IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLOS THERAPEUTICS, INC., SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH; SOUTHERN RESEARCH INSTITUTE; and SRI INTERNATIONAL, INC.,	)	
Plaintiffs,	)	Civil Action No. _____
v.	)	
TEVA PHARMACEUTICALS USA, INC.; SANDOZ INC.; FRESENIUS KABI USA, LLC; DR. REDDY'S LABORATORIES, LTD.; DR. REDDY'S LABORATORIES, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Allos Therapeutics, Inc. ("Allos"); Sloan-Kettering Institute for Cancer Research; Southern Research Institute; and SRI International, Inc. (collectively "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva"), Sandoz, Inc. ("Sandoz"), Fresenius Kabi USA, LLC ("Fresenius"), Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd. (jointly, "Dr. Reddy's") (all defendants collectively, "Defendants") herein allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, arising from the Defendants filing Abbreviated New Drug Applications ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market

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1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, arising from the Defendants filing Abbreviated New Drug Applications ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market

pralatrexate products, which are generic forms of Allos's pharmaceutical product Folotyn®, prior to the expiration of United States Patent Nos. 6,028,071 ("the '071 patent"), 7,622,470 ("the '470 patent"), and 8,299,078 ("the '078 patent"), which cover Folotyn®, and methods of using Folotyn®.

THE PARTIES

Plaintiffs

2. Allos Therapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 11080 Circle Point Road, Suite 430, Westminster, Colorado 80020. Allos is engaged in the business of research, development, manufacture, and sale of pharmaceutical products.

3. Sloan-Kettering Institute for Cancer Research is a non-profit corporation organized and existing under the laws of the State of New York, having its principal place of business at 1275 York Avenue, New York, New York 10065.

4. Southern Research Institute is a non-profit corporation organized and existing under the laws of the State of Alabama, having its principal place of business at 2000 Ninth Avenue South, Birmingham, Alabama 35205.

5. SRI International, Inc. is a non-profit corporation organized and existing under the laws of the State of California, having its principal place of business at 333 Ravenswood Avenue, Menlo Park, California 94025.

Defendants

6. On information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva is in the business of

making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

7. On information and belief, Sandoz is a corporation organized and existing under the laws of the State of Colorado, with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. On information and belief, Sandoz is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

8. On information and belief, Fresenius is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. On information and belief, Fresenius is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

9. On information and belief, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at 71-1-27, Ameerpet, Hyderabad 500 016, Andhra Pradesh, India.

10. On information and belief, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 200 Somerset Corporate Blvd., 7th Floor, Bridgewater, New Jersey 08807.

11. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd., and is controlled by Dr. Reddy's Laboratories, Ltd.

12. On information and belief, both Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. submitted, collaborated, and/or acted in concert in the preparation or submission of ANDA No. 206183.

13. On information and belief, Dr. Reddy's is in the business of making and selling generic pharmaceutical products, which Dr. Reddy's distributes in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

Personal Jurisdiction over Defendants

15. This Court has personal jurisdiction over Teva because, on information and belief, it is a Delaware corporation.

16. This Court also has personal jurisdiction over Teva because, on information and belief, Teva: (1) conducts business in this Judicial District; and (2) has engaged in continuous and systematic contacts with Delaware and/or purposefully availed itself of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Teva pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

17. On information and belief, this Court has personal jurisdiction over Sandoz.

18. This Court has personal jurisdiction over Sandoz because, on information and belief, Sandoz: (1) conducts business in this Judicial District; and (2) has engaged in

continuous and systematic contacts with Delaware and/or purposefully availed itself of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Sandoz pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Further, on information and belief, Sandoz is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesale" of drug products.

19. This Court also has personal jurisdiction over Sandoz because, on information and belief, Sandoz has repeatedly and purposely availed itself of this forum by filing complaints and counterclaims in this jurisdiction in various actions for at least the past several years. *See, e.g.*, Civil Action Nos. 09-2457, 10-0104, 12-2104, 13-01507, and 13-01216.

20. This Court has personal jurisdiction over Fresenius because, on information and belief, it is a Delaware limited liability company.

21. This Court also has personal jurisdiction over Fresenius because, on information and belief, Fresenius: (1) conducts business in this Judicial District; and (2) has engaged in continuous and systematic contacts with Delaware and/or purposefully availed itself of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Fresenius pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities. Further, on information and belief, Fresenius is registered with the Delaware Board of Pharmacy as a "Distributor/ Manufacturer" and "Pharmacy-Wholesale" of drug products.

22. On information and belief, this Court also has personal jurisdiction over Fresenius because Fresenius has repeatedly and purposely availed itself of this forum by filing

complaints and counterclaims in this jurisdiction in various actions for at least the past several years. *See, e.g.*, Civil Action Nos., 13-0467, 13-0925, 13-1015, 13-1893, 14-0160, and 14-0161.

23. This Court has personal jurisdiction over Dr. Reddy's.

24. On information and belief, this Court has personal jurisdiction over Dr. Reddy's because Dr. Reddy's: (1) conducts business in this Judicial District; and (2) has engaged in continuous and systematic contacts with Delaware and/or purposefully availed itself of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Dr. Reddy's pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

25. On information and belief, this Court also has personal jurisdiction over Dr. Reddy's because Dr. Reddy's has repeatedly and purposely availed itself of this forum by filing complaints and counterclaims in this jurisdiction in various actions for at least the past several years. *See, e.g.*, Civil Action Nos. 13-0925, 13-1506, 13-2082, and 14-0160.

Venue

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

THE PATENTS-IN-SUIT

27. On February 22, 2000, the United States Patent and Trademark Office issued U.S. Patent No. 6,028,071, entitled "Purified Compositions of 10-propargyl-10-deazaaminopterin and Methods of Using Same in the Treatment of Tumors." At the time of its issue, the '071 patent was assigned to the Sloan-Kettering Institute for Cancer Research, SRI International, Inc., and Southern Research Institute, which parties currently hold title to the '071 patent. Sloan-Kettering Institute for Cancer Research, SRI International, Inc., and Southern

Research Institute have exclusively licensed the '071 patent to Allos. A copy of the '071 patent is attached hereto as **Exhibit A**.

28. On November 24, 2009, the United States Patent and Trademark Office issued U.S. Patent No. 7,622,470, entitled "Treatment of T-cell Lymphoma Using 10-propargyl-10-deazaaminopterin." At the time of its issue, the '470 patent was assigned to Sloan-Kettering Institute for Cancer Research, which currently holds title to the '470 patent. Sloan-Kettering Institute for Cancer Research has exclusively licensed the '470 patent to Allos. A copy of the '470 patent is attached hereto as **Exhibit B**.

29. On October 30, 2012, the United States Patent and Trademark Office issued U.S. Patent No. 8,299,078, entitled "Treatment of T-cell Lymphoma Using 10-propargyl-10-deazaaminopterin." At the time of its issue, the '078 patent was assigned to Sloan-Kettering Institute for Cancer Research, which currently holds title to the '078 patent. Sloan-Kettering Institute for Cancer Research has exclusively licensed the '078 patent to Allos. A copy of the '078 patent is attached hereto as **Exhibit C**.

FOLOTYN®

30. Allos holds New Drug Application No. 022468 (the "Folotyn® NDA"), which was approved by the FDA on September 24, 2009. Under the Folotyn® NDA, Allos was granted permission to market a pralatrexate drug product for use in treatment of patients with relapsed or refractory peripheral T-cell lymphoma ("PTCL"), in 20 mg and 40 mg dosage strengths as solutions for intravenous infusion at a concentration of 20 mg/ml, under the trade name Folotyn®.

31. The FDA granted Folotyn® seven years of orphan-drug exclusive approval pursuant to Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360cc) for

use in treatment of patients with relapsed or refractory PTCL, barring the marketing of any other pralatrexate drug products until September 26, 2016.

32. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '071, '470, and '078 patents are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") with respect to Folotyn®.

DEFENDANTS' ANDAS

Teva

33. On information and belief, Teva submitted an Abbreviated New Drug Application, ANDA No. 206167, to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market vials of pralatrexate with 20 mg/1 mL vial and 40 mg/2 mL vial dosages ("Teva's ANDA"). The pralatrexate vials described in Teva's ANDA are herein referred to as "Teva's Products."

34. On information and belief, Teva's ANDA refers to and relies upon the Folotyn® NDA and contains data that, according to Teva, demonstrates the bioequivalence of Teva's Products and Folotyn®.

35. By filing Teva's ANDA, Teva has necessarily represented to the FDA that Teva's Products have the same active ingredient as Folotyn®, have the same routes of administration, dosage forms, and strengths as Folotyn®, are bioequivalent to Folotyn®, and have the same or substantially the same proposed labeling as Folotyn®.

36. Allos received a letter from Teva on or around May 22, 2014, and an attached memorandum (collectively "Teva's Notification"), stating that Teva had included a certification in Teva's ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '071, '470,

and '078 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's Products.

37. This action is being brought within forty-five days from the date Allos received Teva's Notification.

Sandoz

38. On information and belief, Sandoz submitted an Abbreviated New Drug Application, ANDA No. 206193, to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market vials of pralatrexate with 20 mg/1 mL vial and 40 mg/2 mL vial dosages ("Sandoz's ANDA"). The pralatrexate vials described in Sandoz's ANDA are herein referred to as "Sandoz's Products."

39. On information and belief, Sandoz's ANDA refers to and relies upon the Folotyn® NDA and contains data that, according to Sandoz, demonstrates the bioequivalence of Sandoz's Products and Folotyn®.

40. By filing Sandoz's ANDA, Sandoz has necessarily represented to the FDA that Sandoz's Products have the same active ingredient as Folotyn®, have the same routes of administration, dosage forms, and strengths as Folotyn®, are bioequivalent to Folotyn®, and have the same or substantially the same proposed labeling as Folotyn®.

41. Allos received a letter from Sandoz on or around May 15, 2014, and an attached memorandum (collectively "Sandoz's Notification"), stating that Sandoz had included a certification in Sandoz's ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '071, '470, and '078 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Sandoz's Products.

42. This action is being brought within forty-five days from the date that Allos received Sandoz's Notification.

Fresenius

43. On information and belief, Fresenius submitted an Abbreviated New Drug Application, ANDA No. 206188, to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market vials of pralatrexate with 20 mg/1 mL vial and 40 mg/2 mL vial dosages ("Fresenius's ANDA"). The pralatrexate vials described in Fresenius's ANDA are herein referred to as "Fresenius's Products."

44. On information and belief, Fresenius's ANDA refers to and relies upon the Folotyn® NDA and contains data that, according to Fresenius, demonstrates the bioequivalence of Fresenius's Products and Folotyn®.

45. By filing Fresenius's ANDA, Fresenius has necessarily represented to the FDA that Fresenius's Products have the same active ingredient as Folotyn®, have the same routes of administration, dosage forms, and strengths as Folotyn®, are bioequivalent to Folotyn®, and have the same or substantially the same proposed labeling as Folotyn®.

46. Allos received a letter from Fresenius on or around May 7, 2014, and an attached memorandum (collectively "Fresenius's Notification"), stating that Fresenius had included a certification in Fresenius's ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '071, '470, and '078 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Fresenius's Products.

47. This action is being brought within forty-five days from the date that Allos received Fresenius's Notification.

Dr. Reddy's

48. On information and belief, Dr. Reddy's submitted an Abbreviated New Drug Application, ANDA No. 206183, to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market vials of pralatrexate with 20 mg/1 mL vial and 40 mg/2 mL vial dosages ("Dr. Reddy's ANDA"). The pralatrexate vials described in Dr. Reddy's ANDA are herein referred to as "Dr. Reddy's Products."

49. On information and belief, Dr. Reddy's ANDA refers to and relies upon the Folotyn® NDA and contains data that, according to Dr. Reddy's, demonstrates the bioequivalence of Dr. Reddy's Products and Folotyn®.

50. By filing Dr. Reddy's ANDA, Dr. Reddy's has necessarily represented to the FDA that Dr. Reddy's Products have the same active ingredient as Folotyn®, have the same routes of administration, dosage forms, and strengths as Folotyn®, are bioequivalent to Folotyn®, and have the same or substantially the same proposed labeling as Folotyn®.

51. Allos received a letter from Dr. Reddy's on or around May 23, 2014, and an attached memorandum (collectively "Dr. Reddy's Notification"), stating that Dr. Reddy's had included a certification in Dr. Reddy's ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '071, '470, and '078 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Dr. Reddy's Products.

52. This action is being brought within forty-five days from the date that Allos received Dr. Reddy's Notification.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 6,028,071

53. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-52 of this Complaint.

54. The '071 patent contains claims directed to, for example (claim 1), "10-Propargyl-10-deazaaminopterin, substantially free of 10-deazaaminopterin."

Teva

55. Teva has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Teva's ANDA, by which Teva seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Teva's Products prior to the expiration of the '071 patent.

56. Teva's commercial manufacture, use, offer to sell, or sale of Teva's Products within the United States, or importation of Teva's Products into the United States, during the term of the '071 patent would further infringe one or more claims of the '071 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

57. Teva's filing of Teva's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Teva's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '071 patent.

58. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of Teva's ANDA shall not be earlier than July 16, 2022, the expiration date of the '071 patent, or any later expiration date to which Plaintiffs become entitled.

59. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Teva, under 35 U.S.C. § 285.

Sandoz

60. Sandoz has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Products prior to the expiration of the '071 patent.

61. Sandoz's commercial manufacture, use, offer to sell, or sale of Sandoz's Products within the United States, or importation of Sandoz's Products into the United States, during the term of the '071 patent would further infringe one or more claims of the '071 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

62. Sandoz's filing of Sandoz's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '071 patent.

63. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Sandoz's ANDA shall not be earlier than July 16, 2022, the expiration date of the '071 patent, or any later expiration date to which Plaintiffs become entitled.

64. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Sandoz, under 35 U.S.C. § 285.

Fresenius

65. Fresenius has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Fresenius's ANDA, by which Fresenius seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Fresenius's Products prior to the expiration of the '071 patent.

66. Fresenius's commercial manufacture, use, offer to sell, or sale of Fresenius's Products within the United States, or importation of Fresenius's Products into the United States, during the term of the '071 patent would further infringe one or more claims of the '071 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

67. Fresenius's filing of Fresenius's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Fresenius's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '071 patent.

68. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Fresenius's ANDA shall not be earlier than July 16, 2022, the expiration date of the '071 patent, or any later expiration date to which Plaintiffs become entitled.

69. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Fresenius, under 35 U.S.C. § 285.

Dr. Reddy's

70. Dr. Reddy's has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the

FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Dr. Reddy's Products prior to the expiration of the '071 patent.

71. Dr. Reddy's commercial manufacture, use, offer to sell, or sale of Dr. Reddy's Products within the United States, or importation of Dr. Reddy's Products into the United States, during the term of the '071 patent would further infringe one or more claims of the '071 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

72. Dr. Reddy's filing of Dr. Reddy's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Dr. Reddy's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '071 patent.

73. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Dr. Reddy's ANDA shall not be earlier than July 16, 2022, the expiration date of the '071 patent, or any later expiration date to which Plaintiffs become entitled.

74. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Dr. Reddy's, under 35 U.S.C. § 285.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 7,622,470

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

76. The '470 patent contains claims directed to, for example (claim 1), "A method for treatment of peripheral T cell lymphoma excluding mycosis fungoides comprising administering to a human having a peripheral T cell lymphoma other than mycosis fungoides a

composition comprising a therapeutically effective amount of 10-propargyl-10-deazaaminopterin."

Teva

77. Teva has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Teva's ANDA, by which Teva seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Teva's Products prior to the expiration of the '470 patent.

78. Teva's commercial manufacture, use, offer to sell, or sale of Teva's Products within the United States, or importation of Teva's Products into the United States, during the term of the '470 patent would further infringe one or more claims of the '470 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

79. Teva's filing of Teva's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Teva's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '470 patent.

80. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Teva's ANDA shall not be earlier than May 31, 2025, the expiration date of the '470 patent, or any later expiration date to which Plaintiffs become entitled.

81. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Teva, under 35 U.S.C. § 285.

Sandoz

82. Sandoz has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Products prior to the expiration of the '470 patent.

83. Sandoz's commercial manufacture, use, offer to sell, or sale of Sandoz's Products within the United States, or importation of Sandoz's Products into the United States, during the term of the '470 patent would further infringe one or more claims of the '470 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

84. Sandoz's filing of Sandoz's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '470 patent.

85. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Sandoz's ANDA shall not be earlier than May 31, 2025, the expiration date of the '470 patent, or any later expiration date to which Plaintiffs become entitled.

86. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Sandoz, under 35 U.S.C. § 285.

Fresenius

87. Fresenius has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Fresenius's ANDA, by which Fresenius seeks approval from the

FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Fresenius's Products prior to the expiration of the '470 patent.

88. Fresenius's commercial manufacture, use, offer to sell, or sale of Fresenius's Products within the United States, or importation of Fresenius's Products into the United States, during the term of the '470 patent would further infringe one or more claims of the '470 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

89. Fresenius's filing of Fresenius's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Fresenius's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '470 patent.

90. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Fresenius's ANDA shall not be earlier than May 31, 2025, the expiration date of the '470 patent, or any later expiration date to which Plaintiffs become entitled.

91. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Fresenius, under 35 U.S.C. § 285.

Dr. Reddy's

92. Dr. Reddy's has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Dr. Reddy's Products prior to the expiration of the '470 patent.

93. Dr. Reddy's commercial manufacture, use, offer to sell, or sale of Dr. Reddy's Products within the United States, or importation of Dr. Reddy's Products into the

United States, during the term of the '470 patent would further infringe one or more claims of the '470 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

94. Dr. Reddy's filing of Dr. Reddy's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Dr. Reddy's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '470 patent.

95. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Dr. Reddy's ANDA shall not be earlier than May 31, 2025, the expiration date of the '470 patent, or any later expiration date to which Plaintiffs become entitled.

96. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Dr. Reddy's, under 35 U.S.C. § 285.

COUNT III

INFRINGEMENT OF U.S. PATENT NO. 8,299,078

97. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-96 of this Complaint.

98. The '078 patent contains claims directed to, for example (claim 1), "A method for treatment of T cell lymphoma comprising administering to a human having a T cell lymphoma a composition comprising a therapeutically effective amount of 10-propargyl-10-deazaaminopterin."

Teva

99. Teva has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Teva's ANDA, by which Teva seeks approval from the FDA to

engage in the commercial manufacture, use, offer to sell, sale, or importation of Teva's Products prior to the expiration of the '078 patent.

100. Teva's commercial manufacture, use, offer to sell, or sale of Teva's Products within the United States, or importation of Teva's Products into the United States, during the term of the '078 patent would further infringe one or more claims of the '078 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

101. Teva's filing of Teva's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Teva's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '078 patent.

102. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Teva's ANDA shall not be earlier than May 31, 2025, the expiration date of the '078 patent, or any later expiration date to which Plaintiffs become entitled.

103. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Teva, under 35 U.S.C. § 285.

Sandoz

104. Sandoz has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Products prior to the expiration of the '078 patent.

105. Sandoz's commercial manufacture, use, offer to sell, or sale of Sandoz's Products within the United States, or importation of Sandoz's Products into the United States,

during the term of the '078 patent would further infringe one or more claims of the '078 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

106. Sandoz's filing of Sandoz's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '078 patent.

107. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Sandoz's ANDA shall not be earlier than May 31, 2025, the expiration date of the '078 patent, or any later expiration date to which Plaintiffs become entitled.

108. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Sandoz, under 35 U.S.C. § 285.

Fresenius

109. Fresenius has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Fresenius's ANDA, by which Fresenius seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Fresenius's Products prior to the expiration of the '078 patent.

110. Fresenius's commercial manufacture, use, offer to sell, or sale of Fresenius's Products within the United States, or importation of Fresenius's Products into the United States, during the term of the '078 patent would further infringe one or more claims of the '078 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

111. Fresenius's filing of Fresenius's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Fresenius's Products upon

receiving FDA approval creates an actual case or controversy with respect to infringement of the '078 patent.

112. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Fresenius's ANDA shall not be earlier than May 31, 2025, the expiration date of the '078 patent, or any later expiration date to which Plaintiffs become entitled.

113. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Fresenius, under 35 U.S.C. § 285.

Dr. Reddy's

114. Dr. Reddy's has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Dr. Reddy's ANDA, by which Dr. Reddy's seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Dr. Reddy's Products prior to the expiration of the '078 patent.

115. Dr. Reddy's commercial manufacture, use, offer to sell, or sale of Dr. Reddy's Products within the United States, or importation of Dr. Reddy's Products into the United States, during the term of the '078 patent would further infringe one or more claims of the '078 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

116. Dr. Reddy's filing of Dr. Reddy's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Dr. Reddy's Products upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '078 patent.

117. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Dr. Reddy's

ANDA shall not be earlier than May 31, 2025, the expiration date of the '078 patent, or any later expiration date to which Plaintiffs become entitled.

118. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees from Dr. Reddy's, under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

A. A declaration that by filing an ANDA, each Defendant has infringed one or more claims of each of the '071, '470, and '078 patents under 35 U.S.C. § 271(e)(2)(A);

B. A declaration that one or more claims of each of the '071, '470, and '078 patents would be infringed by the manufacture, use, offer for sale, or sale of each Defendant's Products within the United States, or by importation of each Defendant's Products into the United States;

C. A permanent injunction enjoining each Defendant, its officers, directors, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling each Defendant's Products within the United States, or importing each Defendant's Products into the United States, prior to the expiration of the '071, '470, and '078 patents (including any extensions thereof);

D. An Order prohibiting each Defendant, its officers, directors, agents, servants, and employees, and those persons in active concert or participation with any of them, from seeking, obtaining, or maintaining approval of the Defendant's ANDA, prior to the expiration of the '071, '470, and '078 patents (including any extensions thereof);

E. A declaration that the effective date of any approval of each Defendant's ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration dates of the '071, '470, and '078 patents (including any extensions thereof);

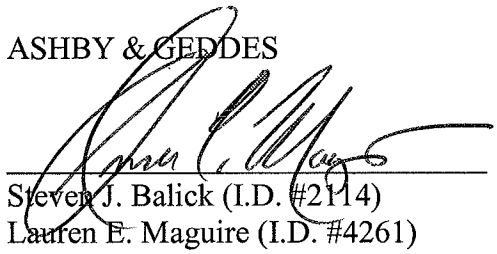
F. A judgment awarding Plaintiffs damages against any Defendant that commercially manufactures, uses, offers to sell, or sells the Defendant's Products within the United States, or imports the Defendant's Products into the United States, prior to the expiration of the '071, '470, and '078 patents (including any extensions thereof), and the trebling of such damages, along with prejudgment and post-judgment interest;

G. A declaration that this is an exceptional case and the entry of judgment awarding Plaintiffs their reasonable attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285 and 271(e)(4);

H. An award to Plaintiffs of the costs and expenses that they reasonably incurred in this action; and

I. Such further and other relief as this Court deems just and proper.

ASHBY & GEDDES



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