IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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INSITE VISION INCORPORATED, MERCK SHARP & DOHME CORP., INSPIRE PHARMACEUTICALS, INC., PFIZER INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,

Defendants.

C.A. NO. _____

InSite Vision Incorporated, Merck Sharp & Dohme Corp., Inspire Pharmaceuticals Incorporated, and Pfizer Inc. ("Plaintiffs") for their Complaint against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Mylan"), hereby allege as follows:

THE PARTIES

1. Plaintiff InSite Vision Incorporated ("InSite") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 965 Atlantic Avenue, Alameda, CA 94501.

2. Plaintiff Merck Sharp & Dohme Corp. ("Merck") is a corporation organized and existing under the laws of the State of New Jersey, having a principle place of business at One Merck Drive, Whitehouse Station, NJ 08889. Merck Sharp & Dohme Corp. is a wholly-owned subsidiary of Merck & Co., Inc., a corporation organized and existing under the laws of the State of New Jersey.

3. Plaintiff Inspire Pharmaceuticals, Inc. ("Inspire") is a corporation organized and existing under the laws of the State of Delaware. Inspire is a wholly-owned subsidiary of Merck & Co., Inc.

4. Plaintiff Pfizer Inc. ("Pfizer") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 235 East 42nd Street, New York, New York 10017.

5. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, having a principle place of business at 1500 Corporate Drive, Canonsburg, PA 15317. Mylan Inc. is registered to do business in the

State of New Jersey and has appointed Corporation Service Company, located at 830 Bear Tavern Road, West Trenton, NJ 08628 as its agent.

6. On information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. Mylan Pharmaceuticals is registered to do business in the State of New Jersey and has appointed Corporation Service Company, located at 830 Bear Tavern Road, West Trenton, NJ 08628 as its agent. Mylan Pharmaceuticals is a subsidiary of Mylan Inc.

NATURE OF THE ACTION

7. This is a civil action for patent infringement under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, arising from Mylan Pharmaceuticals' filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of the pharmaceutical product AzaSite® before the expiration of the Plaintiffs' patents covering AzaSite® and its use.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Mylan Pharmaceuticals because of Mylan Pharmaceuticals' continuous and systematic contacts with this State. On information and belief, Mylan Pharmaceuticals: (1) is registered to do business in the

State of New Jersey; (2) intentionally markets and provides its generic pharmaceutical drug products to residents of this State; (3) maintains a broad distributorship network within this State; and (4) enjoys substantial income from sales in this State. Moreover, Mylan Pharmaceuticals has previously consented to personal jurisdiction in this judicial district.

10. This Court has personal jurisdiction over Mylan Inc. because of Mylan Inc.'s continuous and systematic contacts with this State. On information and belief, Mylan Inc.: (1) is registered to do business in the State of New Jersey; (2) intentionally markets and provides its generic pharmaceutical drug products to residents of this State; (3) intentionally avails itself of the laws of this State by entering into ongoing contractual relationships with companies who market and direct their generic drug products to residents of this state, including but not limited to Mylan Pharmaceuticals; and (4) enjoys substantial income from sales in this State. Moreover, Mylan Inc. has previously consented to personal jurisdiction in this judicial district.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

12. On March 1, 2005, the United States Patent and Trademark Office ("USPTO") duly and legally issued United States Patent No. 6,861,411 ("the '411 patent"), entitled "Method of Treating Eye Infections with Azithromycin." The '411 patent is assigned to Pfizer. A copy of the '411 patent is attached as Appendix A.

13. On May 29, 2001, the USPTO duly and legally issued United States Patent No. 6,239,113 ("the '113 patent"), entitled "Topical Treatment or Prevention of Ocular

Infections." The '113 patent is assigned to InSite. A copy of the '113 patent is attached as Appendix B.

14. On May 27, 2003, the USPTO duly and legally issued United States Patent No. 6,569,443 ("the '443 patent"), entitled "Topical Treatment or Prevention of Ocular Infections." The '443 patent is assigned to InSite. A copy of the '443 patent is attached as Appendix C.

15. On June 6, 2006, the USPTO duly and legally issued United States Patent No. 7,056,893 ("the '893 patent"), entitled "Topical Treatment for Prevention of Ocular Infections." The '893 patent is assigned to InSite. A copy of the '893 patent is attached as Appendix D.

FACTUAL BACKGROUND

AzaSite®

16. Pfizer has granted InSite an exclusive license under the '411 patent as part of an agreement ("InSite-Pfizer Agreement") between the companies for the commercialization of AzaSite®, an ophthalmic solution containing the active ingredient azithromycin (1%), which is indicated for the treatment of bacterial conjunctivitis.

17. InSite has granted Inspire an exclusive license under the '113, '443, and '893 patents, and an exclusive sublicense to the '411 patent, as part of an agreement ("Inspire Agreement") between the companies for the commercialization of AzaSite®.

18. Subsequently, Merck & Co. Inc. acquired Inspire.

19. Merck holds an approved New Drug Application, No. 50-810, for azithromycin ophthalmic solution 1% sterile topical ophthalmic drops (the "AzaSite® NDA").

20. Merck currently markets AzaSite® pursuant to the rights granted under the Inspire Agreement.

21. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '411, '113, '443, and '893 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to AzaSite®.

Mylan's ANDA

22. On information and belief, Mylan Pharmaceuticals submitted Abbreviated New Drug Application No. 20-3788 (the "Mylan ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market azithromycin ophthalmic solution, 1% (the "Mylan Product").

23. On information and belief, Mylan Inc. was actively involved in the preparation and/or submission of the Mylan ANDA.

24. On information and belief, Mylan Inc. actively and knowingly provided Mylan Pharmaceuticals with material information and support in pursuing the Mylan ANDA, and has therefore aided and/or abetted in the filing of the Mylan ANDA.

25. On information and belief, the Mylan ANDA refers to and relies upon the AzaSite® NDA and contains data that, according to Mylan Pharmaceuticals, demonstrates the bioequivalence of the Mylan Product and AzaSite®.

26. On or around May 1, 2013, Mylan Pharmaceuticals sent InSite, Pfizer and Merck a letter and attached memorandum (collectively, the "Mylan Notification") stating that it had included with its ANDA a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '411, '113, '443, and '893 patents are invalid and/or unenforceable, and that certain claims of the '411, '443 and '893 patents would not be infringed by the manufacture, use, importation, sale or offer for sale of the Mylan Product (the "Paragraph IV Certification").

27. The Mylan Notification does not dispute infringement of claims 1-5 and 7 of the '411 patent by the Mylan Product.

28. The Mylan Notification does not dispute infringement of the '113 patent by the Mylan Product.

29. The Mylan Notification does not dispute infringement of claims 1-13, 23-27, 29-34 and 36-44 of the '893 patent by the Mylan Product.

30. The Mylan Notification does not dispute infringement of claims 1-8, 11, 14-16, 41 and 44 of the '443 patent by the Mylan Product.

31. On information and belief, the Mylan Product will have instructions for use that substantially copy the instructions for AzaSite®, including instructions for administering the Mylan Product to treat bacterial conjunctivitis. The instructions accompanying the Mylan Product will actually induce and/or contribute to others using the Mylan Product in the manner set forth in the instructions.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,861,411

32. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–31 of this Complaint.

33. Mylan Pharmaceuticals' filing of ANDA No. 20-3788 for purposes of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale or inducement thereof, of the Mylan Product before the expiration of the '411 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

34. On information and belief, Mylan Inc. actively and knowingly aided, abetted and induced Mylan Pharmaceuticals to submit the Mylan ANDA before the expiration of the '411 patent, which is an act of infringement under 35 U.S.C. § 271(b).

35. On information and belief, Mylan Pharmaceuticals plans, intends to, and will commercially make, use, offer to sell, and/or sell the Mylan Product within the United States, or import the Mylan Product into the United States during the term of the '411 patent, after the Mylan ANDA is approved, which would further infringe the '411 patent under 35 U.S.C. § 271(a).

36. On information and belief, Mylan Pharmaceuticals plans, intends to, and will actively induce, or contribute to, the infringement of the '411 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

37. On information and belief, Mylan Inc. plans, intends to, and will actively induce, or contribute to, the infringement of the '411 patent under 35 U.S.C. § 271(b) and/or § 271(c).

38. On information and belief, Mylan Pharmaceuticals lacked a good faith basis for alleging invalidity of the '411 patent when it filed ANDA No. 20-3788 and made the Paragraph IV certification. Accordingly, Mylan Pharmaceuticals' Paragraph IV certification was wholly unjustified.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,861,411

39. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–38 of this Complaint.

40. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

41. On information and belief, Mylan Pharmaceuticals has taken and plans, intends to, and will take active steps to commercially make, use, offer to sell, and/or sell the Mylan Product within the United States, or import the Mylan Product into the United

States during the term of the '411 patent, after the Mylan ANDA is approved, which would infringe the '411 patent under 35 U.S.C. § 271(a).

42. On information and belief, Mylan Pharmaceuticals' plans, intends to, and will actively induce, or contribute to, the infringement of the '411 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

43. On information and belief, Mylan Inc. plans, intends to, and will actively induce, or contribute to, the infringement of the '411 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 6,239,113

44. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–43 of this Complaint.

45. Mylan Pharmaceuticals' filing of ANDA No. 20-3788 for purposes of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale or inducement thereof, of the Mylan Product before the expiration of the '113 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

46. On information and belief, Mylan Inc. actively and knowingly aided, abetted and induced Mylan Pharmaceuticals to submit the Mylan ANDA before the expiration of the '113 patent, which is an act of patent infringement under 35 U.S.C. § 271(b).

47. On information and belief, Mylan Pharmaceuticals plans, intends to, and will commercially make, use, offer to sell, and/or sell the Mylan Product within the United States, or import the Mylan Product into the United States during the term of the '113 patent, after the Mylan ANDA is approved, which would further infringe the '113 patent under 35 U.S.C. § 271(a).

48. On information and belief, Mylan Pharmaceuticals plans, intends to, and will actively induce, or contribute to, the infringement of the '113 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

49. On information and belief, Mylan Inc. plans, intends to, and will actively induce, or contribute to, the infringement of the '113 patent under 35 U.S.C. § 271(b) and/or § 271(c).

50. On information and belief, Mylan Pharmaceuticals lacked a good faith basis for alleging invalidity of the '113 patent when it filed ANDA No. 20-3788 and made the Paragraph IV certification. Accordingly, Mylan Pharmaceuticals' Paragraph IV certification was wholly unjustified.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,239,113

51. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–50 of this Complaint.

52. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

53. On information and belief, Mylan Pharmaceuticals has taken and plans, intends to, and will take active steps to commercially make, use, offer to sell, and/or sell the Mylan Product within the United States, or import the Mylan Product into the United States during the term of the '113 patent, after the Mylan ANDA is approved, which would infringe the '113 patent under 35 U.S.C. § 271(a).

54. On information and belief, Mylan Pharmaceuticals' plans, intends to, and will actively induce, or contribute to, the infringement of the '113 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

55. On information and belief, Mylan Inc. plans, intends to, and will actively induce, or contribute to, the infringement of the '113 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 6,569,443

56. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–55 of this Complaint.

57. Mylan Pharmaceuticals' filing of ANDA No. 20-3788 for purposes of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale or inducement thereof, of the Mylan Product before the expiration of the '443 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

58. On information and belief, Mylan Inc. actively and knowingly aided, abetted and induced Mylan Pharmaceuticals to submit the Mylan ANDA before the expiration of the '443 patent, which is an act of patent infringement under 35 U.S.C. § 271(b).

59. On information and belief, Mylan Pharmaceuticals plans, intends to, and will commercially make, use, offer to sell, and/or sell the Mylan Product within the United States, or import the Mylan Product into the United States during the term of the '443 patent, after the Mylan ANDA is approved, which would further infringe the '443 patent under 35 U.S.C. § 271(a).

60. On information and belief, Mylan Pharmaceuticals plans, intends to, and will actively induce, or contribute to, the infringement of the '443 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

61. On information and belief, Mylan Inc. plans, intends to, and will actively induce, or contribute to, the infringement of the '443 patent under 35 U.S.C. § 271(b) and/or § 271(c).

62. On information and belief, Mylan Pharmaceuticals lacked a good faith basis for alleging invalidity of the '443 patent when it filed ANDA No. 20-3788 and made the Paragraph IV certification. Accordingly, Mylan Pharmaceuticals' Paragraph IV certification was wholly unjustified.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,569,443

63. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–62 of this Complaint.

64. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

65. On information and belief, Mylan Pharmaceuticals has taken and plans, intends to, and will take active steps to commercially make, use, offer to sell, and/or sell the Mylan Product within the United States, or import the Mylan Product into the United States during the term of the '443 patent, after the Mylan ANDA is approved, which would infringe the '443 patent under 35 U.S.C. § 271(a).

66. On information and belief, Mylan Pharmaceuticals plans, intends to, and will actively induce, or contribute to, the infringement of the '443 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

67. On information and belief, Mylan Inc. plans, intends to, and will actively induce, or contribute to, the infringement of the '443 patent under 35 U.S.C. § 271(b) and/or § 271(c).

COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 7,056,893

68. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–67 of this Complaint.

69. Mylan Pharmaceuticals' filing of ANDA No. 20-3788 for purposes of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale or inducement thereof, of the Mylan Product before the expiration of the '893 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

70. On information and belief, Mylan Inc. actively and knowingly aided, abetted and induced Mylan Pharmaceuticals to submit the Mylan ANDA before the expiration of the '893 patent, which is an act of patent infringement under 35 U.S.C. § 271(b).

71. On information and belief, Mylan Pharmaceuticals plans, intends to, and will commercially make, use, offer to sell, and/or sell the Mylan Product within the United States, or import the Mylan Product into the United States during the term of the '893 patent, after the Mylan ANDA is approved, which would further infringe the '893 patent under 35 U.S.C. § 271(a).

72. On information and belief, Mylan Pharmaceuticals plans, intends to, and will actively induce, or contribute to, the infringement of the '893 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

73. On information and belief, Mylan Inc. plans, intends to, and will actively induce, or contribute to, the infringement of the '893 patent under 35 U.S.C. § 271(b) and/or § 271(c).

74. On information and belief, Mylan Pharmaceuticals lacked a good faith basis for alleging invalidity of the '893 patent when it filed ANDA No. 20-3788 and made the Paragraph IV certification. Accordingly, Mylan Pharmaceuticals' Paragraph IV certification was wholly unjustified.

COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,056,893

75. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–74 of this Complaint.

76. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

77. On information and belief, Mylan Pharmaceuticals has taken and plans, intends to, and will take active steps to commercially make, use, offer to sell, and/or sell the Mylan Product within the United States, or import the Mylan Product into the United States during the term of the '893 patent, after the Mylan ANDA is approved, which would infringe the '893 patent under 35 U.S.C. § 271(a).

78. On information and belief, Mylan Pharmaceuticals plans, intends to, and will actively induce, or contribute to, the infringement of the '893 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Mylan ANDA is approved.

79. On information and belief, Mylan Inc. plans, intends to, and will actively induce, or contribute to, the infringement of the '893 patent under 35 U.S.C. § 271(b) and/or § 271(c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor against Defendants Mylan Pharmaceuticals and Mylan Inc. as follows:

A. That Defendants, either individually or collectively, have infringed or will infringe, after the Mylan ANDA is approved, one or more claims of the '411 patent;

B. That Defendants, either individually or collectively, have infringed or will

infringe, after the Mylan ANDA is approved, one or more claims of the '113 patent;

C. That Defendants, either individually or collectively, have infringed or will infringe, after the Mylan ANDA is approved, one or more claims of the '443 patent;

D. That Defendants, either individually or collectively, have infringed or will infringe, after the Mylan ANDA is approved, one or more claims of the '893 patent;

E. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Mylan Pharmaceuticals and Mylan Inc., their officers, agents, servants, and employees, and those persons in active concert or privity with any of them are permanently enjoined from making, using, selling, or offering to sell the Mylan Products within the United States, or importing the Mylan Product into the United States prior to the expiration of the '411, '113, '443, and '893 patents;

F. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 20-3788 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '411, '113, '443, and '893 patents, including any extensions;

G. If either Mylan Pharmaceuticals or Mylan Inc., commercially makes, uses, sells, or offers to sell the Mylan Product within the United States, or imports the Mylan Product into the United States, prior to the expiration of any one of the '411, '113, '443, and '893 patents, including any extensions, that Plaintiffs be awarded monetary damages for those infringing acts to the fullest extent allowed by law,

and be awarded prejudgment interest based on those monetary damages;

H. That this case be deemed exceptional under 35 U.S.C. § 285;

I. That Plaintiffs be awarded reasonable attorney's fees, costs, and expenses; and

J. That Plaintiffs be awarded such other relief as the Court deems just and proper.

Dated: June 14, 2013

Respectfully Submitted,

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