IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VELOXIS PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ACCORD HEALTHCARE, INC. and INTAS PHARMACEUTICALS LTD.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Veloxis Pharmaceuticals, Inc. ("Veloxis"), by its undersigned attorneys, for its Complaint against Defendants Accord Healthcare, Inc. ("Accord Healthcare") and Intas Pharmaceuticals Ltd. ("Intas") (collectively "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq*., arising from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 217255 to the United States Food and Drug Administration ("FDA"). Defendants' ANDA seeks FDA approval to market and sell 0.75 mg, 1 mg, and 4 mg extended-release tablets of tacrolimus ("Defendants' ANDA Products") prior to the expiration of U.S. Patent Nos. 8,685,998 ("the '998 Patent"); 9,549,918 ("the '918 Patent"); 10,166,190 ("the '190 Patent"); 10,864,199 ("the '199 Patent"); 11,110,081 ("the '081 Patent"); and 11,123,331 ("the '331 Patent").

2. Veloxis owns the patents-in-suit and is the holder of FDA approved New Drug Application ("NDA") No. 206406 for the brand name drug ENVARSUS XR® (tacrolimus). The patents-in-suit generally cover oral dosage forms and methods of use and administration of

tacrolimus, including ENVARSUS XR®. Defendants' ANDA Products are generic versions of ENVARSUS XR®.

THE PARTIES

3. Plaintiff Veloxis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2000 Regency Parkway, Suite 500, Cary, NC 27518.

4. Upon information and belief, Defendant Accord Healthcare is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210 Durham, North Carolina 27703. Upon information and belief, Accord Healthcare is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products, including for the United States market.

5. Upon information and belief, Defendant Intas is a corporation organized and existing under the laws of India, having a principal place of business at Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad – 380054, Gujarat, India. Upon information and belief, Intas is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products, including for the United States market.

6. Upon information and belief, Accord Healthcare is a wholly-owned subsidiary of Intas and is controlled and/or dominated by Intas. Upon information and belief, Accord Healthcare is the commercial arm of Intas. Upon information and belief, Accord Healthcare and Intas are agents of each other and/or operate in concert as integrated parts of the same business group.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), and this Court has personal jurisdiction over Defendants.

9. Accord Healthcare, through their counsel, by email dated June 23, 2022, have consented to personal jurisdiction and venue in this Court for purposes of this matter.

10. This Court also has personal jurisdiction over Accord Healthcare because Accord Healthcare, itself and/or through its parent Intas, has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Accord Healthcare, directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Upon information and belief, Accord Healthcare, on its own or acting in concert with Intas, prepared and filed ANDA No. 217255 with the FDA. Upon information and belief, Accord Healthcare, on its own or acting in concert with Intas, will manufacture, import, market, offer to sell, sell and/or distribute Defendants' ANDA Products in the United States, including Delaware, upon approval of ANDA No. 217255, and will derive substantial revenue from the use or consumption of Defendants' ANDA Products in Delaware.

11. This Court also has personal jurisdiction over Intas because Intas, itself and/or through its subsidiary Accord Healthcare, has purposefully availed itself of the benefits and protections of the State of Delaware and, therefore, could reasonably anticipate being sued in this Judicial District. Upon information and belief, Intas, directly or indirectly, manufactures, imports, markets, offers to sell, sells and/or distributes generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA Products. Upon information and belief, Intas, on its own or acting in concert with Accord Healthcare, prepared and

submitted ANDA No. 217255 to the FDA. Upon information and belief, Intas, on its own or acting in concert with Accord Healthcare, will manufacture, import, market, offer to sell, sell and/or distribute Defendants' ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 217255, and will derive substantial revenue from the use or consumption of Defendants' ANDA Products in Delaware.

12. In the alternative, this Court also has personal jurisdiction over Intas pursuant to Rule 4(k)(2), Fed. R. Civ. P. This action arises from actions of Intas directed toward Delaware, and Intas has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Intas regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware, either on its own or through affiliates. Upon information and belief, Intas derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business in Delaware.

13. Venue is also proper in this Court with respect to Intas because, upon information and belief, Intas is a foreign corporation that may be sued in any judicial district where it is subject to the personal jurisdiction of the Court.

14. Personal jurisdiction and venue are also proper in this Judicial District because Defendants have availed themselves of the legal protections of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in this Court. *See e.g.*, *Celgene Corp. et al. v. Accord Healthcare Inc.*, No. 21-1795 (D. Del. Dec. 22, 2021); *Teva Pharmaceuticals International GmbH et al v. Accord Healthcare Inc.*, No. 21-952 (D. Del. June 29, 2021); *Taiho Pharmaceutical Co., Ltd. et al v. Accord Healthcare Inc. et al*, No. 21-838 (D. Del. June 9, 2021); *Bayer Pharma AG et al v. Accord Healthcare Inc. et al*, No. 21-566 (D. Del. Apr. 22, 2021);

Purdue Pharma L.P. et al v. Accord Healthcare Inc., No. 20-1362 (D. Del. Oct. 8, 2020); *Otsuka Pharmaceutical Co., Ltd. et al v. Accord Healthcare Inc.*, No. 20-1287 (D. Del. Sep. 25, 2020); *Sanofi-Aventis U.S. LLC et al v. Accord Healthcare Inc.*, No. 20-803 (D. Del. Jun. 12, 2020). *Merck Sharp & Dohme Corp. v. Accord Healthcare Inc. et al.*, No. 19-2192 (D. Del. Jan. 24, 2020); *Novartis Pharm. Co. v. Accord Healthcare Inc. et al.*, No. 18-1043 (D. Del. Aug. 8, 2018); *Amgen Inc. v. Accord Healthcare et al.*, No. 18-956 (D. Del. June 28, 2018).

PATENTS-IN-SUIT

15. On April 1, 2014, the ’998 Patent, titled “Tacrolimus for Improved Treatment of Transplant Patients,” was duly and lawfully issued by the United States Patent and Trademark Office (“USPTO”). Veloxis is the assignee of the ’998 Patent. A true copy of the ’998 Patent is attached hereto as **Exhibit A**.

16. On January 24, 2017, the ’918 Patent, titled “Stabilized Tacrolimus Composition,” was duly and lawfully issued by the USPTO. Veloxis is the assignee of the ’918 Patent. A true copy of the ’918 Patent is attached hereto as **Exhibit B**.

17. On January 1, 2019, the ’190 Patent, titled “Stabilized Tacrolimus Composition,” was duly and lawfully issued by the USPTO. Veloxis is the assignee of the ’190 Patent. A true copy of the ’190 Patent is attached hereto as **Exhibit C**.

18. On December 15, 2020, the ’199 Patent, titled “Tacrolimus for Improved Treatment of Transplant Patients,” was duly and lawfully issued by the USPTO. Veloxis is the assignee of the ’199 Patent. A true copy of the ’199 Patent is attached hereto as **Exhibit D**.

19. On September 7, 2021, the ’081 Patent, titled “Tacrolimus for Improved Treatment of Transplant Patients,” was duly and lawfully issued by the USPTO. Veloxis is the assignee of the ’081 Patent. A true copy of the ’081 Patent is attached hereto as **Exhibit E.**

20. On September 21, 2021, the '331 Patent, titled "Tacrolimus for Improved Treatment of Transplant Patients," was duly and lawfully issued by the USPTO. Veloxis is the assignee of the '331 Patent. A true copy of the '331 Patent is attached hereto as **Exhibit F**.

VELOXIS' ENVARSUS XR®

21. Veloxis holds approved NDA No. 206406 for extended-release tablets containing the active ingredient tacrolimus. Veloxis markets and sells tacrolimus extended-release tablets under the trade name ENVARSUS XR®.

22. ENVARSUS XR® is a calcineurin-inhibitor immunosuppressant indicated for: (1) the prophylaxis of organ rejection in de novo kidney transplant patients in combination with other immunosuppressants and (2) the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants. A copy of the complete prescribing information for ENVARSUS XR® is attached hereto as **Exhibit G.**

23. Pursuant to 21 U.S.C. § 355(b)(1) and related FDA regulations, Veloxis listed the '998, '918, '190, '199, '081, and '331 patents in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to ENVARSUS XR®. The prescribing information for ENVARSUS XR® instructs and encourages physicians, other healthcare workers and patients to administer ENVARSUS XR® tablets according to one or more of the methods claimed in the patents-in-suit.

ACTS GIVING RISE TO THIS ACTION

24. By letter dated May 23, 2022 ("Notice Letter"), Accord Healthcare notified Veloxis that Accord Healthcare had submitted ANDA No. 217255 to the FDA under Section 505(j) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Veloxis received the Notice Letter no earlier than May 26, 2022.

25. The Notice Letter states that Accord Healthcare seeks approval from the FDA to engage in the commercial manufacture, use, sale, offer to sell, and/or importation in the United States of Defendants' ANDA Products before expiration of the '998, '918, '190, '199, '081, and '331 patents. Upon information and belief, Defendants intend to, directly or indirectly, engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA Products promptly upon receiving FDA approval.

26. By filing ANDA No. 217255, Defendants have necessarily represented to the FDA that Defendants' ANDA Products have the same active ingredient, the same dosage form, the same route of administration, and the same strengths as ENVARSUS XR®. By submitting ANDA No. 217255, Defendants also have necessarily represented to the FDA that Defendants' ANDA Products are bioequivalent to ENVARSUS XR®. Upon information and belief, Defendants are seeking approval to market and sell their ANDA Products for the same approved indications as ENVARSUS XR®.

27. In the Notice Letter, Accord Healthcare states that Defendants' ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") asserting that the claims of the '998 patent are invalid under 35 U.S.C. §§ 102 and/or 103. The Notice Letter does not contest that the claims of the '998 patent are enforceable and will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of Defendants' ANDA Products.

28. In the Notice Letter, Accord Healthcare states that its ANDA contains a Paragraph IV Certification asserting that the claims of the ’918 patent are not infringed. The Notice Letter does not contest that the claims of the ‘918 patent are valid and enforceable.

29. In the Notice Letter, Accord Healthcare states that its ANDA contains a Paragraph IV Certification asserting that the claims of the ’190 patent are not infringed. The Notice Letter does not contest that the claims of the ‘190 patent are valid and enforceable.

30. In the Notice Letter, Accord Healthcare states that its ANDA contains a Paragraph IV Certification asserting that the claims of the ’199 patent are invalid under 35 U.S.C. § 103. In the Notice Letter, Accord Healthcare also states that its Paragraph IV Certification against the ‘199 asserts that claims 1-13 and 17-19 of the ’199 patent are not infringed. The Notice Letter does not contest that claims 14-16 of the ‘199 patent are enforceable and will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of Defendants’ ANDA Products.

31. In the Notice Letter, Accord Healthcare does not address the ‘081 Patent, even though it is listed in the Orange Book. The Notice Letter does not contest that the claims of the ‘081 patent are valid, enforceable and will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of Defendants’ ANDA Products.

32. In the Notice Letter, Accord Healthcare states that its ANDA contains a Paragraph IV Certification asserting that the claims of the ’331 patent are invalid under 35 U.S.C. §§ 112. The Notice Letter does not contest that the claims of the ‘331 patent are enforceable and will be infringed by the commercial manufacture, use, offer to sell, sale, and/or importation of Defendants’ ANDA Products. The Notice Letter also does contest the validity of the claims of the ‘331 patent under 35 U.S.C. §§ 102 or 103.

COUNT I
INFRINGEMENT OF THE '998 PATENT

33. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

34. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '998 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

35. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '998 Patent.

36. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '998 patent.

37. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '998 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States.

38. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '998 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '998 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '998 patent.

39. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '998 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '998 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

40. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '998 patent is not enjoined.

41. Veloxis does not have an adequate remedy at law.

42. Upon information and belief, Defendants had knowledge of the '998 patent prior to filing their ANDA with the FDA.

43. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
INFRINGEMENT OF THE '918 PATENT

44. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

45. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '918 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

46. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '918 Patent.

47. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '918 patent.

48. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '918 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States.

49. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '918 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '918 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '918 patent.

50. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '918 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '918 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

51. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '918 patent is not enjoined.

52. Veloxis does not have an adequate remedy at law.

53. Upon information and belief, Defendants had knowledge of the '918 patent prior to filing their ANDA with the FDA.

54. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE '190 PATENT

55. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

56. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '190 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

57. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '190 Patent.

58. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '190 patent.

59. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '190 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States.

60. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '190 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '190 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '190 patent.

61. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '190 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '190 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

62. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '190 patent is not enjoined.

63. Veloxis does not have an adequate remedy at law.

64. Upon information and belief, Defendants had knowledge of the '190 patent prior to filing their ANDA with the FDA.

65. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV
INFRINGEMENT OF THE '199 PATENT

66. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

67. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '199 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 14.

68. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 14 of the '199 Patent.

69. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '199 patent.

70. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '199 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '199 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '199 patent.

71. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '199 patent under 35 U.S.C. § 271€ by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products

in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '199 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

72. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '199 patent is not enjoined.

73. Veloxis does not have an adequate remedy at law.

74. Upon information and belief, Defendants had knowledge of the '199 patent prior to filing their ANDA with the FDA.

75. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT V
INFRINGEMENT OF THE '081 PATENT

76. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

77. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '081 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271€(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

78. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '081 Patent.

79. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '081 patent.

80. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '081 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '081 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '081 patent.

81. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '081 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '081 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

82. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '081 patent is not enjoined.

83. Veloxis does not have an adequate remedy at law.

84. Upon information and belief, Defendants had knowledge of the '081 patent prior to filing their ANDA with the FDA.

85. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VI
INFRINGEMENT OF THE '331 PATENT

86. Veloxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

87. Defendants' submission of their ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Defendants' ANDA Products, prior to the expiration of the '331 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including at least claim 1.

88. Upon information and belief, Defendants' ANDA Products and/or their use in accordance with the product label satisfies each and every element of at least claim 1 of the '331 Patent.

89. There is a justiciable controversy between the parties hereto as to the infringement and/or validity of the '331 patent.

90. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will induce infringement of one or more claims of the '331 patent under 35 U.S.C. §271(b) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products in the United States. Upon information and belief, upon FDA approval of Defendants' ANDA Products, Defendants will intentionally encourage acts of direct infringement with knowledge of the '331 patent and knowledge that their acts are encouraging infringement, with specific intent to induce infringement of the '331 patent.

91. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA Products, Defendants will contributorily infringe one or more claims of the '331 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' ANDA Products

in the United States. Upon information and belief, Defendants have had and continue to have knowledge that Defendants' ANDA Products are especially adapted for a use that infringes one or more claims of the '331 patent and that there is no substantial non-infringing use for Defendants' ANDA Products.

92. Veloxis will be substantially and irreparably damaged and harmed if Defendants' infringement of the '331 patent is not enjoined.

93. Veloxis does not have an adequate remedy at law.

94. Upon information and belief, Defendants had knowledge of the '331 patent prior to filing their ANDA with the FDA.

95. This case is an exceptional one, and Veloxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Veloxis respectfully requests the following relief:

A. An entry of Judgment that Defendants have infringed the patents-in-suit through the submission of ANDA No. 217255 to the FDA;

B. An entry of Judgment that, Defendants have infringed, and that Defendants' making, using, selling, offering to sell, or importing Defendants' ANDA Products will infringe one or more claims of the patents-in-suit;

C. The issuance of an order that the effective date of any FDA approval of Defendants' ANDA Products shall be no earlier than the expiration date of the patents-in-suit and any additional periods of exclusivity to which Veloxis is or becomes entitled;

D. An entry of a preliminary and permanent injunctions enjoining Defendants and others acting in concert with Defendants from commercially manufacturing, using, selling,

offering for sale, and/or importing Defendants' ANDA Products within the United States, until after the expiration date of the patents-in-suit and any additional periods of exclusivity to which Veloxis is or becomes entitled;

E. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from practicing any compositions or methods claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Veloxis is or becomes entitled;

F. A Declaration that the commercial manufacture, use, sale, or offer for sale, and/or importation into the United States of Defendants' ANDA Products will directly infringe, induce, and/or contribute to infringement of the patents-in-suit;

G. To the extent that Defendants have committed any acts with respect to the compositions or methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Veloxis be awarded damages for such acts;

H. If Defendants engage in the commercial manufacture, use, sale, or offer for sale, or importation into the United States of Defendants' ANDA Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Veloxis resulting from such infringement, together with interest;

I. An award to Veloxis of attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

J. An award to Veloxis of costs and expenses in this action; and

K. An award to Veloxis of any further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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