



InSite Vision Incorporated, Inspire Pharmaceuticals Incorporated, and Pfizer Inc. (“Plaintiffs”) for their Complaint against Defendants Sandoz Inc., Sandoz GmbH, and Sandoz Industrial Products S.A., 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 Inspire Pharmaceuticals, Inc. (“Inspire”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 8081 Arco Corporate Drive, Suite 400, Raleigh, NC 27617. Inspire is a wholly-owned subsidiary of Merck & Co. Inc.
3. 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 42<sup>nd</sup> Street, New York, New York 10017.
4. On information and belief, Defendant Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.
5. On information and belief, Defendant Sandoz GmbH is a corporation organized and existing under the laws of Austria, having a principle place of business at Biochemiestr. 10, Kundl, Austria.
6. On information and belief, Defendant Sandoz Industrial Products S.A. is a corporation organized and existing under the laws of Spain, having a principle place of

business at Road from Granollers to Cordedeu, Km. 4.3, E-08520 Les Franqueses del Valles, Barcelona, Spain.

### **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 Sandoz Inc.'s 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 Plaintiffs' five 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 Sandoz Inc. because of Sandoz Inc.'s continuous and systematic contacts with this State. On information and belief, Sandoz Inc.: (1) maintains its principle place of business in this State; (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, Sandoz Inc. has previously consented to personal jurisdiction in this judicial district.

10. This Court has personal jurisdiction over Sandoz GmbH because of Sandoz GmbH's continuous and systematic contacts with this State. On information and belief, Sandoz GmbH: (1) intentionally markets and provides active pharmaceutical ingredients, including azithromycin, to pharmaceutical manufacturers located within this State; (2)

intentionally avails itself of the laws of this State by entering into ongoing contractual relationships with companies who market and direct their generic pharmaceutical drug products to residents of this State, including but not limited to Sandoz Inc.; and (3) provides material information and support to companies operating in this State seeking approval of generic pharmaceutical drug products by the FDA, including but not limited to Sandoz Inc.

11. This Court has personal jurisdiction over Sandoz Industrial Products S.A. because of Sandoz Industrial Products S.A.'s continuous and systematic contacts with this State. On information and belief, Sandoz Industrial Products S.A.: (1) intentionally markets and provides active pharmaceutical ingredients, including azithromycin, to pharmaceutical manufacturers located within this State; (2) intentionally avails itself of the laws of this State by entering into ongoing contractual relationships with companies who market and direct their generic pharmaceutical drug products to residents of this State, including but not limited to Sandoz Inc.; and (3) provides material information and support to companies operating in this State seeking approval of generic pharmaceutical drug products by the FDA, including but not limited to Sandoz Inc.

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

#### **THE PATENTS-IN-SUIT**

13. 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.

14. On December 12, 2000, the USPTO duly and legally issued United States Patent No. 6,159,458 (“the ‘458 patent”), entitled “Sustained Release Ophthalmic Compositions Containing Water Soluble Medicaments.” The ‘458 patent is assigned to InSite. A copy of the ‘458 patent is attached as Appendix B.

15. On May 29, 2001, the USPTO duly and legally issued the 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 C.

16. On May 27, 2003, the USPTO duly and legally issued the 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 D.

17. 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 E.

### **FACTUAL BACKGROUND**

#### **AzaSite®**

18. 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.

19. InSite has granted Inspire Pharmaceuticals, Inc. (“Inspire”) an exclusive license under the ‘113, ‘458, ‘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®.

20. Inspire holds an approved New Drug Application No. 50-810 for azithromycin ophthalmic solution 1% sterile topical ophthalmic drops (the “AzaSite® NDA”), which are sold by Inspire under the trade name AzaSite®.

21. Inspire has commercialized and currently markets AzaSite® pursuant to the rights granted under the Inspire Agreement.

22. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ‘411, ‘458, ‘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®.

**Sandoz’s ANDA**

23. On information and belief, Sandoz Inc. submitted Abbreviated New Drug Application No. 202308 (the “Sandoz ANDA”) to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market azithromycin ophthalmic solution, 1% (the “Sandoz Product”).

24. On information and belief, Sandoz GmbH makes the Sandoz Product and/or the active pharmaceutical ingredient (“API”) used in the Sandoz Product, azithromycin. At the direction of Sandoz Inc., Sandoz GmbH supplies or will supply the API and/or the Sandoz Product to Sandoz Inc. Accordingly, Sandoz GmbH has aided and/or abetted in the filing of the Sandoz ANDA.

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

26. On information and belief, Sandoz Industrial Products S.A. makes the Sandoz Product and/or the API. At the direction of Sandoz Inc., Sandoz Industrial Products S.A. supplies or will supply the API and/or the Sandoz Product to Sandoz Inc. Accordingly, Sandoz Industrial Products S.A. has aided and/or abetted in the filing of the Sandoz ANDA.

27. On information and belief, Sandoz Industrial Products S.A. actively and knowingly provided Sandoz Inc. with material information and support in pursuing the Sandoz ANDA, and has therefore aided and/or abetted in the filing of the Sandoz ANDA.

28. On information and belief, the Sandoz ANDA refers to and relies upon the AzaSite® NDA and contains data that, according to Sandoz Inc., demonstrate the bioequivalence of the Sandoz Product and AzaSite®.

29. On or around April 15, 2011, Sandoz Inc. sent InSite, Pfizer and Inspire a letter and attached memorandum (collectively, the "Sandoz 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, '458, '113, '443, and '893 patents are invalid and/or unenforceable, and that the claims of the '458 patent would not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz Product (the "Paragraph IV Certification").

30. The Sandoz Notification does not assert that the claims of the '411 patent are not infringed by the Sandoz Product.

31. The Sandoz Notification does not assert that the claims of the '113 patent are not infringed by the Sandoz Product.

32. The Sandoz Notification does not assert that the claims of the '893 patent are not infringed by the Sandoz Product.

33. The Sandoz Notification does not assert that all claims of the '443 patent are not infringed by the Sandoz Product.

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

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

35. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–34 of this Complaint.

36. Sandoz Inc.'s filing of ANDA No. 202308 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 Sandoz Product before the expiration of the '411 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

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

38. On information and belief, Sandoz Industrial Products S.A. actively and knowingly aided, abetted and induced Sandoz Inc. to submit the Sandoz ANDA before



the expiration of the '411 patent, which is an act of patent infringement under 35 U.S.C. § 271(b).

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

40. On information and belief, Sandoz 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), after the Sandoz ANDA is approved.

41. On information and belief, Sandoz GmbH 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

42. On information and belief, Sandoz Industrial Products S.A. 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

43. On information and belief, Sandoz Inc. lacked a good faith basis for alleging invalidity of the '411 patent when it filed ANDA No. 202308 and made the Paragraph IV certification. Accordingly, Sandoz Inc.'s Paragraph IV certification was wholly unjustified.

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

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

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

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

47. On information and belief, Sandoz 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), after the Sandoz ANDA is approved.

48. On information and belief, Sandoz GmbH 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

49. On information and belief, Sandoz Industrial Products S.A. 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

**COUNT III: INFRINGEMENT OF U.S. PATENT NO. 6,159,458**

50. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–49 of this Complaint.

51. Sandoz Inc.'s filing of ANDA No. 202308 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 Sandoz Product before the expiration of the '458 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

52. On information and belief, Sandoz GmbH actively and knowingly aided, abetted and induced Sandoz Inc. to submit the Sandoz ANDA before the expiration of the '458 patent, which is an act of patent infringement under 35 U.S.C. § 271(b).

53. On information and belief, Sandoz Industrial Products S.A. actively and knowingly aided, abetted and induced Sandoz Inc. to submit the Sandoz ANDA before the expiration of the '458 patent, which is an act of patent infringement under 35 U.S.C. § 271(b).

54. On information and belief, Sandoz Inc. plans, intends to, and will commercially make, use, offer to sell, and/or sell the Sandoz Product within the United States, or import the Sandoz Product into the United States during the term of the '458 patent, after the Sandoz ANDA is approved, which would further infringe the '458 patent under 35 U.S.C. § 271(a).

55. On information and belief, Sandoz Inc. plans, intends to, and will actively induce, or contribute to, the infringement of the '458 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Sandoz ANDA is approved.

56. On information and belief, Sandoz GmbH plans, intends to, and will actively induce, or contribute to, the infringement of the '458 patent under 35 U.S.C. § 271(b) and/or § 271(c) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

57. On information and belief, Sandoz Industrial Products S.A. plans, intends to, and will actively induce, or contribute to, the infringement of the '458 patent under 35 U.S.C. § 271(b) and/or § 271(c) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

58. On information and belief, Sandoz Inc. lacked a good faith basis for alleging invalidity of the '458 patent when it filed ANDA No. 202308 and made the Paragraph IV certification. Accordingly, Sandoz Inc.'s Paragraph IV certification was wholly unjustified.

**COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S.  
PATENT NO. 6,159,458**

59. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–58 of this Complaint.

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

61. On information and belief, Sandoz Inc. has taken and plans, intends to, and will take steps to commercially make, use, offer to sell, and/or sell the Sandoz Product within the United States, or import the Sandoz Product into the United States during the term of the '458 patent, after the Sandoz ANDA is approved, which would infringe the '458 patent under 35 U.S.C. § 271(a).

62. On information and belief, Sandoz Inc. plans, intends to, and will actively induce, or contribute to, the infringement of the '458 patent under 35 U.S.C. § 271(b) and/or § 271(c), after the Sandoz ANDA is approved.

63. On information and belief, Sandoz GmbH plans, intends to, and will actively induce, or contribute to, the infringement of the '458 patent under 35 U.S.C. § 271(b) and/or § 271(c) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

64. On information and belief, Sandoz Industrial Products S.A. plans, intends to, and will actively induce, or contribute to, the infringement of the '458 patent under 35 U.S.C. § 271(b) and/or § 271(c) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

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

65. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–64 of this Complaint.

66. Sandoz Inc.'s filing of ANDA No. 202308 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 Sandoz Product before the expiration of the '113 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

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

68. On information and belief, Sandoz Industrial Products S.A. actively and knowingly aided, abetted and induced Sandoz Inc. to submit the Sandoz ANDA before

the expiration of the '113 patent, which is an act of patent infringement under 35 U.S.C. § 271(b).

69. On information and belief, Sandoz Inc. plans, intends to, and will commercially make, use, offer to sell, and/or sell the Sandoz Product within the United States, or import the Sandoz Product into the United States during the term of the '113 patent, after the Sandoz ANDA is approved, which would further infringe the '113 patent under 35 U.S.C.

§ 271(a).

70. On information and belief, Sandoz 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), after the Sandoz ANDA is approved.

71. On information and belief, Sandoz GmbH 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

72. On information and belief, Sandoz Industrial Products S.A. 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

73. On information and belief, Sandoz Inc. lacked a good faith basis for alleging invalidity of the '113 patent when it filed ANDA No. 202308 and made the Paragraph IV certification. Accordingly, Sandoz Inc.'s Paragraph IV certification was wholly unjustified.

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

74. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–73 of this Complaint.

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

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

77. On information and belief, Sandoz 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), after the Sandoz ANDA is approved.

78. On information and belief, Sandoz GmbH 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

79. On information and belief, Sandoz Industrial Products S.A. 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

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

80. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–79 of this Complaint.

81. Sandoz Inc.'s filing of ANDA No. 202308 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 Sandoz Product before the expiration of the '443 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

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

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

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

85. On information and belief, Sandoz 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), after the Sandoz ANDA is approved.



86. On information and belief, Sandoz GmbH 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

87. On information and belief, Sandoz Industrial Products S.A. 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

88. On information and belief, Sandoz Inc. lacked a good faith basis for alleging invalidity of the '443 patent when it filed ANDA No. 202308 and made the Paragraph IV certification. Accordingly, Sandoz Inc.'s Paragraph IV certification was wholly unjustified.

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

89. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–88 of this Complaint.

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

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

92. On information and belief, Sandoz 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), after the Sandoz ANDA is approved.

93. On information and belief, Sandoz GmbH 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

94. On information and belief, Sandoz Industrial Products S.A. 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

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

95. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-94 of this Complaint.

96. Sandoz Inc.'s filing of ANDA No. 202308 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 Sandoz Product before the expiration of the '893 patent is an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

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

98. On information and belief, Sandoz Industrial Products S.A. actively and knowingly aided, abetted and induced Sandoz Inc. to submit the Sandoz ANDA before

the expiration of the '893 patent, which is an act of patent infringement under 35 U.S.C. § 271(b).

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

100. On information and belief, Sandoz 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), after the Sandoz ANDA is approved.

101. On information and belief, Sandoz GmbH 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

102. On information and belief, Sandoz Industrial Products S.A. 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) by supplying Sandoz Inc. with the API or the Sandoz Product after the Sandoz ANDA is approved.

103. On information and belief, Sandoz Inc. lacked a good faith basis for alleging invalidity of the '893 patent when it filed ANDA No. 202308 and made the Paragraph IV certification. Accordingly, Sandoz Inc.'s Paragraph IV certification was wholly unjustified.

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

104. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–103 of this Complaint.

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

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

107. On information and belief, Sandoz 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), after the Sandoz ANDA is approved.

108. On information and belief, Sandoz GmbH 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) by supplying Sandoz Inc. with the API or the Sandoz Product, after the Sandoz ANDA is approved.

109. On information and belief, Sandoz Industrial Products S.A. 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) by supplying Sandoz Inc. with the API or the Sandoz Product after the Sandoz ANDA is approved.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for a judgment in their favor against Defendants

Sandoz Inc., Sandoz GmbH, and Sandoz Industrial Products S.A., as follows:

- A. That Defendants, either individually or collectively, have infringed or will infringe, after the Sandoz 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 Sandoz ANDA is approved, one or more claims of the '458 patent;
- C. That Defendants, either individually or collectively, have infringed or will infringe, after the Sandoz ANDA is approved, one or more claims of the '113 patent;
- D. That Defendants, either individually or collectively, have infringed or will infringe, after the Sandoz ANDA is approved, one or more claims of the '443 patent;
- E. That Defendants, either individually or collectively, have infringed or will infringe, after the Sandoz ANDA is approved, one or more claims of the '893 patent;
- F. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Sandoz Inc., its 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 Sandoz Products within the United States, or importing the Sandoz Product into the United States prior to the expiration of the '411, '458, '113, '443, and '893 patents;
- G. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of

ANDA No. 90-332 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, '458, '113, '443, and '893 patents, including any extensions;

- H. If either Sandoz Inc., Sandoz GmbH, or Sandoz Industrial Products S.A. commercially makes, uses, sells, or offers to sell the Sandoz Product within the United States, or imports the Sandoz Product into the United States, prior to the expiration of any one of the '411, '458, '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;
- I. That this case be deemed exceptional under 35 U.S.C. § 285;
- J. That Plaintiffs be awarded reasonable attorney's fees, costs, and expenses; and
- K. That Plaintiffs be awarded such other relief as the Court deems just and proper.

Dated: May 26, 2011

Respectfully Submitted,

By:                   s/ Sheila F. McShane                  

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