United States Patent No. 6,043,230 ("the '230 Patent," copy attached as Exhibit D), entitled "Antiviral Phosphonomethoxy Nucleotide analogs having increased oral bioavailability," was duly and legally issued by the USPTO on March 28, 2000. The claims of the '230 Patent cover, *inter alia*, treating a patient with tenofovir disoproxil fumarate (the active ingredient in Viread® and one of the active ingredients in Truvada® and Atripla®), and is listed in the FDA Orange Book for Viread®, Truvada®, and Atripla®.

27. 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

28. Tenofovir disoproxil fumarate can be referred to by any of several chemical names. Tenofovir disoproxil fumarate is described in the Viread® label as "a fumaric acid salt of bis-isopropoxycarbonyloxymethyl ester derivative of tenofovir." Chemical names recited for tenofovir disoproxil fumarate in the '946 Patent are "9-[2-(R)[[bis[[(isopropoxycarbonyl)oxy]methoxy]phosphinoyl]methoxy]propyl]adenine.fumaric acid" and "bis(POC)PMPA fumarate."

29. The named inventors on the '695, '089, and '230 Patents are Murty N. Arimilli, Kenneth C. Cundy, Joseph P. Dougherty, Choung U. Kim, Reza Oliyai, and Valentino J. Stella. William A. Lee was added as a named inventor to the '695, '089, and '230 Patents during their re-examination.

30. Murty N. Arimilli, Kenneth C. Cundy, Joseph P. Dougherty, Choung U. Kim, Reza Oliyai, Valentino J. Stella, and William A. Lee assigned the '695, '089, and '230 Patents to Gilead.

31. The named inventors on the '946 Patent are John D. Munger, Jr., John C. Rohloff, and Lisa M. Schultze.

32. John D. Munger, Jr., John C. Rohloff, and Lisa M. Schultze assigned the '946 Patent to Gilead.

COUNT 1
Infringement of U.S. Patent No. 5,922,695 (ANDA No. 91-612)

33. Plaintiff repeats and realleges paragraphs 1-32 above as if set forth herein.

34. On information and belief, Teva submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 91-612, to the FDA

seeking approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate.

35. On information and belief, ANDA No. 91-612 seeks approval to manufacture, use, and sell tenofovir disoproxil fumarate for the purpose of treating HIV infection in adults.

36. By letter dated January 25, 2010 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "January 25, 2010 Viread® Notice Letter"), Teva notified Plaintiff that it had submitted ANDA No. 91-612 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '695 Patent.

37. In its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 91-612, 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 '695 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 '695 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."

38. Teva alleged in its January 25, 2010 Viread® Notice Letter that Claims 1-5, 9, 11-13, 15, 21, 25-30, and 32-34 of the '695 Patent are invalid and Claims 6-8, 10, 14, 16-20, 22-24, and 31 of the '695 Patent would not be infringed by the commercial manufacture, use, and sale of its proposed product that is the subject of ANDA No. 91-612.

39. By filing ANDA No. 91-612 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate, before the '695 Patent's expiration, Teva has committed an act of infringement of the '695 Patent under 35 U.S.C. § 271(e)(2).

40. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-612 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '695 Patent.

41. On information and belief, the commercial manufacture, use, and/or sale of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 91-612 will infringe, induce infringement and/or contributorily infringe one or more claims of the '695 Patent.

42. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '695 Patent.

43. Teva's ANDA No. 91-612, which was produced in this litigation, cites to and relies on Cipla's DMF No. 020003.

44. Cipla manufactures the tenofovir disoproxil fumarate API for tablets containing 300 mg of tenofovir disoproxil fumarate, as described in ANDA No. 91-612.

45. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 91-612, which seeks approval to offer tablets containing 300 mg of tenofovir disoproxil fumarate for commercial sale in violation of the '695 Patent. The information and material supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 91-612. By doing so, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '695 Patent.

46. On information and belief, Cipla will, without authority, manufacture and will cause the importation of tenofovir disoproxil fumarate API into the United States, and/or use, offer for sale, or sell it to Teva within the United States for subsequent commercial sale by Teva under ANDA No. 91-612, if approved.

47. On information and belief, upon approval of ANDA No. 91-612, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States in violation of the '695 Patent. By doing so, Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '695 Patent.

48. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-612, and/or importation into the United States of the tenofovir disoproxil

fumarate API described in ANDA No. 91-612, will infringe the '695 Patent directly and will induce or otherwise contribute to acts of infringement of the '695 Patent by Teva.

COUNT 2
Infringement of U.S. Patent No. 5,935,946 (ANDA No. 91-612)

49. Plaintiff repeats and realleges paragraphs 1-32, 34-35, 43-44 and 46 above as if set forth herein.

50. By its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 91-612 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '946 Patent.

51. In its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that, as a part of its ANDA No. 91-612, it had filed a Paragraph IV certification with respect to the '946 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 '946 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."

52. Teva alleged in its January 25, 2010 Viread® Notice Letter that Claims 1-6, 9-14, and 16-18 of the '946 Patent are invalid and Claim 7 of the '946 Patent would not be infringed by the commercial manufacture, use, and sale of its proposed product that is the subject of ANDA No. 91-612.

53. By filing ANDA No. 91-612 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate, before the '946 Patent's expiration, Teva has committed an act of infringement of the '946 Patent under 35 U.S.C. § 271(e)(2).

54. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-612 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '946 Patent.

55. On information and belief, the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 91-612 will infringe, induce infringement and/or contributorily infringe one or more claims of the '946 Patent.

56. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '946 Patent.

57. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 91-612, which seeks approval to offer tablets containing 300 mg of tenofovir disoproxil fumarate for commercial sale in violation of the '946 Patent. The information and material

supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 91-612. By doing so, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '946 Patent.

58. On information and belief, upon approval of ANDA No. 91-612, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States in violation of the '946 Patent. By doing so, Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '946 Patent.

59. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-612, and/or importation into the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-612, will infringe the '946 Patent directly and will induce or otherwise contribute to acts of infringement of the '946 Patent by Teva.

COUNT 3
Infringement of U.S. Patent No. 5,977,089 (ANDA No. 91-612)

60. Plaintiff repeats and realleges paragraphs 1-32, 34-35, 43-44 and 46 above as if set forth herein.

61. By its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 91-612 to the FDA seeking approval to engage in the commercial

manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '089 Patent.

62. In its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that, as a part of its ANDA No. 91-612, it had filed a Paragraph IV certification with respect to the '089 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 '089 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."

63. Teva alleged in its January 25, 2010 Viread® Notice Letter that Claims 1-3 of the '089 Patent are invalid.

64. By filing ANDA No. 91-612 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate, before the '089 Patent's expiration, Teva has committed an act of infringement of the '089 Patent under 35 U.S.C. § 271(e)(2).

65. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-612 was filed and when the Paragraph IV certification was made.

Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '089 Patent.

66. On information and belief, the commercial manufacture, use, and/or sale of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 91-612 will infringe, induce infringement and/or contributorily infringe one or more claims of the '089 Patent.

67. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '089 Patent.

68. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 91-612, which seeks approval to offer tablets containing 300 mg of tenofovir disoproxil fumarate for commercial sale in violation of the '089 Patent. The information and material supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 91-612. By doing so, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '089 Patent.

69. On information and belief, upon approval of ANDA No. 91-612, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States in violation of the '089 Patent. By doing so, Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '089 Patent.

70. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-612, and/or importation into the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-612, will infringe the '089 Patent directly and will induce or otherwise contribute to acts of infringement of the '089 Patent by Teva.

COUNT 4
Infringement of U.S. Patent No. 6,043,230 (ANDA No. 91-612)

71. Plaintiff repeats and realleges paragraphs 1-32, 34-35, 43-44 and 46 above as if set forth herein.

72. By its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that it had submitted ANDA No. 91-612 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '230 Patent.

73. In its January 25, 2010 Viread® Notice Letter, Teva notified Plaintiff that, as a part of its ANDA No. 91-612, it had filed a Paragraph IV certification with respect to the '230 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 '230 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."

74. Teva alleged in its January 25, 2010 Viread® Notice Letter that Claims 1-4 of the '230 Patent are invalid.

75. By filing ANDA No. 91-612 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 300 mg of tenofovir disoproxil fumarate, before the '230 Patent's expiration, Teva has committed an act of infringement of the '230 Patent under 35 U.S.C. § 271(e)(2).

76. On information and belief, Teva lacked a good faith basis for alleging invalidity when ANDA No. 91-612 was filed and when the Paragraph IV certification was made. Teva's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '230 Patent.

77. On information and belief, the commercial manufacture, use, and/or sale of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Teva seeks approval in ANDA No. 91-612 will infringe, induce infringement and/or contributorily infringe one or more claims of the '230 Patent.

78. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '230 Patent.

79. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 91-612, which seeks approval to offer tablets containing 300 mg of tenofovir disoproxil fumarate for commercial sale in violation of the '230 Patent. The information and material

supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 91-612. By doing so, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '230 Patent.

80. On information and belief, upon approval of ANDA No. 91-612, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States in violation of the '230 Patent. By doing so, Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '230 Patent.

81. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-612, and/or importation into the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-612, will infringe the '230 Patent directly and will induce or otherwise contribute to acts of infringement of the '230 Patent by Teva.

COUNT 5
Infringement of U.S. Patent 5,922,695 (ANDA No. 90-894)

82. Plaintiff repeats and realleges paragraphs 1-32 above as if set forth herein.

83. On information and belief, Teva submitted or caused to be submitted an 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.

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

85. 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 Plaintiff 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 '695 Patent.

86. In its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 90-894, it had filed a Paragraph IV certification with respect to the '695 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 '695 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."

87. Teva alleged in its January 28, 2010 Truvada® Notice Letter that Claims 1-5, 9, 11-13, 15, 21, 25-30, and 32-34 of the '695 Patent are invalid and Claims 6-8, 10, 14, 16-

20, 22-24, and 31 of the '695 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.

88. 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 '695 Patent's expiration, Teva has committed an act of infringement of the '695 Patent under 35 U.S.C. § 271(e)(2).

89. 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 '695 Patent.

90. 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 '695 Patent.

91. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '695 Patent.

92. Teva's ANDA No. 90-894, which was produced in this litigation, cites to and relies on Cipla's DMF No. 020003.

93. Cipla manufactures the tenofovir disoproxil fumarate API for tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, as described in ANDA No. 90-894.

94. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 90-894, which seeks approval to offer tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for commercial sale in violation of the '695 Patent. The information and material supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 90-894. By doing so, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '695 Patent.

95. On information and belief, Cipla will, without authority, manufacture and will cause the importation of tenofovir disoproxil fumarate API into the United States, and/or use, offer for sale, or sell it to Teva within the United States for subsequent commercial sale by Teva under ANDA No. 90-894, if approved.

96. On information and belief, upon approval of ANDA No. 90-894, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States in violation of the '695 Patent. By doing so, Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '695 Patent.

97. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 90-894, and/or importation into the United States of the tenofovir disoproxil

fumarate API described in ANDA No. 90-894, will infringe the '695 Patent directly and will induce or otherwise contribute to acts of infringement of the '695 Patent by Teva.

COUNT 6
Infringement of U.S. Patent 5,935,946 (ANDA No. 90-894)

98. Plaintiff repeats and realleges paragraphs 1-32, 83-84, 92-93 and 95 above as if set forth herein.

99. By its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff 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 '946 Patent.

100. In its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 90-894, it had filed a Paragraph IV certification with respect to the '946 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 '946 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."

101. Teva alleged in its January 28, 2010 Truvada® Notice Letter that Claims 1-6, 9-14, and 16-18 of the '946 Patent are invalid and Claim 7 of the '946 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.

102. 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 '946 Patent's expiration, Teva has committed an act of infringement of the '946 Patent under 35 U.S.C. § 271(e)(2).

103. 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 '946 Patent.

104. 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 '946 Patent.

105. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '946 Patent.

106. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 90-894, which seeks approval to offer tablets containing 200 mg of emtricitabine and 300

mg of tenofovir disoproxil fumarate for commercial sale in violation of the '946 Patent. The information and material supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 90-894. By doing so, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '946 Patent.

107. On information and belief, upon approval of ANDA No. 90-894, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States in violation of the '946 Patent. By doing so, Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '946 Patent.

108. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 90-894, and/or importation into the United States of the tenofovir disoproxil fumarate API described in ANDA No. 90-894, will infringe the '946 Patent directly and will induce or otherwise contribute to acts of infringement of the '946 Patent by Teva.

COUNT 7
Infringement of U.S. Patent 5,977,089 (ANDA No. 90-894)

109. Plaintiff repeats and realleges paragraphs 1-32, 83-84, 92-93 and 95 above as if set forth herein.

110. By its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff 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 '089 Patent.

111. In its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 90-894, it had filed a Paragraph IV certification with respect to the '089 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 '089 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."

112. Teva alleged in its January 28, 2010 Truvada® Notice Letter that Claims 1-3 of the '089 Patent are invalid.

113. 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 '089 Patent's expiration, Teva has committed an act of infringement of the '089 Patent under 35 U.S.C. § 271(e)(2).

114. 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 '089 Patent.

115. 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 '089 Patent.

116. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '089 Patent.

117. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 90-894, which seeks approval to offer tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for commercial sale in violation of the '089 Patent. The information and material supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 90-894. By doing so, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '089 Patent.

118. On information and belief, upon approval of ANDA No. 90-894, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States in violation of the '089 Patent. By doing so, Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '089 Patent.

119. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 90-894, and/or importation into the United States of the tenofovir disoproxil fumarate API described in ANDA No. 90-894, will infringe the '089 Patent directly and will induce or otherwise contribute to acts of infringement of the '089 Patent by Teva.

COUNT 8
Infringement of U.S. Patent 6,043,230 (ANDA No. 90-894)

120. Plaintiff repeats and realleges paragraphs 1-32, 83-84, 92-93 and 95 above as if set forth herein.

121. By its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff 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 '230 Patent.

122. In its January 28, 2010 Truvada® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 90-894, it had filed a Paragraph IV certification with respect to the

'230 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 '230 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."

123. Teva alleged in its January 28, 2010 Truvada® Notice Letter that Claims 1-4 of the '230 Patent are invalid.

124. 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 '230 Patent's expiration, Teva has committed an act of infringement of the '230 Patent under 35 U.S.C. § 271(e)(2).

125. 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 '230 Patent.

126. 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 '230 Patent.

127. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '230 Patent.

128. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 90-894, which seeks approval to offer tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for commercial sale in violation of the '230 Patent. The information and material supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 90-894. By doing so, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '230 Patent.

129. On information and belief, upon approval of ANDA No. 90-894, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States in violation of the '230 Patent. By doing so, Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '230 Patent.

130. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 90-894, and/or importation into the United States of the tenofovir disoproxil

fumarate API described in ANDA No. 90-894, will infringe the '230 Patent directly and will induce or otherwise contribute to acts of infringement of the '230 Patent by Teva.

COUNT 9
Infringement of U.S. Patent No. 5,922,695 (ANDA No. 91-215)

131. Plaintiff repeats and realleges paragraphs 1-32 above as if set forth herein.

132. 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.

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

134. 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 Plaintiff 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 '695 Patent.

135. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 91-215, it had filed a Paragraph IV certification with respect to the '695 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 '695 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."

136. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1-5, 9, 11-13, 15, 21, 25-30, and 32-34 of the '695 Patent are invalid and Claims 6-8, 10, 14, 16-20, 22-24, and 31 of the '695 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.

137. 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 '695 Patent's expiration, Teva has committed an act of infringement of the '695 Patent under 35 U.S.C. § 271(e)(2).

138. 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 '695 Patent.

139. 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 and/or contributorily infringe one or more claims of the '695 Patent.

140. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '695 Patent.

141. Teva's ANDA No. 91-215, which was produced in this litigation, cites to and relies on Cipla's DMF No. 020003.

142. Cipla manufactures the tenofovir disoproxil fumarate API for tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, as described in ANDA No. 91-215.

143. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 91-215, which seeks approval to offer tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for commercial sale in violation of the '695 Patent. The information and material supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 91-215. By doing so, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '695 Patent.

144. On information and belief, Cipla will, without authority, manufacture and will cause the importation of tenofovir disoproxil fumarate API into the United States, and/or use, offer for sale, or sell it to Teva within the United States for subsequent commercial sale by Teva under ANDA No. 91-215, if approved.

145. On information and belief, upon approval of ANDA No. 91-215, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States in violation of the '695 Patent. By doing so, Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '695 Patent.

146. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-215, and/or importation into the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-215, will infringe the '695 Patent directly and will induce or otherwise contribute to acts of infringement of the '695 Patent by Teva.

COUNT 10
Infringement of U.S. Patent No. 5,935,946 (ANDA No. 91-215)

147. Plaintiff repeats and realleges paragraphs 1-32, 132-133, 141-142 and 144 above as if set forth herein.

148. By its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff 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 '946 Patent.

149. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 91-215, it had filed a Paragraph IV certification with respect to the '946 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 '946 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."

150. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1-6, 9-14, and 16-18 of the '946 Patent are invalid and Claim 7 of the '946 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.

151. 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 '946 Patent's expiration, Teva has committed an act of infringement of the '946 Patent under 35 U.S.C. § 271(e)(2).

152. 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 '946 Patent.

153. 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 and/or contributorily infringe one or more claims of the '946 Patent.

154. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '946 Patent.

155. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 91-215, which seeks approval to offer tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for commercial sale in violation of the '946 Patent. The information and material supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 91-215. By doing so, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '946 Patent.

156. On information and belief, upon approval of ANDA No. 91-215, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States in violation of the '946 Patent. By doing so,

Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '946 Patent.

157. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-215, and/or importation into the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-215, will infringe the '946 Patent directly and will induce or otherwise contribute to acts of infringement of the '946 Patent by Teva.

COUNT 11
Infringement of U.S. Patent No. 5,977,089 (ANDA No. 91-215)

158. Plaintiff repeats and realleges paragraphs 1-32, 132-133, 141-142 and 144 above as if set forth herein.

159. By its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff 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 '089 Patent.

160. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 91-215, it had filed a Paragraph IV certification with respect to the '089 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 '089 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."

161. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1-3 of the '089 Patent are invalid.

162. 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 '089 Patent's expiration, Teva has committed an act of infringement of the '089 Patent under 35 U.S.C. § 271(e)(2).

163. 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 '089 Patent.

164. 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 and/or contributorily infringe one or more claims of the '089 Patent.

165. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '089 Patent.

166. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 91-215, which seeks approval to offer tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for commercial sale in violation of the '089 Patent. The information and material supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 91-215. By doing so, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '089 Patent.

167. On information and belief, upon approval of ANDA No. 91-215, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States in violation of the '089 Patent. By doing so, Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '089 Patent.

168. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-215, and/or importation into the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-215, will infringe the '089 Patent directly and will induce or otherwise contribute to acts of infringement of the '089 Patent by Teva.

COUNT 12
Infringement of U.S. Patent No. 6,043,230 (ANDA No. 91-215)

169. Plaintiff repeats and realleges paragraphs 1-32, 132-133, 141-142 and 144 above as if set forth herein.

170. By its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff 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 '230 Patent.

171. In its January 28, 2010 Atripla® Notice Letter, Teva notified Plaintiff that, as a part of ANDA No. 91-215, it had filed a Paragraph IV certification with respect to the '230 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 '230 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."

172. Teva alleged in its January 28, 2010 Atripla® Notice Letter that Claims 1-4 of the '230 Patent are invalid.

173. 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 '230 Patent's expiration, Teva has committed an act of infringement of the '230 Patent under 35 U.S.C. § 271(e)(2).

174. 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 '230 Patent.

175. 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 and/or contributorily infringe one or more claims of the '230 Patent.

176. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '230 Patent.

177. On information and belief, Cipla has and will continue to provide information and material to Teva in connection with the preparation and submission of ANDA No. 91-215, which seeks approval to offer tablets containing 600 mg efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for commercial sale in violation of the '230 Patent. The information and material supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 91-215. By doing so, Cipla has and will knowingly and

intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '230 Patent.

178. On information and belief, upon approval of ANDA No. 91-215, Cipla will supply tenofovir disoproxil fumarate API to Teva for incorporation into generic tenofovir disoproxil fumarate products, with the knowledge and intent that Teva will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic tenofovir disoproxil fumarate tablets in the United States under in violation of the '230 Patent. By doing so, Cipla will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '230 Patent.

179. On information and belief, Cipla's supply, commercial manufacture, use, offer for sale or sale within the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-215, and/or importation into the United States of the tenofovir disoproxil fumarate API described in ANDA No. 91-215, will infringe the '230 Patent directly and will induce or otherwise contribute to acts of infringement of the '230 Patent by Teva.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-612 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 '695 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(b) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-612 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 '946 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(c) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-612 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 '089 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(d) A judgment declaring that the effective date of any approval of Teva's ANDA No. 91-612 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 '230 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(e) 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 '695 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(f) 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 '946 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(g) 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 '089 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(h) 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 '230 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(i) 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 '695 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(j) 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 '946 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(k) 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 '089 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(l) 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 '230 Patent or any later date of exclusivity to which Plaintiff are or become entitled;

(m) A judgment declaring that the '695 Patent remains valid, enforceable and has been infringed by Teva and/or Cipla;

(n) A judgment declaring that the '946 Patent remains valid, enforceable and has been infringed by Teva and/or Cipla;

(o) A judgment declaring that the '089 Patent remains valid, enforceable and has been infringed by Teva and/or Cipla;

(p) A judgment declaring that the '230 Patent remains valid, enforceable and has been infringed by Teva and/or Cipla;

(q) A permanent injunction against any infringement of the '695 Patent by Teva and/or Cipla, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(r) A permanent injunction against any infringement of the '946 Patent by Teva and/or Cipla, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(s) A permanent injunction against any infringement of the '089 Patent by Teva, and/or Cipla, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(t) A permanent injunction against any infringement of the '230 Patent by Teva, and/or Cipla, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(u) A permanent injunction restraining and enjoining Teva and/or Cipla from importing tenofovir disoproxil or tenofovir disoproxil fumarate into the United States in violation of the '695, '946, '089 and '230 Patents;

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

(w) To the extent that Teva and/or Cipla has committed any acts with respect to the subject matter claimed in the '695 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;

(x) To the extent that Teva and/or Cipla has committed any acts with respect to the subject matter claimed in the '946 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;

(y) To the extent that Teva and/or Cipla has committed any acts with respect to the subject matter claimed in the '089 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;

(z) To the extent that Teva and/or Cipla has committed any acts with respect to the subject matter claimed in the '230 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;

(aa) Costs and expenses in this action; and

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

June 15, 2011

Respectfully submitted,

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