IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

GILEAD SCIENCES, INC. and EMORY UNIVERSITY, Plaintiffs, v. MYLAN INC. and MYLAN PHARMACEUTICALS INC., Defendants.	Civil Action No.: 1:15-CV-149 (Keeley) Electronically filed: 08/31/2015

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Gilead Sciences, Inc. ("Gilead") and Emory University ("Emory") (collectively, "Plaintiffs"), for their complaint against Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan"), hereby allege as follows:

Nature of Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code.

The Parties

2. Gilead is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. Emory is a non-profit corporation of the State of Georgia, having an office at 201 Dowman Drive, Atlanta, Georgia 30322.

4. On information and belief, defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of

business at 1500 Corporate Drive, Canonsburg, PA 15317. On information and belief, Mylan Inc. has actual control over the activities of Mylan Pharmaceuticals Inc.

5. On information and belief, defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, and a wholly-owned subsidiary and agent of Mylan Inc., having a principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505.

Jurisdiction and Venue

6. 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).

7. On information and belief, this Court has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals Inc.

8. On information and belief, Mylan Inc., itself or through one of its wholly-owned subsidiaries, derives substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in West Virginia and this District.

9. On information and belief, Mylan Inc. is registered with the West Virginia Secretary of State to do business as a foreign corporation in West Virginia and, due to this registration, has authorized the West Virginia Secretary of State to accept service on its behalf.

10. On information and belief, Mylan Inc. has also authorized Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302, to accept service on its behalf.

11. On information and belief, Mylan Inc., itself or through one of its wholly-owned subsidiaries, manufactures pharmaceutical drug products that are sold and used throughout the United States, including in West Virginia and this District.

12. On information and belief, Mylan Inc., itself or through one of its wholly-owned subsidiaries, has sale representatives focused on the sale of pharmaceutical drug products in West Virginia and this District.

13. On information and belief, residents of the State of West Virginia purchase pharmaceutical drug products from Mylan Inc. in the State of West Virginia.

14. On information and belief, Mylan Inc., itself or through one of its wholly-owned subsidiaries, has authorized distributors in the State of West Virginia to distribute Mylan's pharmaceutical drug products throughout the State of West Virginia.

15. On information and belief, Mylan Pharmaceuticals Inc. derives substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in West Virginia and this District.

16. On information and belief, Mylan Pharmaceuticals Inc. is a registered corporation with the West Virginia Secretary of State to do business as a domestic corporation in West Virginia and, due to this registration, has authorized the West Virginia Secretary of State to accept service on its behalf.

17. On information and belief, Mylan Pharmaceuticals Inc. has also authorized Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302, to accept service on its behalf.

18. On information and belief, Mylan Pharmaceuticals Inc. currently holds active "Manufacturer," "Wholesale Distributor," "Medical Examiner," and "Miscellaneous" licenses with the West Virginia Board of Pharmacy.

19. On information and belief, Mylan Pharmaceuticals Inc. manufactures pharmaceutical drug products that are sold and used throughout the United States, including in West Virginia and this District.

20. On information and belief, Mylan Pharmaceuticals Inc. has sale representatives focused on the sale of pharmaceutical drug products in West Virginia and this District.

21. On information and belief, residents of the State of West Virginia purchase pharmaceutical drug products from Mylan Pharmaceuticals Inc. in the State of West Virginia.

22. On information and belief, Mylan Pharmaceuticals Inc., itself or through one of its agents, has authorized distributors in the State of West Virginia to distribute Mylan's pharmaceutical drug products throughout the State of West Virginia.

23. On information and belief, Mylan Pharmaceuticals Inc.'s submission of Abbreviated New Drug Application ("ANDA") No. 20-8452, discussed below, indicates Mylan Inc.'s and Mylan Pharmaceuticals Inc.'s intention to engage in the commercial manufacture, use, sale and/or importation of products that will compete directly with Gilead's Complera® product, which is currently being sold throughout the United States, including in West Virginia and this District. On information and belief, Mylan Inc. and Mylan Pharmaceuticals Inc. will sell the tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for the use for which Mylan seeks approval in ANDA No. 20-8452, if approved, throughout the United States, including in West Virginia and this District.

24. On information and belief, Mylan Inc. and Mylan Pharmaceuticals Inc. have previously consented to personal jurisdiction in this District.

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

Background

26. Gilead is the holder of New Drug Application ("NDA") No. 20-2123 which relates to tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate. On August 10, 2011, the United States Food and Drug Administration ("FDA") approved the use of the tablets described in NDA No. 20-2123 for the treatment of HIV-1 infection in adults. These tablets are prescribed and sold in the United States under the trademark Complera®.

27. United States Patent No. 6,642,245 ("the '245 Patent," copy attached as Exhibit A), entitled "Antiviral Activity and Resolution of 2-Hydroxymethyl-5-(5-fluorocytosin-1-yl) -1,3-oxathiolane," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2003. The '245 Patent claims, *inter alia*, methods for treating HIV infection in humans with emtricitabine (one of the active ingredients in Complera®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Complera®.

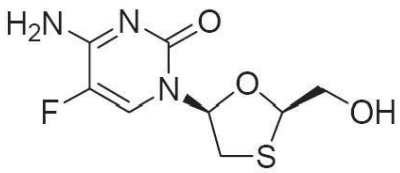
28. United States Patent No. 6,703,396 ("the '396 Patent," copy attached as Exhibit B), entitled "Method of Resolution and Antiviral Activity of 1,3-Oxathiolane Nucleoside Enantiomers," was duly and legally issued by the United States Patent and Trademark Office on March 9, 2004. The '396 Patent claims,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

29. United States Patent No. 8,592,397 ("the '397 Patent," copy attached as Exhibit C), entitled "Compositions and Methods for Combination Antiviral Therapy," was duly and legally issued by the United States Patent and Trademark Office on November 26, 2013. The '397 Patent claims, *inter alia*, a pharmaceutical combination tablet containing emtricitabine and tenofovir disoproxil fumarate (two active ingredients in Complera®) and methods for treating HIV infection

in humans with the emtricitabine and tenofovir disoproxil fumarate combination. The ’397 Patent is also listed in the FDA Orange Book for Complera®.

30. United States Patent No. 8,716,264 (“the ’264 Patent,” copy attached as Exhibit D), entitled “Compositions and Methods for Combination Antiviral Therapy,” was duly and legally issued by the United States Patent and Trademark Office on May 6, 2014. The ’264 Patent claims, *inter alia*, a pharmaceutical combination tablet containing emtricitabine and tenofovir disoproxil fumarate (two active ingredients in Complera®) and methods for treating HIV infection in humans with the emtricitabine and tenofovir disoproxil fumarate combination. The ’264 Patent is also listed in the FDA Orange Book for Complera®.

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



32. Emtricitabine can be referred to by any of several chemical names. The chemical name given to emtricitabine in the Complera® label is “5-fluoro-1-[(2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine.” Two chemical names recited for emtricitabine in the ’245 Patent are “(–)-β-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl) -1,3-oxathiolane” and “β-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane.” Two chemical names recited for emtricitabine in the ’396 Patent are “(–)-cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one” and “(–)-enantiomer of cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one.”

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

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

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

36. The named inventors of the ’397 and ’264 Patents are Terrence C. Dahl, Mark M. Menning and Reza Oliyai.

37. Terrence C. Dahl, Mark M. Menning and Reza Oliyai assigned the ’397 and ’264 Patents to Gilead.

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

38. Plaintiffs repeat and reallege paragraphs 1-37 above as if set forth herein.

39. On information and belief, Mylan submitted or caused to be submitted an Abbreviated New Drug Application (“ANDA”), specifically ANDA No. 20-8452, to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing the combination of 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for the purpose of treating HIV infection.

40. By letter dated July 24, 2015 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the “July 24, 2015 Notice Letter”), Mylan notified Plaintiffs that it had submitted ANDA No. 20-8452 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the ’245 Patent.

41. In its July 24, 2015 Notice Letter, Mylan notified Plaintiffs that, as a part of ANDA No. 20-8452, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '245 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '245 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

42. Mylan alleged in its July 24, 2015 Notice Letter that Claims 1-22 of the '245 Patent are invalid and expired and that Claims 9-16 and 20-22 of the '245 Patent would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 20-8452.

43. The July 24, 2015 Notice Letter does not allege non-infringement of Claims 1-8 and 17-19 of the '245 Patent other than solely stating that the '245 Patent is invalid.

44. The July 24, 2015 Notice Letter does not provide the full and detailed statement of Mylan's factual and legal basis to support its non-infringement and invalidity allegations as to the '245 Patent.

45. Accordingly, the July 24, 2015 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.

46. By filing ANDA No. 20-8452 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, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate before the '245 Patent's expiration, Mylan has committed an act of infringement of the '245 Patent under 35 U.S.C. § 271(e)(2).

47. On information and belief, Mylan lacked a good faith basis for alleging invalidity when ANDA No. 20-8452 was filed and when the Paragraph IV certification was made. Mylan's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '245 Patent.

48. Mylan's submission of ANDA No. 20-8452 and service of the July 24, 2015 Notice Letter indicates a refusal to change its current course of action.

49. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for which Mylan seeks approval in ANDA No. 20-8452, if approved, will infringe one or more claims of the '245 Patent.

50. On information and belief, the tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for the use for which Mylan seeks approval in ANDA No. 20-8452, if approved, will be administered to human patients in an effective amount for treating HIV infection. This administration will infringe one or more claims of the '245 Patent. On information and belief, this administration will occur at Mylan's active behest and with its intent, knowledge and encouragement. On information and belief, Mylan will actively encourage, aid and abet this administration with knowledge that it is in

contravention of Plaintiffs' rights under the '245 Patent. Further, by filing ANDA No. 20-8452 with a Paragraph IV certification, Mylan admits that it has knowledge of the '245 Patent.

51. The July 24, 2015 Notice Letter does not allege and does not address unenforceability of any claims of the '245 Patent. By not addressing unenforceability of any claims of the '245 Patent in its July 24, 2015 Notice Letter, Mylan admits that all of the claims of the '245 Patent are enforceable.

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

52. Plaintiffs repeat and reallege paragraphs 1-37 above as if set forth herein.

53. On information and belief, Mylan submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 20-8452, to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing the combination of 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for the purpose of treating HIV infection.

54. By letter dated July 24, 2015 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "July 24, 2015 Notice Letter"), Mylan notified Plaintiffs that it had submitted ANDA No. 20-8452 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '396 Patent.

55. In its July 24, 2015 Notice Letter, Mylan notified Plaintiffs that, as a part of its ANDA No. 20-8452, it had filed a Paragraph IV certification with respect to the '396 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '396 Patent, "is invalid or will not be

infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

56. Mylan alleged in its July 24, 2015 Notice Letter that Claims 1-28 of the '396 Patent are invalid and set to expire on September 29, 2015 and, therefore, would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 20-8452.

57. The July 24, 2015 Notice Letter does not allege non-infringement of Claims 1-28 of the '396 Patent other than solely stating that the '396 Patent is invalid.

58. The July 24, 2015 Notice Letter does not provide the full and detailed statement of Mylan's factual and legal basis to support its non-infringement and invalidity allegations as to the '396 Patent.

59. Accordingly, the July 24, 2015 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.

60. By filing ANDA No. 20-8452 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, eq. 25 mg base of rilpiverine hydrochloride, and 300

mg of tenofovir disoproxil fumarate before the '396 Patent's expiration, Mylan has committed an act of infringement of the '396 Patent under 35 U.S.C. § 271(e)(2).

61. On information and belief, Mylan lacked a good faith basis for alleging invalidity when ANDA No. 20-8452 was filed and when the Paragraph IV certification was made. Mylan's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '396 Patent.

62. Mylan's submission of ANDA No. 20-8452 and service of the July 24, 2015 Notice Letter indicates a refusal to change its current course of action.

63. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for which Mylan seeks approval in ANDA No. 20-8452, if approved, will infringe one or more claims of the '396 Patent.

64. The July 24, 2015 Notice Letter does not allege and does not address unenforceability of any claims of the '396 Patent. By not addressing unenforceability of any claims of the '396 Patent in its July 24, 2015 Notice Letter, Mylan admits that all of the claims of the '396 Patent are enforceable.

COUNT 3
Infringement of U.S. Patent No. 8,592,397

65. Plaintiffs repeat and reallege paragraphs 1-37 above as if set forth herein.

66. On information and belief, Mylan submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 20-8452, to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing the combination of 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for the purpose of treating HIV infection.

67. On information and belief, ANDA No. 20-8452 seeks approval to manufacture, use, sell and/or import a combination tablet containing emtricitabine, rilpiverine hydrochloride, and tenofovir disoproxil fumarate for the purpose of treating HIV infection.

68. By letter dated July 24, 2015 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "July 24, 2015 Notice Letter"), Mylan notified Plaintiffs that it had submitted ANDA No. 20-8452 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '397 Patent.

69. In its July 24, 2015 Notice Letter, Mylan notified Plaintiffs that, as a part of ANDA No. 20-8452, 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 '397 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 '397 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

70. Mylan alleged in its July 24, 2015 Notice Letter that Claims 1-26 of the '397 Patent are invalid and that Claims 7-13, 17-18, and 23 of the '397 Patent would not be infringed by the

commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 20-8452.

71. The July 24, 2015 Notice Letter does not allege non-infringement of Claims 1-6, 14-16, 19-22, and 24-26 of the '397 Patent other than solely stating that the '397 Patent is invalid.

72. The July 24, 2015 Notice Letter does not provide the full and detailed statement of Mylan's factual and legal basis to support its non-infringement and invalidity allegations as to the '397 Patent.

73. Accordingly, the July 24, 2015 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.

74. By filing ANDA No. 20-8452 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, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate before the '397 Patent's expiration, Mylan has committed an act of infringement of the '397 Patent under 35 U.S.C. § 271(e)(2).

75. On information and belief, Mylan lacked a good faith basis for alleging invalidity when ANDA No. 20-8452 was filed and when the Paragraph IV certification was made. Mylan's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '397 Patent.

76. Mylan's submission of ANDA No. 20-8452 and service of the July 24, 2015 Notice Letter indicates a refusal to change its current course of action.

77. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for which Mylan seeks approval in ANDA No. 20-8452, if approved, will infringe one or more claims of the '397 Patent.

78. On information and belief, the tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for the use for which Mylan seeks approval in ANDA No. 20-8452, 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 '397 Patent. On information and belief, this administration will occur at Mylan's active behest and with its intent, knowledge and encouragement. On information and belief, Mylan will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '397 Patent. Further, by filing ANDA No. 20-8452 with a Paragraph IV certification, Mylan admits that it has knowledge of the '397 Patent.

79. The July 24, 2015 Notice Letter does not allege and does not address unenforceability of any claims of the '397 Patent. By not addressing unenforceability of any claims of the '397 Patent in its July 24, 2015 Notice Letter, Mylan admits that all of the claims of the '397 Patent are enforceable.

COUNT 4
Infringement of U.S. Patent No. 8,716,264

80. Plaintiffs repeat and reallege paragraphs 1-37 above as if set forth herein.

81. On information and belief, Mylan submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 20-8452, to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing the combination of 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for the purpose of treating HIV infection.

82. On information and belief, ANDA No. 20-8452 seeks approval to manufacture, use, sell and/or import a combination tablet containing emtricitabine, rilpiverine hydrochloride, and tenofovir disoproxil fumarate for the purpose of treating HIV infection.

83. By letter dated July 24, 2015 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "July 24, 2015 Notice Letter"), Mylan notified Plaintiffs that it had submitted ANDA No. 20-8452 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '264 Patent.

84. In its July 24, 2015 Notice Letter, Mylan notified Plaintiffs that, as a part of ANDA No. 20-8452, 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 '264 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 '264 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

85. Mylan alleged in its July 24, 2015 Notice Letter that Claims 1-38 of the '264 Patent are invalid and that Claims 18-24, 26-32, and 35-38 of the '264 Patent would not be infringed by

the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 20-8452.

86. The July 24, 2015 Notice Letter does not allege non-infringement of Claims 1-17, 25, and 33-34 of the '264 Patent other than solely stating that the '264 Patent is invalid.

87. The July 24, 2015 Notice Letter does not provide the full and detailed statement of Mylan's factual and legal basis to support its non-infringement and invalidity allegations as to the '264 Patent.

88. Accordingly, the July 24, 2015 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. 20-8452 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, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate before the '264 Patent's expiration, Mylan has committed an act of infringement of the '264 Patent under 35 U.S.C. § 271(e)(2).

90. On information and belief, Mylan lacked a good faith basis for alleging invalidity when ANDA No. 20-8452 was filed and when the Paragraph IV certification was made. Mylan's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '264 Patent.

91. Mylan's submission of ANDA No. 20-8452 and service of the July 24, 2015 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 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for which Mylan seeks approval in ANDA No. 20-8452, if approved, will infringe one or more claims of the '264 Patent.

93. On information and belief, the tablets containing 200 mg of emtricitabine, eq. 25 mg base of rilpiverine hydrochloride, and 300 mg of tenofovir disoproxil fumarate for the use for which Mylan seeks approval in ANDA No. 20-8452, 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 '264 Patent. On information and belief, this administration will occur at Mylan's active behest and with its intent, knowledge and encouragement. On information and belief, Mylan will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '264 Patent. Further, by filing ANDA No. 20-8452 with a Paragraph IV certification, Mylan admits that it has knowledge of the '264 Patent.

94. The July 24, 2015 Notice Letter does not allege and does not address unenforceability of any claims of the '264 Patent. By not addressing unenforceability of any claims of the '264 Patent in its July 24, 2015 Notice Letter, Mylan admits that all of the claims of the '264 Patent are enforceable.

95. This case is an exceptional one because, *inter alia*, Mylan lacks a good faith belief in its July 24, 2015 Notice Letter to assert the invalidity and/or non-infringement of the '245, '396, '397 and '264 Patents, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Mylan's ANDA No. 20-8452 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '245 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(b) A judgment declaring that the effective date of any approval of Mylan's ANDA No. 20-8452 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '396 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(c) A judgment declaring that the effective date of any approval of Mylan's ANDA No. 20-8452 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 '397 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(d) A judgment declaring that the effective date of any approval of Mylan's ANDA No. 20-8452 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 '264 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(e) A judgment declaring that the '245 Patent remains valid, enforceable and that one or more claims have been infringed by Mylan;

(f) A judgment declaring that the '396 Patent remains valid, enforceable and that one or more claims have been infringed by Mylan;

(g) A judgment declaring that the '397 Patent remains valid, enforceable and that one or more claims have been infringed by Mylan;

(h) A judgment declaring that the '264 Patent remains valid, enforceable and that one or more claims have been infringed by Mylan;

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

(j) A permanent injunction against any infringement of the ’396 Patent by Mylan, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(k) A permanent injunction against any infringement of the ’397 Patent by Mylan, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(l) A permanent injunction against any infringement of the ’264 Patent by Mylan, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(m) A judgment that Mylan’s conduct is exceptional in this case;

(n) An award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(o) To the extent that Mylan has committed any acts with respect to the subject matter claimed in the ’245 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(p) To the extent that Mylan has committed any acts with respect to the subject matter claimed in the ’396 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(q) To the extent that Mylan has committed any acts with respect to the subject matter claimed in the ’397 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) To the extent that Mylan has committed any acts with respect to the subject matter claimed in the ’264 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;

(s) Costs and expenses in this action; and

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

August 31, 2015 Respectfully submitted,

/s/ Chad L. Taylor
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