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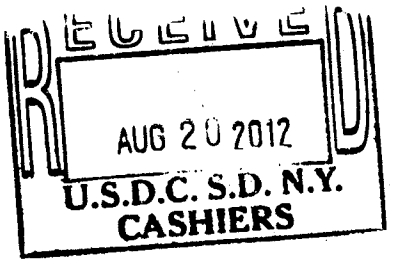
IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK



GILEAD SCIENCES, INC.,

Plaintiff,

v.

CIPLA LIMITED,

Defendant.

Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Gilead Sciences, Inc. ("Gilead" or "Plaintiff") for its Complaint against Cipla Ltd. ("Cipla"), 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, 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

4. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202; and 35 U.S.C. § 271.

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

6. On information and belief, Cipla manufactures active pharmaceutical ingredients ("APIs") for various generic copies of branded pharmaceutical products that are sold throughout the United States, including in New York and this District. On information and belief, Cipla manufactures, markets and sells various generic copies of branded pharmaceutical products throughout the United States, including in New York and this District.

7. On information and belief, Cipla derives substantial revenue from selling APIs that are incorporated into generic pharmaceutical products sold throughout the United States, including New York and this District. On information and belief, Cipla derives substantial revenue from selling various generic copies of branded pharmaceutical products throughout the United States, including New York and this District.

8. Cipla's submission of Abbreviated New Drug Application ("ANDA") No. 078800, discussed below, indicates its intention to engage in the commercial manufacture, use, sale and/or importation of pharmaceutical drug products that will compete directly with Gilead's pharmaceutical drug products which are currently sold throughout the United States, including New York and this District.

9. On information and belief, Byron Chemical Company, Inc. ("Byron") is a New York corporation having a principal place of business at 40-11 23rd Street, Long Island City, NY 11101.

10. On information and belief, Byron operates within the pharmaceutical industry as sales, marketing, and regulatory agents for international manufacturers, including for Cipla.

11. On information and belief, as a sales and regulatory agent, Byron facilitates the importation and distribution of APIs and finished dosage products within the United States, including New York and this District, for international manufacturers, including for Cipla.

12. On information and belief, Cipla has systematic and continuous contacts with the state of New York, by itself and through Byron.

13. On information and belief, Byron was the regulatory agent for Cipla concerning ANDA No. 078800.

14. On information and belief, the FDA has directed and continues to direct correspondence concerning ANDA No. 078800 to Byron's New York address.

15. On information and belief, Cipla is subject to personal jurisdiction in New York because, *inter alia*, Cipla has purposely availed itself of the benefits and protections of the laws of New York such that it should reasonably anticipate being haled into court here; Cipla has had systematic and continuous contacts with the state of New York by itself and through Byron including Cipla's sales of various generic copies of branded pharmaceutical products in New York and this District, and Cipla's sales of APIs to generic pharmaceutical companies for

incorporation into various generic copies of branded pharmaceutical products sold in New York and this District.

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

Background

17. 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 and sold in the United States under the trademark Viread®.

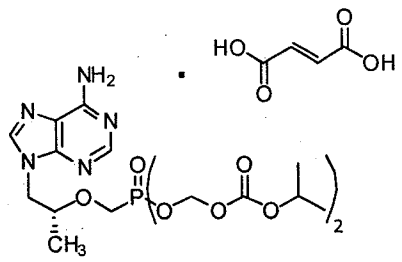
18. United States Patent No. 5,922,695 ("the '695 Patent," copy attached as Exhibit A), entitled "Antiviral Phosphonomethoxy Nucleotide analogs having increased oral bioavailability," was duly and legally issued by the United States Patent and Trademark Office on July 13, 1999. The claims of the '695 Patent cover, *inter alia*, tenofovir disoproxil fumarate (the active ingredient in Viread®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Viread®.

19. 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 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®.

20. 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 is listed in the FDA Orange Book for Viread®.

21. 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 is listed in the FDA Orange Book for Viread®.

22. 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:



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23. 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."

24. 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.

25. 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.

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

27. 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. 078800)

28. Plaintiff repeats and realleges paragraphs 1-27 above as if set forth herein.

29. On information and belief, Cipla submitted or caused to be submitted ANDA No. 078800 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 300 mg of tenofovir disoproxil fumarate.

30. On information and belief, ANDA No. 078800 seeks approval to manufacture, use, sell and import tenofovir disoproxil fumarate for the purpose of treating HIV infection.

31. By letter dated July 30, 2012, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "July 30, 2012 Notice Letter"), Cipla notified Plaintiff that it had submitted ANDA No. 078800 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '695 Patent.

32. In its July 30, 2012 Notice Letter, Cipla notified Plaintiff that, as a part of ANDA No. 078800, 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 the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include, "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

33. On information and belief, at the time the July 30, 2012 Notice Letter was served, Cipla was aware of the statutory provisions and regulations referred to in paragraph 32, above.

34. Cipla alleged in its July 30, 2012 Notice Letter that Claims 1-5, 7, 9, 11-13, 15, 19-21, and 25-34 of the '695 Patent are invalid and Claims 6, 8, 10, 14, 16-20, 22-24, and 30-31 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. 078800.

35. The July 30, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 32, above), does not allege non-infringement of all claims of the '695 Patent.

36. The July 30, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 32, above), does not allege invalidity of all claims of the '695 Patent.

37. The July 30, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 32, above), does not allege unenforceability of all claims of the '695 Patent.

38. Even where asserted, the July 30, 2012 Notice Letter does not provide the full and detailed statement of Cipla's factual and legal basis to support its non-infringement and invalidity allegations as to the '695 Patent.

39. Accordingly, the July 30, 2012 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

40. By filing ANDA No. 078800 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 300 mg of tenofovir disoproxil fumarate before the '695 Patent's expiration, Cipla has committed an act of infringement of the '695 Patent under 35 U.S.C. § 271(e)(2).

41. On information and belief, Cipla lacked a good faith basis for alleging invalidity when ANDA No. 078800 was filed and when the Paragraph IV certification was made. Cipla's ANDA No. 078800 and Paragraph IV certification is a wholly unjustified infringement of the '695 Patent.

42. Cipla's submission of ANDA No. 078800 and service of the July 30, 2012 Notice Letter indicates a refusal to change its current course of action.

43. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Cipla seeks approval in ANDA No. 078800 will infringe one or more claims of the '695 Patent.

44. On information and belief, the tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Cipla seeks approval in ANDA No. 078800, if approved, will be administered to human patients in an effective amount for treating HIV infection. This administration will infringe one or more claims of the '695 Patent. On information and belief, this administration will occur at Cipla's active behest and with its intent, knowledge and encouragement. On information and belief, Cipla will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '695 Patent. Further, by filing ANDA No. 078800 with a Paragraph IV certification, Cipla admits that it has knowledge of the '695 Patent.

45. The July 30, 2012 Notice Letter does not allege and does not address non-infringement of all claims of the '695 Patent. By not addressing non-infringement of all claims

of the '695 Patent in its July 30, 2012 Notice Letter, Cipla admits that the commercial manufacture, use, sale and importation of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '695 Patent will infringe the unaddressed '695 Patent claims.

46. The July 30, 2012 Notice Letter does not allege and does not address invalidity of all claims of the '695 Patent. By not addressing invalidity of all claims of the '695 Patent in its July 30, 2012 Notice Letter, Cipla admits that the unaddressed claims of the '695 Patent are valid.

47. The July 30, 2012 Notice Letter does not allege and does not address unenforceability of any of the claims of the '695 Patent. By not addressing unenforceability of any of the claims of the '695 Patent in its July 30, 2012 Notice Letter, Cipla admits that all of the claims of the '695 Patent are enforceable.

COUNT 2
Infringement of U.S. Patent No. 5,935,946 (ANDA No. 078800)

48. Plaintiff repeats and realleges paragraphs 1-27, and 29-30 above as if set forth herein.

49. By its July 30, 2012 Notice Letter, Cipla notified Plaintiff that it had submitted ANDA No. 078800 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '946 Patent.

50. In its July 30, 2012 Notice Letter, Cipla notified Plaintiff that, as a part of its ANDA No. 078800, 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 the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include, "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

51. On information and belief, at the time the July 30, 2012 Notice Letter was served, Cipla was aware of the statutory provisions and regulations referred to in paragraph 50, above.

52. Cipla alleged in its July 30, 2012 Notice Letter that Claims 1-7, 9-14 and 16-18 of the '946 Patent are invalid and Claims 7 and 12-14 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. 078800. Teva also alleges that the Claims of the '946 patent are unenforceable due to inequitable conduct.

53. The July 30, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 50, above), does not allege non-infringement of all claims of the '946 Patent.

54. The July 30, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 50, above), does not allege invalidity of all claims of the '946 Patent.

55. Even where asserted, the July 30, 2012 Notice Letter does not provide the full and detailed statement of Cipla's factual and legal basis to support its non-infringement, invalidity and unenforceability allegations as to the '946 Patent.

56. Accordingly, the July 30, 2012 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

57. By filing ANDA No. 078800 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 300 mg of tenofovir disoproxil fumarate before the '946 Patent's expiration, Cipla has committed an act of infringement of the '946 Patent under 35 U.S.C. § 271(e)(2).

58. On information and belief, Cipla lacked a good faith basis for alleging invalidity when ANDA No. 078800 was filed and when the Paragraph IV certification was made. Cipla's ANDA No. 078800 and Paragraph IV certification is a wholly unjustified infringement of the '946 Patent.

59. Cipla's submission of ANDA No. 078800 and service of the July 30, 2012 Notice Letter indicates a refusal to change its current course of action.

60. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Cipla seeks approval in ANDA No. 078800 will infringe one or more claims of the '946 Patent.

61. On information and belief, the tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Cipla seeks approval in ANDA No. 078800, if approved, will be administered to human patients in an effective amount for treating HIV infection. This administration will infringe one or more claims of the '946 Patent. On information and belief, this administration will occur at Cipla's active behest and with its intent, knowledge and encouragement. On information and belief, Cipla will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '946 Patent. Further, by filing ANDA No. 078800 with a Paragraph IV certification, Cipla admits that it has knowledge of the '946 Patent.

62. The July 30, 2012 Notice Letter does not allege and does not address non-infringement of all claims of the '946 Patent. By not addressing non-infringement of all claims of the '946 Patent in its July 30, 2012 Notice Letter, Cipla admits that the commercial manufacture, use, sale and importation of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '946 Patent will infringe the unaddressed '946 Patent claims.

63. The July 30, 2012 Notice Letter does not allege and does not address invalidity of all claims of the '946 Patent. By not addressing invalidity of all claims of the '946 Patent in its July 30, 2012 Notice Letter, Cipla admits that the unaddressed claims of the '946 Patent are valid.

COUNT 3
Infringement of U.S. Patent No. 5,977,089 (ANDA No. 078800)

64. Plaintiff repeats and realleges paragraphs 1-27 and 29-30 above as if set forth herein.

65. By its July 30, 2012 Notice Letter, Cipla notified Plaintiff that it had submitted ANDA No. 078800 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '089 Patent.

66. In its July 30, 2012 Notice Letter, Cipla notified Plaintiff that, as a part of its ANDA No. 078800, 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 the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include, "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

67. On information and belief, at the time the July 30, 2012 Notice Letter was served, Cipla was aware of the statutory provisions and regulations referred to in paragraph 66, above.

68. Cipla alleged in its July 30, 2012 Notice Letter that Claims 1-3 of the '089 Patent are invalid.

69. The July 30, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 66, above), does not allege non-infringement of any claims of the '089 Patent.

70. The July 30, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 66, above), does not allege unenforceability of all claims of the '089 Patent.

71. Even where asserted, the July 30, 2012 Notice Letter does not provide the full and detailed statement of Cipla's factual and legal basis to support its invalidity allegations as to the '089 Patent.

72. Accordingly, the July 30, 2012 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

73. By filing ANDA No. 078800 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 300 mg of tenofovir disoproxil fumarate before the '089 Patent's expiration, Cipla has committed an act of infringement of the '089 Patent under 35 U.S.C. § 271(e)(2).

74. On information and belief, Cipla lacked a good faith basis for alleging invalidity when ANDA No. 078800 was filed and when the Paragraph IV certification was made. Cipla's ANDA No. 078800 and Paragraph IV certification is a wholly unjustified infringement of the '089 Patent.

75. Cipla's submission of ANDA No. 078800 and service of the July 30, 2012 Notice Letter indicates a refusal to change its current course of action.

76. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Cipla seeks approval in ANDA No. 078800 will infringe one or more claims of the '089 Patent.

77. On information and belief, the tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Cipla seeks approval in ANDA No. 078800, if approved, will be administered to human patients in an effective amount for treating HIV infection. This administration will infringe one or more claims of the '089 Patent. On information and belief, this administration will occur at Cipla's active behest and with its intent, knowledge and encouragement. On information and belief, Cipla will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '089 Patent. Further, by filing ANDA No. 078800 with a Paragraph IV certification, Cipla admits that it has knowledge of the '089 Patent.

78. The July 30, 2012 Notice Letter does not allege and does not address non-infringement of any claims of the '089 Patent. By not addressing non-infringement of any claims of the '089 Patent in its July 30, 2012 Notice Letter, Cipla admits that the commercial manufacture, use, sale and importation of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '089 Patent will infringe the unaddressed '089 Patent claims.

79. The July 30, 2012 Notice Letter does not allege and does not address unenforceability of any of the claims of the '089 Patent. By not addressing unenforceability of any of the claims of the '089 Patent in its July 30, 2012 Notice Letter, Cipla admits that all of the claims of the '089 Patent are enforceable.

COUNT 4
Infringement of U.S. Patent No. 6,043,230 (ANDA No. 078800)

80. Plaintiff repeats and realleges paragraphs 1-27, and 29-30 above as if set forth herein.

81. By its July 30, 2012 Notice Letter, Cipla notified Plaintiff that it had submitted ANDA No. 078800 to the FDA seeking approval to engage in the commercial manufacture, use, sale and importation of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '230 Patent.

82. In its July 30, 2012 Notice Letter, Cipla notified Plaintiff that, as a part of its ANDA No. 078800, 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 the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include, "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

83. On information and belief, at the time the July 30, 2012 Notice Letter was served, Cipla was aware of the statutory provisions and regulations referred to in paragraph 82, above.

84. Cipla alleged in its July 30, 2012 Notice Letter that Claims 1-4 of the '230 Patent are invalid.

85. The July 30, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 82, above), does not allege non-infringement of any claims of the '230 Patent.

86. The July 30, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 82, above), does not allege unenforceability of all claims of the '230 Patent.

87. Even where asserted, the July 30, 2012 Notice Letter does not provide the full and detailed statement of Cipla's factual and legal basis to support its invalidity allegations as to the '230 Patent.

88. Accordingly, the July 30, 2012 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

89. By filing ANDA No. 078800 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 300 mg of tenofovir disoproxil fumarate before the '230 Patent's expiration, Cipla has committed an act of infringement of the '230 Patent under 35 U.S.C. § 271(e)(2).

90. On information and belief, Cipla lacked a good faith basis for alleging invalidity when ANDA No. 078800 was filed and when the Paragraph IV certification was made. Cipla's ANDA No. 078800 and Paragraph IV certification is a wholly unjustified infringement of the '230 Patent.

91. Cipla's submission of ANDA No. 078800 and service of the July 30, 2012 Notice Letter indicates a refusal to change its current course of action.

92. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Cipla seeks approval in ANDA No. 078800 will infringe one or more claims of the '230 Patent.

93. On information and belief, the tablets containing 300 mg of tenofovir disoproxil fumarate for the use for which Cipla seeks approval in ANDA No. 078800, if approved, will be administered to human patients in an effective amount for treating HIV infection. This administration will infringe one or more claims of the '230 Patent. On information and belief, this administration will occur at Cipla's active behest and with its intent, knowledge and encouragement. On information and belief, Cipla will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '230 Patent. Further, by filing ANDA No. 078800 with a Paragraph IV certification, Cipla admits that it has knowledge of the '230 Patent.

94. The July 30, 2012 Notice Letter does not allege and does not address non-infringement of any claims of the '230 Patent. By not addressing non-infringement of any claims of the '230 Patent in its July 30, 2012 Notice Letter, Cipla admits that the commercial manufacture, use, sale and importation of tablets containing 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '230 Patent will infringe the unaddressed '230 Patent claims.

95. The July 30, 2012 Notice Letter does not allege and does not address unenforceability of any of the claims of the '230 Patent. By not addressing unenforceability of

any of the claims of the '230 Patent in its July 30, 2012 Notice Letter, Cipla admits that all of the claims of the '230 Patent are enforceable.

* * *

96. 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 Cipla's ANDA No. 078800 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 is or becomes entitled, including pediatric exclusivity;

(b) A judgment declaring that the effective date of any approval of Cipla's ANDA No. 078800 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 is or becomes entitled, including pediatric exclusivity;

(c) A judgment declaring that the effective date of any approval of Cipla's ANDA No. 078800 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 is or becomes entitled, including pediatric exclusivity;

(d) A judgment declaring that the effective date of any approval of Cipla's ANDA No. 078800 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 is or becomes entitled, including pediatric exclusivity;

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

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

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

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

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

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

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

(l) A permanent injunction against any infringement of the '230 Patent by Cipla, their officers, agents, attorneys, subsidiaries and employees, and those acting in privity or contract with them;

(m) 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;

(n) To the extent that 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;

(o) To the extent that 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;

(p) To the extent that 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;

(q) To the extent that 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;

(r) Costs and expenses in this action; and

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

August 20, 2012

Respectfully submitted,

Nicholas M. Cannella (NC 9543)
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