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

JANSSEN PRODUCTS, L.P., JANSSEN R&D IRELAND, and G.D. SEARLE, LLC, Plaintiffs, v. LUPIN LIMITED, LUPIN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., MYLAN PHARMACEUTICALS INC., and MYLAN INC., Defendants.	)	Civil Action No. 12-CV-5358-WHW-SCM (Consolidated with 10-CV-5954-WHW-SCM)

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Janssen Products, L.P. and Janssen R&D Ireland (collectively, "Janssen"), and G.D. Searle, LLC ("Searle") (Janssen and Searle, collectively, "Plaintiffs") for their Complaint against defendants Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals Inc. ("Lupin Pharmaceuticals") (collectively "Lupin"), Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") and Mylan Inc. (collectively "Mylan"), and Teva Pharmaceuticals USA, Inc.

("Teva USA") and Teva Pharmaceutical Industries, Ltd. ("Teva Industries") (collectively, "Teva") (Lupin, Mylan, and Teva, collectively, "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent No. RE43,596 (the "'596 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. and for a declaratory judgment of infringement of the '596 Patent and U.S. Patent Nos. 7,772,411 ("the '411 Patent"), 7,126,015 ("the '015 Patent"), and 7,595,408 ("the '408 Patent") (the '411, '015, and '408 patents collectively, "the Process Patents") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. and 28 U.S.C. §§ 2201 and 2202. This action arises out of Defendants' filing of Abbreviated New Drug Applications ("ANDAs") seeking approval to sell generic copies of plaintiff Janssen's highly successful PREZISTA® (darunavir) 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg products and Defendants' efforts to import, use, offer for sale, and/or sell those generic products prior to the expiration of patents owned by and exclusively licensed to Plaintiffs.

THE PARTIES

2. Plaintiff Janssen Products, L.P., is a partnership organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

3. Plaintiff Janssen R&D Ireland (formerly known as Tibotec Pharmaceuticals) is an Irish corporation having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

4. Plaintiff G.D. Searle, LLC is a Delaware limited liability company having a principal place of business at 235 East 42nd Street, New York, New York 10017.

5. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Lupin Pharmaceuticals.

6. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals is a wholly owned subsidiary of Lupin Ltd.

7. 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, WV 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. Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc.

8. On information and belief, Mylan Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business located at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing 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.

9. On information and belief, Teva Industries is an Israeli corporation, having a principal place of business located at 5 Basel St., Petach Tikva 49131, Israel. On information and belief, Teva Industries is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Teva USA.

10. On information and belief, Teva USA is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454. On information and belief, Teva USA is in the business of manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Teva USA is a wholly owned subsidiary of Teva Industries.

JURISDICTION AND VENUE

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

12. On information and belief, this Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Ltd. 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.

13. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals because Lupin Pharmaceuticals has purposely availed itself of the benefits and

protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin 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.

14. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals operate and act in concert as an integrated, unitary business. For example, Lupin Ltd. includes within its Annual Report the activities of Lupin Pharmaceuticals, including revenue earned.

15. On information and belief, Lupin Pharmaceuticals is registered to do business in New Jersey.

16. On information and belief, Lupin Pharmaceuticals has appointed National Registered Agents, Inc. of Princeton, New Jersey as its registered agent for the receipt of service of process.

17. Lupin Ltd. and Lupin Pharmaceuticals have stipulated and/or consented to personal jurisdiction in this district in numerous prior patent cases and in this consolidated action, *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, 10-cv-5954 (WHW) (MCA) (the "Consolidated Action").

18. 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 New Jersey'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.

19. On information and belief, Mylan Pharmaceuticals is registered to do business in New Jersey.

20. On information and belief, Mylan Pharmaceuticals has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey as its registered agent for the receipt of service of process.

21. 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 New Jersey'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, manufacturing and/or selling pharmaceutical products that are sold in this judicial district, its operation of offices in this district, and its filing of claims and counterclaims in this district.

22. Mylan Pharmaceuticals and Mylan Inc. have previously stipulated and/or consented to personal jurisdiction in this district in numerous prior patent cases as well as in this Consolidated Action.

23. On information and belief, this Court has personal jurisdiction over Teva USA because Teva USA has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Teva USA 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.

24. On information and belief, this Court has personal jurisdiction over Teva Industries because Teva Industries has purposely availed itself of the benefits and protections of

New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Teva Industries 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.

25. On information and belief, Teva USA and Teva Industries operate and act in concert as an integrated, unitary business. For example, Teva Industries includes within its Annual Report the activities of Teva USA, including revenue earned.

26. On information and belief, Teva USA is registered to do business in New Jersey.

27. On information and belief, Teva USA retains a registered agent in this judicial district.

28. Teva Industries and Teva USA have stipulated and/or consented to personal jurisdiction in this district in numerous prior patent cases as well as in this Consolidated Action.

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

BACKGROUND

30. On August 21, 2012, the United States Patent and Trademark Office ("the PTO") issued the '596 Patent, entitled "α- and β-Amino Acid Hydroxyethylamino Sulfonamides Useful as Retroviral Protease Inhibitors." A true and correct copy of the '596 Patent is attached hereto as Exhibit A.

31. Plaintiff Searle holds title to the '596 Patent.

32. The '596 Patent is a reissue of U.S. Patent No. 6,060,476 ("the '476 Patent").

33. The '476 Patent was filed on March 2, 1994, and issued on May 9, 2000.

34. Plaintiff Janssen R&D Ireland has an exclusive license to the '596 Patent.

35. The '596 Patent expires on May 9, 2017.

36. The United States Food and Drug Administration ("FDA") has awarded 6 months of pediatric exclusivity for PREZISTA®. The period of pediatric exclusivity applicable to the '596 Patent does not expire until November 9, 2017.

37. Janssen Products, L.P. is the holder of approved New Drug Application ("NDA") No. 21-976 for PREZISTA®. The NDA was formerly held by Tibotec Inc. The NDA was transferred to Janssen Products, L.P. on December 23, 2011.

38. PREZISTA® is included in the 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).

39. The FDA's "Orange Book" also lists patents associated with approved drugs. The '596 Patent, U.S. Patent Nos. RE42,889 ("the '889 Patent"), 5,843,946 ("'the '946 Patent"), 6,248,775 ("'the '775 Patent"), and 7,700,645 ("'the '645 Patent") are listed in the "Orange Book" in association with PREZISTA® (darunavir). The claims of the '596, '889, '946, '775, and '645 Patents cover PREZISTA® or its use.

40. On August 10, 2010, the United States Patent and Trademark Office ("PTO") issued the '411 Patent, entitled "Process for the Preparation of (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl(1S,2R)-3[[(4-aminophenyl)sulfonyl](isobutyl)amino]-1-benzyl-2-hydroxypropylcarbamate." A true and correct copy of the '411 Patent is attached hereoto as Exhibit B.

41. Janssen R&D Ireland holds title to the '411 Patent.

42. The '411 Patent expires on February 22, 2027.

43. On October 24, 2006, the PTO issued the '015 Patent, entitled "Method for the Preparation of Hexahydro-furo-[2,3-b]furan-3-ol." A true and correct copy of the '015 Patent is attached hereto as Exhibit C.

44. Janssen R&D Ireland holds title to the '015 Patent.

45. The '015 Patent expires on June 21, 2023.

46. On September 29, 2009, the PTO issued the '408 Patent, entitled "Methods for the Preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol." A true and correct copy of the '408 Patent is attached hereto as Exhibit D.

47. Janssen R&D Ireland holds title to the '408 Patent.

48. The '408 Patent expires on May 6, 2025.

49. The '411, '015, and '408 Patents claim processes useful for the preparation of darunavir, the active ingredient in PREZISTA, or the preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol ("bis-THF") found in darunavir.

50. On information and belief, Lupin Ltd., itself and/or through its subsidiary, agent and alter ego, Lupin Pharmaceuticals, submitted ANDA No. 202-073 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, offer for sale, and sale of generic versions of the PREZISTA® 75 mg, 150 mg, 300 mg, 400 mg and 600 mg tablets ("Lupin's Generic Tablets").

51. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals collaborated in the research, development, preparation, and filing of ANDA No. 202-073 for Lupin's Generic Tablets.

52. On information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin's Generic Tablets if ANDA No. 202-073 is approved by the FDA.

53. On information and belief, Lupin Pharmaceuticals participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of ANDA No. 202-073.

54. Plaintiffs received letters from Lupin (the "Lupin Paragraph IV letters") stating that Lupin had submitted ANDA No. 202-073 seeking approval to manufacture, use, and sell Lupin's Generic Tablets prior to the expiration of the '889, '946, '775, and '645 Patents.

55. The Lupin Paragraph IV letters also stated that Lupin ANDA No. 202-073 included certifications, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that claims of the '889, '946, '775, and '645 Patents are invalid and/or not infringed.

56. Plaintiffs are asserting the '889, '946, '775, and '645 Patents against Lupin in this Consolidated Action.

57. The '596 Patent had not issued at the time Lupin submitted its ANDA or certifications, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

58. The '596 Patent was listed in the "Orange Book" in association with PREZISTA® (darunavir) within thirty days of its issuance.

59. On information and belief, Lupin had actual and constructive notice of the '596 Patent.

60. On information and belief, Lupin has sought or will seek approval to manufacture, use, and sell Lupin's Generic Tablets prior to the expiration of the '596 Patent.

61. On information and belief, Lupin has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Lupin's Generic Tablets prior to the expiration of patents owned by and exclusively licensed to Plaintiffs.

62. On information and belief, Lupin's actions include, but are not limited to, the development of Lupin's Generic Tablets and the filing of an ANDA with a Paragraph IV certification.

63. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals continue to seek approval of ANDA No. 202-073 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of Lupin's Generic Tablets (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves ANDA No. 202-073.

64. Based on documents recently provided by Lupin in this Consolidated Action, Janssen has learned the nature of the processes Lupin uses to produce the bis-THF in its generic darunavir tablets.

65. On information and belief, Lupin uses the processes covered by the claims of the '015 and '408 Patents to prepare the bis-THF in Lupin's Generic Tablets.

66. On information and belief, Lupin has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '015 and '408 Patents prior to their expiration.

67. On information and belief, Lupin's preparations include, but are not limited to, the development of Lupin's Generic Tablets and the filing of an ANDA with a Paragraph IV Certification.

68. On information and belief, Lupin intends to use processes claimed in the '015 and '408 Patents to prepare the bis-THF in its generic darunavir tablets.

69. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals continue to collaborate in seeking approval of ANDA No. 202-073 from the FDA, including defending the Consolidated Action and asserting counterclaims alleging that the '946, '775, '645, and '889 Patents are invalid and/or not infringed.

70. On July 20, 2012, and thereafter, Janssen requested that Lupin provide additional information concerning Lupin's processes for preparing the bis-THF in Lupin's Generic Tablets. Lupin has refused to provide additional information describing its methods for preparing the bis-THF in Lupin's Generic Tablets.

71. On information and belief, Lupin had actual and constructive notice of the '015 and '408 Patents.

72. On information and belief, Mylan Pharmaceuticals submitted ANDA No. 202-136 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, offer for sale, and sale of generic versions of the PREZISTA® 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg tablets ("Mylan's Generic Tablets").

73. On information and belief, Mylan Inc. and Mylan Pharmaceuticals collaborated in the research, development, preparation, and filing of ANDA No. 202-136 for Mylan's Generic Tablets.

74. On information and belief, Mylan Inc. participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of ANDA No. 202-136.

75. Plaintiffs received letters from Mylan (the "Mylan Paragraph IV letters") stating that Mylan had submitted ANDA No. 202-136 seeking approval to manufacture, use, and sell Mylan's Generic Tablets prior to the expiration of the '946, '775, and '645 Patents.

76. The Mylan Paragraph IV letters also stated that Mylan ANDA No. 202-136 included certifications, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '946, '775, and '645 Patents are invalid and/or not infringed.

77. Mylan has also alleged that the '889 Patent is invalid and/or not infringed.

78. Plaintiffs are asserting the '889, '946, '775 and '645 Patents against Mylan in this Consolidated Action.

79. The '596 Patent had not issued at the time Mylan submitted its ANDA or certifications, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

80. On information and belief, Mylan had actual and constructive notice of the '596 Patent after it issued.

81. On information and belief, Mylan has sought or will seek approval to manufacture, use, and sell Mylan's Generic Tablets prior to the expiration of the '596 Patent.

82. On information and belief, Mylan has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Mylan's Generic Tablets prior to the expiration of patents owned by and exclusively licensed to Plaintiffs.

83. On information and belief, Mylan's actions include, but are not limited to, the development of Mylan's Generic Tablets and the filing of an ANDA with a Paragraph IV certification.

84. On information and belief, Mylan Pharmaceuticals and Mylan Inc. continue to seek approval of ANDA No. 202-136 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 New Jersey) in the event that the FDA approves ANDA No. 202-136.

85. Based on documents recently provided by Mylan in this Consolidated Action, Janssen has learned the nature of the processes Mylan uses to produce the darunavir in its generic tablets.

86. On information and belief, Mylan uses processes covered by the claims of the '411 Patent to prepare the darunavir in Mylan's Generic Tablets.

87. On information and belief, Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '411 Patent prior to its expiration.

88. On information and belief, Mylan's preparations include, but are not limited to, the development of Mylan's Generic Tablets and the filing of an ANDA with a Paragraph IV Certification.

89. On information and belief, Mylan intends to use processes claimed in the '411 Patent to prepare the darunavir in its generic tablets.

90. On information and belief, Mylan Inc. and Mylan Pharmaceuticals continue to collaborate in seeking approval of ANDA No. 202-136 from the FDA, including defending the Consolidated Action and asserting counterclaims alleging that the '946, '775, '645, and '889 Patents are invalid and/or not infringed.

91. On information and belief, Mylan had actual and constructive notice of the '411 Patent.

92. On information and belief, Teva Industries, itself and/or through its subsidiary, agent and alter ego, Teva USA, submitted ANDA No. 202-118 to the FDA under § 505(j) of the FDCA, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® 75 mg, 150 mg, 400 mg, and 600 mg tablets ("Teva's Generic Tablets").

93. On information and belief, Teva Industries and Teva USA collaborated in the research, development, preparation and filing of ANDA No. 202-118 for Teva's Generic Tablets.

94. On information and belief, Teva Industries participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of ANDA No. 202-118.

95. Plaintiffs received a letter from Teva (the "Teva Paragraph IV letter") stating that Teva had submitted ANDA No. 202-118 seeking approval to manufacture, use, and sell Teva's Generic Tablets prior to the expiration of the '946, '775, and '645 Patents.

96. The Teva Paragraph IV letter also stated that Teva ANDA No. 202-118 included certifications, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '946, '775, and '645 Patents are invalid and/or not infringed.

97. Teva has also alleged that the '889 Patent is invalid and/or not infringed.

98. Plaintiffs are asserting the '889, '946, '775, and '645 Patents against Teva in this Consolidated Action.

99. The '596 Patent had not issued at the time Teva submitted its ANDA or certifications, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

100. On information and belief, Teva had actual and constructive notice of the '596 Patent after it issued.

101. On information and belief, Teva has sought or will seek approval to manufacture, use, and sell Teva's Generic Tablets prior to the expiration of the '596 Patent.

102. On information and belief, Teva has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Teva's Generic Tablets prior to the expiration of patents owned by and exclusively licensed to Plaintiffs.

103. On information and belief, Teva's actions include, but are not limited to, the development of Teva's Generic Tablets and the filing of an ANDA with a Paragraph IV certification.

104. On information and belief, Teva Industries and Teva USA continue to seek approval of ANDA No. 202-118 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of Teva's Generic Tablets (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves ANDA No. 202-118.

105. Based on documents recently provided by Teva and Cipla Ltd. ("Cipla"), the holder of the Drug Master File ("DMF") for Teva's Generic Tablets, Janssen has learned the nature of the processes used to produce the bis-THF in Teva's Generic Tablets.

106. On information and belief, the bis-THF in Teva's Generic Tablets is prepared using the processes covered by the claims of the '015 and '408 Patents.

107. On information and belief, Teva has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '015 and '408 Patents prior to their expiration.

108. On information and belief, Teva's preparations include, but are not limited to, the development of Teva's Generic Tablets and the filing of an ANDA with a Paragraph IV Certification.

109. On information and belief, Teva intends to use processes claimed in the '015 and '408 Patents to prepare the bis-THF in its generic darunavir tablets.

110. On information and belief, Teva Industries and Teva USA continue to collaborate in seeking approval of ANDA No. 202-118 from the FDA, including defending the Consolidated Action and asserting counterclaims alleging that the '946, '775, '645, and '889 Patents are invalid and/or not infringed.

111. On July 20, 2012 and thereafter, Janssen requested that Teva and Cipla provide additional information concerning the processes for the preparation of the bis-THF in Teva's Generic Tablets. Teva and Cipla have refused to provide additional information describing the methods for preparing the bis-THF in Teva's Generic Tablets.

112. On information and belief, Teva had actual and constructive notice of the '015 and '408 Patents.

COUNT I

Infringement of the '596 Patent by Lupin under 35 U.S.C. § 271(e)(2)(A)

113. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 112 hereof, as if fully set forth herein.

114. Lupin Ltd. and Lupin Pharmaceuticals have infringed the '596 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-073 and seeking FDA approval of ANDA No. 202-073 prior to patent expiry.

115. Plaintiffs have no adequate remedy at law to redress the infringement by Lupin.

116. Plaintiffs will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to infringement of the '596 Patent.

COUNT II

Infringement of the '596 Patent by Mylan under 35 U.S.C. § 271(e)(2)(A)

117. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 116 hereof, as if fully set forth herein.

118. Mylan Pharmaceuticals and Mylan Inc. have infringed the '596 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-136 and seeking FDA approval of ANDA No. 202-136 prior to patent expiry.

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

120. Plaintiffs will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '596 Patent.

COUNT III

Infringement of the '596 Patent by Teva under 35 U.S.C. § 271(e)(2)(A)

121. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 120 hereof, as if fully set forth herein.

122. Teva Industries and Teva USA have infringed the '596 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-118 and seeking FDA approval of ANDA No. 202-118 prior to patent expiry.

123. Plaintiffs have no adequate remedy at law to redress the infringement by Teva.

124. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of the '596 Patent.

COUNT IV

Declaratory Judgment of Infringement by Lupin of the '596 Patent Under 35 U.S.C. § 271(a), (b), and/or (c)

125. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 124 hereof, as if fully set forth herein.

126. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Lupin regarding infringement of the '596 Patent.

127. Lupin has made and will continue to make substantial preparation manufacture, offer to sell, sell and/or import Lupin's Generic Tablets.

128. Lupin's actions, including, but not limited to, the filing of ANDA No. 202-073, systematically attempting to meet the applicable regulatory requirements for approval of

ANDA No. 202-073, and engaging in litigation to manufacture, offer to sell, sell and/or import Lupin's Generic Tablets prior to the expiration of patents listed in the Orange Book in association with PREZISTA®, indicate a refusal to change its course of action.

129. Any commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '596 Patent.

130. Plaintiffs are entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '596 Patent.

COUNT V

Declaratory Judgment of Infringement by Mylan of the '596 Patent Under 35 U.S.C. § 271(a), (b), and/or (c)

131. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 130 hereof, as if fully set forth herein.

132. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Mylan regarding infringement of the '596 Patent.

133. Mylan has made and will continue to make substantial preparation manufacture, offer to sell, sell and/or import Mylan's Generic Tablets.

134. Mylan's actions, including, but not limited to, the filing of ANDA No. 202-136, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-136, and engaging in litigation to manufacture, offer to sell, sell and/or import Mylan's Generic Tablets prior to the expiration of patents listed in the Orange Book in

association with PREZISTA®, indicate a refusal to change its course of action.

135. Any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '596 Patent.

136. Plaintiffs are entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '596 Patent.

COUNT VI

Declaratory Judgment of Infringement by Teva of the '596 Patent Under 35 U.S.C. § 271(a), (b), and/or (c)

137. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 136 hereof, as if fully set forth herein.

138. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Teva regarding infringement of the '596 Patent.

139. Teva has made and will continue to make substantial preparation to manufacture, offer to sell, sell and/or import Teva's Generic Tablets.

140. Teva's actions, including, but not limited to, the filing of ANDA No. 202-118, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-118, and engaging in litigation to manufacture, offer to sell, sell and/or import Teva's Generic Tablets prior to the expiration of patents listed in the Orange Book in association with PREZISTA®, indicate a refusal to change its course of action.

141. Any commercial manufacture, use, offer for sale, sale, and/or importation

of Teva's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '596 Patent.

142. Plaintiffs are entitled to a judicial declaration that the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Generic Tablets will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '596 Patent.

COUNT VII

Declaratory Judgment of Infringement by Lupin of the '015 Patent Under 35 U.S.C. § 271(g)

143. Janssen repeats and realleges each and every allegation contained in paragraphs 1-142 hereof, as if set forth fully herein.

144. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Lupin regarding infringement of the '015 Patent.

145. Lupin has made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '015 Patent prior to its expiration.

146. Lupin's actions, including, but not limited to, the filing of ANDA No. 202-073, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-073, and engaging in litigation to manufacture, offer to sell, sell, use, and/or import Lupin's Generic Tablets prior to the expiration of the '015 Patent, including the assertion of counterclaims, indicate a refusal to change its course of action.

147. Any importation into the United States and/or use, offer for sale, and/or sale in the United States of Lupin's Generic Tablets will constitute infringement of the '015 Patent.

148. Janssen is entitled to a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of Lupin's Generic Tablets will constitute infringement of the '015 Patent.

COUNT VIII

Declaratory Judgment of Infringement by Lupin of the '408 Patent Under 35 U.S.C. § 271(g)

149. Janssen repeats and realleges each and every allegation contained in paragraphs 1-148 hereof, as if set forth fully herein.

150. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Lupin regarding infringement of the '408 Patent.

151. Lupin has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '408 Patent prior to its expiration.

152. Lupin's actions, including, but not limited to, the filing of ANDA No. 202-073, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-073, and engaging in litigation to manufacture, offer to sell, sell, use, and/or import Lupin's Generic Tablets prior to the expiration of the '408 Patent, including the assertion of counterclaims, indicate a refusal to change its course of action.

153. Any importation into the United States and/or use, offer for sale, and/or sale in the United States of Lupin's Generic Tablets will constitute infringement of the '408 Patent.

154. Janssen is entitled to a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of Lupin's Generic Tablets will constitute infringement of the '408 Patent.

COUNT IX

Declaratory Judgment of Infringement by Mylan of the '411 Patent Under 35 U.S.C. § 271(g)

155. Janssen repeats and realleges each and every allegation contained in paragraphs 1-154 hereof, as if set forth fully herein.

156. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Mylan regarding infringement of the '411 Patent.

157. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, or use within the United States a product which is made by a process patented by the '411 Patent prior to its expiration.

158. Mylan's actions, including, but not limited to, the filing of ANDA No. 202-136, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-136, and engaging in litigation to manufacture, offer to sell, sell, use, and/or import Mylan's Generic Tablets prior to the expiration of the '411 Patent, including the assertion of counterclaims, indicate a refusal to change its course of action.

159. Any importation into the United States and/or use, offer for sale, and/or sale in the United States of Mylan's Generic Tablets will constitute infringement of the '411 Patent.

160. Janssen is entitled to a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of Mylan's Generic Tablets will constitute infringement of the '411 Patent.

COUNT X

Declaratory Judgment of Infringement by Teva of the '015 Patent Under 35 U.S.C. § 271(g)

161. Janssen repeats and realleges each and every allegation contained in paragraphs 1-160 hereof, as if set forth fully herein.

162. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Teva regarding infringement of the '015 Patent.

163. Teva has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '015 Patent prior to its expiration.

164. Teva's actions, including, but not limited to, the filing of ANDA No. 202-118, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-118, and engaging in litigation to manufacture, offer to sell, sell, use, and/or import Teva's Generic Tablets prior to the expiration of the '015 Patent, including the assertion of counterclaims, indicate a refusal to change its course of action.

165. Any importation into the United States and/or use, offer for sale, and/or sale in the United States of Teva's Generic Tablets will constitute infringement of the '015 Patent.

166. Janssen is entitled to a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of Teva's Generic Tablets will constitute infringement of the '015 Patent.

COUNT XI

Declaratory Judgment of Infringement by Teva of the '408 Patent Under 35 U.S.C. § 271(g)

167. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1-166 hereof, as if set forth fully herein.

168. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Teva regarding infringement of the '408 Patent.

169. Teva has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '408 Patent prior to its expiration.

170. Teva's actions, including, but not limited to, the filing of ANDA No. 202-118, systematically attempting to meet the applicable regulatory requirements for approval of ANDA No. 202-118, and engaging in litigation to manufacture, offer to sell, sell, use, and/or import Teva's Generic Tablets prior to the expiration of the '408 Patent, including the assertion of counterclaims, indicate a refusal to change its course of action.

171. Any importation into the United States or use, offer for sale, and/or sale in the United States of Teva's Generic Tablets will constitute infringement of the '408 Patent.

172. Janssen is entitled to a judicial declaration that the importation into the United States and/or use, offer for sale, and/or sale in the United States of Teva's Generic Tablets will constitute infringement of the '408 Patent.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that Defendants have infringed the '596 Patent 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 FDA approval of Lupin ANDA No. 202-073, Mylan ANDA No. 202-136, and Teva ANDA No. 202-118 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 period of pediatric exclusivity applicable to the '596 Patent;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in ANDA No. 202-073, ANDA No. 202-136 and ANDA No. 202-118 would constitute infringement of the '596 Patent, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment declaring that importing, selling, offering to sell, or using the generic darunavir tablets described in ANDA Nos. 202-073 and 202-118, respectively, would constitute infringement of the '015 and '408 Patents, or inducing or contributing to such conduct, by Lupin and Teva respectively pursuant to 35 U.S.C. § 271(g);

(e) a judgment declaring that importing, selling, offering to sell, or using the generic darunavir tablets described in ANDA Nos. 202-136 would constitute infringement of the '411 Patent, or inducing or contributing to such conduct, by Mylan pursuant to 35 U.S.C. § 271(g);

(f) a judgment permanently enjoining Defendants and each of their officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in ANDA No. 202-073, ANDA No. 202-136 and ANDA No. 202-118 until the day after the expiration of the period of pediatric exclusivity applicable to the '596 Patent;

(g) a judgment permanently enjoining Lupin and Teva and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially importing, selling, offering for sale, or using the generic darunavir tablets described in ANDA Nos. 202-073 and 202-118, respectively, until after the expiration of the '015 and '408 Patents;

(h) a judgment permanently enjoining Mylan and its officers, agents, servants and employees, and those persons in active concert or participation with it, from commercially importing, selling, offering for sale, or using the generic darunavir tablets described in ANDA No. 202-136 until after the expiration of the '411 Patent;

(i) a declaration that this case is exceptional;

(j) 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

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

Respectfully submitted,

s/John E. Flaherty

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