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

ALLOS THERAPEUTICS, INC., SLOAN-  
KETTERING INSTITUTE FOR CANCER  
RESEARCH; SOUTHERN RESEARCH  
INSTITUTE; and SRI INTERNATIONAL, INC.

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, INC; and  
DR. REDDY'S LABORATORIES, LTD.

Defendants.

Civil Action No. \_\_\_\_\_

**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 Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (jointly, "Dr. Reddy's" or "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 Dr. Reddy's 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 Folutyn<sup>®</sup>, 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 Folutyn<sup>®</sup>, and methods of using Folutyn<sup>®</sup>.

## 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, 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.

7. 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.

8. 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.

9. 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.

10. 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 New Jersey and throughout the United States.

**JURISDICTION AND VENUE**

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

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

13. On information and belief, this Court has personal jurisdiction over Dr. Reddy's because: (1) 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; (2) 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.; (3) Dr. Reddy's conducts business in this Judicial District; and (4) Dr. Reddy's has engaged in continuous and systematic contacts with New Jersey 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.

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

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

15. 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**.

16. 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**.

17. 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<sup>®</sup>**

18. Allos holds New Drug Application No. 022468 (the “Folotyn<sup>®</sup> NDA”), which was approved by the FDA on September 24, 2009. Under the Folotyn<sup>®</sup> 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<sup>®</sup>.

19. The FDA granted Folotyn<sup>®</sup> 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.

20. 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 Folutyn<sup>®</sup>.

#### **DR. REDDY'S ANDA**

21. 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."

22. On information and belief, Dr. Reddy's ANDA refers to and relies upon the Folutyn<sup>®</sup> NDA and contains data that, according to Dr. Reddy's, demonstrates the bioequivalence of Dr. Reddy's Products and Folutyn<sup>®</sup>.

23. 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 Folutyn<sup>®</sup>, have the same routes of administration, dosage forms, and strengths as Folutyn<sup>®</sup>, are bioequivalent to Folutyn<sup>®</sup>, and have the same or substantially the same proposed labeling as Folutyn<sup>®</sup>.

24. Allos received a letter from Dr. Reddy's on or around May 27, 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.

25. 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**

26. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-25 of this Complaint.

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

28. 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.

29. 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).

30. 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.

31. 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.

32. 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**

33. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-32 of this Complaint.

34. 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."

35. 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.

36. 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).

37. 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.



38. 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.

39. 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**

40. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-39 of this Complaint.

41. 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."

42. 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.

43. 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).

44. 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.

45. 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.

46. 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, Dr. Reddy's 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 Dr. Reddy's Products within the United States, or by importation of Dr. Reddy's Products into the United States;

C. A permanent injunction enjoining Dr. Reddy's, 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 Dr. Reddy's Products within the

United States, or importing Dr. Reddy'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 Dr. Reddy's, 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 Dr. Reddy'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 Dr. Reddy'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 Dr. Reddy's for the commercial manufacture, use, offer to sell, or sale of Dr. Reddy's Products within the United States, or imports Dr. Reddy'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.

MCCARTER & ENGLISH, LLP

s/ John E. Flaherty

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July 7, 2014

**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter of the following actions:

- *Allos Therapeutics, Inc., Sloan-Kettering Institute for Cancer Research, Southern Research Institute, and SRI International, Inc. v. Teva Pharmaceuticals USA, Inc., Sandoz Inc., Fresenius Kabi USA, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd.*, Civil Action No. 1:14-cv-00778-RGA (D. Del.).

MCCARTER & ENGLISH, LLP

s/ John E. Flaherty \_\_\_\_\_  
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July 7, 2014