IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA, N.V., JANSSEN SCIENCES IRELAND UC, GILEAD SCIENCES, INC., and GILEAD SCIENCES IRELAND UC Plaintiffs, v. MYLAN PHARMACEUTICALS, INC. and MYLAN, INC. Defendants.	Civ. Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceutica, N.V. and Janssen Sciences Ireland UC (together, "Janssen") and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (together, "Gilead"), (collectively "Plaintiffs"), for their Complaint against defendants Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") and Mylan Inc. (together, "Mylan" or "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement by Mylan of U.S. Patent Nos. 8,841,310 B2 ("the '310 Patent"), 7,125,879 B2 ("the '879 Patent") and 8,101,629 B2 ("the '629 Patent") (collectively, "the Patents-in-suit") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. This action arises out of Mylan's filing of Abbreviated New Drug Application ("ANDA") No. 208452 seeking approval from the United States Food and Drug Administration ("FDA") to sell generic copies of Plaintiffs' highly successful COMPLERA®

(emtricitabine, rilpivirine, and tenofovir disoproxil fumarate) tablets prior to the expiration of the Patents-in-suit.

THE PARTIES

2. Plaintiff Janssen Pharmaceutica, N.V. is a corporation organized under the laws of Belgium, having its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

3. Plaintiff Janssen Sciences Ireland UC is an Irish company, having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

4. Plaintiff Gilead Sciences, Inc. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

5. Plaintiff Gilead Sciences Ireland UC is an Irish company, having its principal place of business at IDA Business & Technology Park, Carrigtohill, Ireland.

6. On information and belief, Mylan Pharmaceuticals is a corporation organized under the laws of the State of West Virginia, with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc.

7. On information and belief, Mylan Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Inc. is in the business of, among other things, marketing and selling generic copies of branded

pharmaceutical products for the U.S. market, alone and/or through its wholly owned subsidiary and agent, Mylan Pharmaceuticals.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals because Mylan Pharmaceuticals has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

10. On information and belief, Mylan Pharmaceuticals derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

11. On information and belief, Mylan Pharmaceuticals is registered to do business in Delaware, and has thereby consented to suit in Delaware.

12. On information and belief, Mylan Pharmaceuticals has appointed Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808, as its registered agent for the receipt of service of process.

13. On information and belief, Mylan Pharmaceuticals is registered with the Delaware Board of Pharmacy as a "Pharmacy-Wholesale[r]" and a "Distributor/Manufacturer CSR." *See Acorda Therapeutics v. Mylan Pharms. Inc.*, 2015 U.S. Dist. LEXIS 4056, at *5 (D. Del. Jan. 14, 2015).

14. This Court has repeatedly exercised jurisdiction over Mylan Pharmaceuticals in prior cases under the Hatch-Waxman Act. *See e.g. Acorda Therapeutics v. Mylan Pharms. Inc.*, No. 14-935-LPS (D. Del. Jan. 14, 2015); *Forest Labs, Inc. v. Amneal Pharms, LLC*, No. 14-508-LPS (D. Del. Feb. 26, 2015); *Novartis Pharms. Corp. v. Mylan Inc.*, No. 14-820-RGA (D. Del. March 16, 2015); *Astrazeneca AB v. Mylan Pharms. Inc.*, No. 14-696-GMS (D. Del. Nov. 5, 2014).

15. On information and belief, this Court has personal jurisdiction over Mylan Inc. because Mylan Inc. has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Inc. has had persistent and continuous contacts with this judicial district, including developing, marketing and/or selling pharmaceutical products that are sold in this judicial district.

16. On information and belief, Mylan Inc., directly and/or through Mylan Pharmaceuticals, markets, distributes and sells generic pharmaceutical products throughout the United States, including in this judicial district.

17. On information and belief, Mylan Inc. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

18. On information and belief, Mylan Inc., directly and/or through Mylan Pharmaceuticals, has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers and distributors in this judicial district.

19. On information and belief, Mylan Inc. has at least 20 subsidiaries incorporated in the State of Delaware. *See Acorda Therapeutics v. Mylan Pharms. Inc.*, 2015 U.S. Dist. LEXIS 4056, at *6 (D. Del. Jan. 14, 2015).

20. On information and belief, Mylan Pharmaceuticals acts as the agent of Mylan Inc., and has submitted regulatory filings for generic pharmaceutical products to the FDA on behalf of Mylan Inc.

21. Mylan also engaged in Delaware-related activities in connection with its efforts to obtain FDA approval to market its generic copies of Complera tablets. On information and belief, Mylan Pharmaceuticals, as the agent of Mylan Inc., sent a letter dated July 24, 2015 to Plaintiff Gilead Sciences, Inc., a corporation organized under the laws of the State of Delaware, stating that Mylan had submitted ANDA No. 208452 seeking approval to commercially manufacture, use, import, offer for sale and sell generic copies of Complera prior to the expiration of the Patents-in-suit ("the Mylan Paragraph IV Letter"). If Mylan succeeds in obtaining FDA approval, it would sell its generic version of Complera in Delaware and other states, causing injury to Plaintiffs in Delaware.

22. On information and belief, Mylan Inc. and Mylan Pharmaceuticals operate and act in concert as an integrated, unitary business.

23. On information and belief, Mylan Pharmaceuticals and Mylan Inc. have previously invoked this Court's jurisdiction, or have stipulated and/or consented to personal jurisdiction in this district, in numerous prior patent cases.

24. Mylan Pharmaceuticals has "litigat[ed], as a defendant, over 50 other civil actions initiated in this jurisdiction in the last 19 years and affirmatively invoked this Court's jurisdiction by asserting counterclaims in at least 46 of those cases" and Mylan Inc. has

"litigat[ed] as a defendant and assert[ed] counterclaims in at least 15 cases initiated in this jurisdiction over the past ten years." *See Acorda Therapeutics v. Mylan Pharms. Inc.*, 2015 U.S. Dist. LEXIS 4056, at *6-7 (D. Del. Jan. 14, 2015).

25. On information and belief, Mylan litigates patent cases in federal courts as part of its business model as a manufacturer of generic drugs, including in this judicial district—where the highest percentage of all Hatch-Waxman cases were filed in the past five years. *See Acorda Therapeutics v. Mylan Pharms. Inc.*, 2015 U.S. Dist. LEXIS 4056, at *51 n.24 (D. Del. Jan. 14, 2015); *Astrazeneca AB v. Mylan Pharms. Inc.*, 2014 U.S. DIST. LEXIS 156660, at *19 (D. Del. Nov. 5, 2014).

26. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

27. On September 23, 2014, the United States Patent and Trademark Office ("the PTO") issued the '310 Patent, entitled "Combinations of a Pyrimidine Containing NNRTI with RT Inhibitors." A true and correct copy of the '310 Patent is attached hereto as Exhibit A.

28. Plaintiff Janssen Sciences Ireland UC holds title to the '310 Patent.

29. On October 24, 2006, the PTO issued the '879 Patent, entitled "HIV Inhibiting Pyrimidines Derivatives." A true and correct copy of the '879 Patent is attached hereto as Exhibit B.

30. Plaintiff Janssen Pharmaceutica, N.V. holds title to the '879 Patent.

31. On January 24, 2012, the PTO issued the '629 Patent, entitled "Salt of 4-[[4-[[4-(2-Cyanoethenyl)-2,6-Dimethylphenyl]amino]-2-Pyrimidinyl]Amino]Benzonitrile." A true and correct copy of the '629 Patent is attached hereto as Exhibit C.

32. Plaintiff Janssen Pharmaceutica N.V. holds title to the '629 Patent.

33. Janssen and Gilead have entered into a collaboration agreement for the development and commercialization of Complera.

34. Gilead has an exclusive license under Janssen's '310, '879 and '629 Patents for the development and commercialization of Complera.

35. Gilead Sciences, Inc. is the holder of approved New Drug Application ("NDA") No. 202123 for Complera and distributes Complera in the U.S.

36. Complera is included in FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

37. The FDA's "Orange Book" also lists patents associated with approved drugs. The '310, '879 and '629 Patents are listed in the "Orange Book" in association with Complera. The claims of the '310, '879 and '629 Patents cover Complera or its use.

38. On information and belief, Mylan Inc. itself and/or through its subsidiary, agent and alter ego, Mylan Pharmaceuticals, submitted ANDA No. 208452 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of generic copies of Complera tablets ("Mylan's Generic Tablets").

39. On information and belief, Mylan Inc. and Mylan Pharmaceuticals collaborated in the research, development, preparation and filing of ANDA No. 208452 for Mylan's Generic Tablets.

40. On information and belief, Mylan Pharmaceuticals is Mylan Inc.'s authorized U.S. agent for ANDA No. 208452.

41. On information and belief, Mylan Pharmaceuticals will market and/or distribute Mylan's Generic Tablets if ANDA No. 208452 is approved by the FDA.

42. On information and belief, Mylan Inc. participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 208452.

43. On or about July 27, 2015 Plaintiffs received a letter dated July 24, 2015, the Mylan Paragraph IV Letter, stating that Mylan had submitted ANDA No. 208452 seeking approval to commercially manufacture, use, import, offer for sale and sell Mylan's Generic Tablets prior to the expiration of the '879, '310 and '629 Patents.

44. The Mylan Paragraph IV Letter also states that the Mylan ANDA No. 208452 included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("PIV certification"), that the claims of the '310, '879, or '629 Patents are invalid.

45. In the Mylan Paragraph IV Letter, Mylan did not dispute that the commercial manufacture, use, importation, offer for sale and sale of Mylan's Generic Tablets would infringe the claims of the '310 and the '629 Patents. Mylan also did not dispute that the commercial manufacture, use, importation, offer for sale and sale of Mylan's Generic Tablets would infringe claims 1-3, 5-8, and 11-19 of the '879 Patent.

46. On information and belief, Mylan had actual and constructive notice of the Patents-in-suit prior to the filing of ANDA No. 208452.

47. On information and belief, Mylan Inc. and Mylan Pharmaceuticals continue to seek approval of ANDA No. 208452 from the FDA and intend to collaborate in the commercial manufacture, marketing and sale of Mylan's Generic Tablets (including the commercial marketing and sale of such products in the State of Delaware) in the event that the FDA approves ANDA No. 208452.

48. Plaintiffs commenced this action within forty-five days of the date they received Mylan's Paragraph IV Notice of ANDA No. 208452 containing the PIV certifications.

COUNT I

Infringement of the '310 Patent by Mylan Under 35 U.S.C. § 271(e)(2)(A)

49. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 48 above, as if fully set forth here.

50. Under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed the '310 Patent by submitting ANDA No. 208452 with a Paragraph IV certification and seeking FDA approval of ANDA No. 208452 to market Mylan's Generic Tablets prior to the expiration of the '310 Patent.

51. Upon information and belief, Mylan's commercial manufacture, importation, use, sale and/or offer for sale of Mylan's Generic Tablets prior to the expiration of the '310 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '310 Patent.

52. Mylan's Paragraph IV Letter does not dispute that Mylan's Generic Tablets infringe the claims of the '310 Patent.

53. Mylan had actual and constructive notice of the '310 Patent prior to filing ANDA No. 208452.

54. Plaintiffs have no adequate remedy at law to redress the infringement by Mylan.

55. Plaintiffs will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '310 Patent.

COUNT II

Infringement of the '879 Patent by Mylan Under 35 U.S.C. § 271(e)(2)(A)

56. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 55 above, as if fully set forth here.

57. Under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed the '879 Patent by submitting ANDA No. 208452 with a Paragraph IV certification and seeking FDA approval of ANDA No. 208452 to market Mylan's Generic Tablets prior to the expiration of the '879 Patent.

58. Upon information and belief, Mylan's commercial manufacture, importation, use, sale and/or offer for sale of Mylan's Generic Tablets prior to the expiration of the '879 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '879 Patent.

59. Mylan's Paragraph IV Letter does not dispute that Mylan's Generic Tablets or their use infringe claims 1-3, 5-8, 11-19 of the '879 Patent.

60. Mylan had actual and constructive notice of the '879 Patent prior to filing ANDA No. 208452.

61. Plaintiffs have no adequate remedy at law to redress the infringement by Mylan.

62. Plaintiffs will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '879 Patent.

COUNT III

Infringement of the '629 Patent by Mylan Under 35 U.S.C. § 271(e)(2)(A)

63. Plaintiffs repeat and reallege each and every allegation contained in

paragraphs 1 through 62 above, as if fully set forth here.

64. Under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed the '629 Patent by submitting ANDA No. 208452 with a Paragraph IV certification and seeking FDA approval of ANDA No. 208452 to market Mylan's Generic Tablets prior to the expiration of the '629 Patent.

65. Upon information and belief, Mylan's commercial manufacture, importation, use, sale and/or offer for sale of Mylan's Generic Tablets prior to the expiration of the '629 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '629 Patent.

66. Mylan's Paragraph IV Letter does not dispute that Mylan's Generic Tablets infringe the claims of the '629 Patent.

67. Mylan had actual and constructive notice of the '629 Patent prior to filing ANDA No. 208452.

68. Plaintiffs have no adequate remedy at law to redress the infringement by Mylan.

69. Plaintiffs will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '629 Patent.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) a judgment that Mylan has infringed the '310, '879 and '629 Patents under 35 U.S.C. § 271(e)(2)(A);

(b) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Mylan's ANDA No. 208452 under § 505(j) of the Federal Food, Drug and

Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the '310, '879 and '629 Patents, including any additional exclusivity period applicable to those patents;

(c) a judgment declaring that the making, using, offering to sell, selling or importing of the Mylan generic tablets described in ANDA No. 208452 would constitute infringement by Mylan of the '310, '879 and '629 Patents, or inducing or contributing to such conduct, pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Mylan and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling, offering for sale, using, or importing the Mylan generic tablets described in ANDA No. 208452 until the day after the expiration of the '310, '879 and '629 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing one or more claims of the '310, '879 and '629 Patents;

(e) a declaration that this case is exceptional;

(f) an award of Plaintiffs' costs, expenses, reasonable attorneys' fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(g) such other and further relief as the Court may deem just and proper.

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