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

GENZYME CORPORATION, SOUTHERN RESEARCH INSTITUTE, and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMA GLOBAL INC., and SUN PHARMACEUTAL INDUSTRIES, INC., Defendants.	Civil Action No. **COMPLAINT** *Electronically Filed*

Plaintiffs Genzyme Corporation ("Genzyme"), Southern Research Institute ("Southern Research"), and sanofi-aventis U.S. LLC ("Sanofi") (collectively, "Plaintiffs") by their attorneys,

for their Complaint against Sun Pharma Global FZE ("Sun FZE"), Sun Pharmaceutical Industries, Ltd. ("Sun Ltd."), Sun Pharma Global Inc. ("Sun Global"), and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") (collectively, "Sun Defendants") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 5,661,136 ("'136 patent") arising under the Patent Laws of the United States, Title 35, United States Code, Sections 100 *et seq*. This action relates to an Abbreviated New Drug Application ("ANDA") No. 208936, filed by Sun FZE with the United States Food and Drug Administration ("FDA") for approval to market a generic version of the Clolar® (clofarabine) injection drug product.

THE PARTIES

2. Genzyme is a corporation organized and existing under the laws of Massachusetts, having its principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

3. Southern Research is a corporation organized and existing under the laws of Alabama, having its principal place of business at 2000 Ninth Avenue South, Birmingham, Alabama 35205-5305.

4. Sanofi is a limited liability company organized and existing under the laws of the State of Delaware corporation with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

5. On information and belief, Sun Ltd. is a corporation organized and existing under the laws of India having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400 063, Maharashtra, India.

6. On information and belief, Sun Global is a corporation organized and existing under the laws of the British Virgin Islands having a post office box at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. On information and belief, Sun Global is a wholly owned subsidiary of Sun Ltd. and is controlled and/or dominated by Sun Ltd.

7. On information and belief, Sun FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office # 43, Block Y, SAIF Zone, P.O. Box # 122304, Sharjah, United Arab Emirates. On information and belief, Sun FZE is indirectly a wholly owned subsidiary of Sun Global and is controlled and/or dominated by Sun Global.

8. On information and belief, Sun Inc. is a corporation organized and existing under the laws of the State of Michigan having a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512. Sun Inc. is registered to do business in the State of New Jersey. On information and belief, Sun Inc. is a wholly owned subsidiary of Sun Ltd. and is controlled and/or dominated by Sun Ltd.

9. On information and belief, Sun Ltd. conducts business through and with Sun Global, Sun FZE, and Sun Inc.

10. On information and belief, Sun Ltd., Sun Global, and Sun FZE operate in the United States through Sun Inc.

11. On information and belief, the acts of Sun FZE complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Sun Inc., Sun Ltd., and Sun Global. On information and belief, the acts of Sun FZE

complained of herein were done at least in part for the benefit of Sun Inc., Sun Ltd., and Sun Global.

JURISDICTION AND VENUE

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

13. On information and belief, Sun FZE, with the assistance and/or at the direction of Sun Inc., Sun Ltd., and/or Sun Global, develops, formulates, manufactures, imports, offers for sale, sells, commercializes, markets, and/or distributes generic versions of branded pharmaceutical products in/into the United States, including in the State of New Jersey.

14. On information and belief and as stated in the letter dated February 11, 2016 and received on or about February 12, 2016, purporting to be a notice pursuant to Section 505(j)(2)(B)(i), (ii), (iii), and (iv) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)) and 21 C.F.R. § 314.95 (the "Notice Letter"), Sun FZE submitted ANDA No. 208936 to the FDA under Section 505(j) seeking approval to engage in the commercial manufacture, importation, use, and sale of a clofarabine injection, 1mg/mL, 20mL in single dose vials ("Clofarabine ANDA Injection") as a generic version of the Clolar® (clofarabine) injection drug product throughout the United States, including within the State of New Jersey, prior to the expiration of the '136 patent.

15. On information and belief, Sun Inc., Sun Ltd., and/or Sun Global acted in concert with Sun FZE to develop the Sun FZE's generic copy of Clolar®.

16. On information and belief, Sun Inc., Sun Ltd., and/or Sun Global participated in the preparation and/or filing of ANDA No. 208936 seeking approval from the FDA to sell the

Clofarabine ANDA Injection throughout the United States, including within the State of New Jersey.

17. This Court has personal jurisdiction over the Sun Defendants because, *inter alia*, they have committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs. For example, on information and belief, following approval of ANDA No. 208936, the Sun Defendants will work in concert with one another to make, use, import, sell, and/or offer for sale the Clofarabine ANDA Injection in/into the United States, including in this State, prior to the expiration of the '136 patent.

18. This Court has personal jurisdiction over Sun FZE because, *inter alia*, Sun FZE, on information and belief: (1) avails itself of the laws of the State of New Jersey and engages in a course of conduct in the State of New Jersey by at least indicating that an offer to access confidential information relating to ANDA No. 208936 "shall be governed by the laws of the State of New Jersey"; (2) intends to market, sell, or distribute the Clofarabine ANDA Injection to residents of this State; (3) maintains a broad distributorship network within this State; (4) continuously and systematically places goods into the stream of commerce for distribution in the United States, including in the State of New Jersey; and (5) generates substantial revenue and income from sales of its generic pharmaceutical products throughout the United States, including within the State of New Jersey.

19. Additionally, on information and belief, Sun FZE has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See*, *e.g.*, *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. HEC Pharm Group et al.*, Civil Action No. 15-cv-05982-PGS-TJB

(D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd. et al.*, Civil Action No. 14-cv-04307-JBS-KMW (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd. et al.*, Civil Action No. 14-cv-06397-JBS-KMW (D.N.J.); and *Takeda Pharmaceutical Company Limited et al. v. Sun Pharma Global FZE et al.*, Civil Action No. 14-cv-04616-MLC-TJB (D.N.J.).

20. Alternatively, to the extent the above facts do not establish personal jurisdiction over Sun FZE, this Court may exercise jurisdiction over Sun FZE pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Sun FZE would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Sun FZE has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun FZE satisfies due process.

21. On information and belief, Sun Inc. develops, manufactures, and/or distributes generic versions of branded pharmaceutical products for distribution in the United States, including in the State of New Jersey.

22. This Court has personal jurisdiction over Sun Inc. because, *inter alia*, Sun Inc., on information and belief: (1) maintains substantial, systematic, and continuous contacts with the State of New Jersey; (2) avails itself of the laws of the State of New Jersey and engages in a course of conduct in the State of New Jersey by having a principal place of business in New Jersey; (3) is registered to do business in New Jersey under entity ID No. 0100970132; (4) is registered as a Wholesale Drug and Medical Device manufacturer and wholesaler by the New Jersey Department of Health and Senior Services; (5) intends to market, sell, or distribute the Clofarabine ANDA Injection to residents of this State; (6) maintains a broad distributorship

network within this State; (7) continuously and systematically places goods into the stream of commerce for distribution in the United States, including in the State of New Jersey; and (8) generates substantial revenue and income from sales of its generic pharmaceutical products throughout the United States, including within the State of New Jersey.

23. Additionally, on information and belief, Sun Inc. has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Dexcel Pharma Technologies Ltd. et al. v. Sun Pharma Global FZE et al.*, Civil Action No. 15-cv-08017-SDW-LDW (D.N.J.); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. HEC Pharm Group et al.*, Civil Action No. 15-cv-05982-PGS-TJB (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd. et al.*, Civil Action No. 14-cv-04307-JBS-KMW (D.N.J.); and *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd. et al.*, Civil Action No. 14-cv-06397-JBS-KMW (D.N.J.).

24. On information and belief, Sun Ltd. develops, manufactures, and/or distributes generic versions of branded pharmaceutical products for distribution in the United States, including in the State of New Jersey.

25. This Court has personal jurisdiction over Sun Ltd. because, *inter alia*, Sun Ltd., on information and belief: (1) controls Defendants Sun Global and Sun Inc.; (2) maintains systematic and continuous contacts with the State of New Jersey, including, but not limited to, ongoing communications and contacts with its U.S. subsidiary, Sun Inc.; (3) avails itself of the laws of the State of New Jersey and engages in a course of conduct in the State of New Jersey by at least its U.S. subsidiary, Sun Inc., having a principal place of business in New Jersey, being registered to do business in New Jersey, and being registered as a Wholesale Drug and Medical

Device manufacturer and wholesaler by the New Jersey Department of Health and Senior Services; (4) intends to market, sell, or distribute the Clofarabine ANDA Injection to residents of this State; (5) maintains a broad distributorship network within this State; (6) continuously and systematically places goods into the stream of commerce for distribution in the United States, including in the State of New Jersey; and (7) generates substantial revenue and income from sales of its generic pharmaceutical products throughout the United States, including within the State of New Jersey.

26. Additionally, on information and belief, Sun Ltd. has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Dexcel Pharma Technologies Ltd. et al. v. Sun Pharma Global FZE et al.*, Civil Action No. 15-cv-08017-SDW-LDW (D.N.J.); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. HEC Pharm Group et al.*, Civil Action No. 15-cv-05982-PGS-TJB (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd. et al.*, Civil Action No. 14-cv-04307-JBS-KMW (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd. et al.*, Civil Action No. 14-cv-06397-JBS-KMW (D.N.J.); and *Takeda Pharmaceutical Company Limited et al. v. Sun Pharma Global FZE et al.*, Civil Action No. 14-cv-04616-MLC-TJB (D.N.J.).

27. Alternatively, to the extent the above facts do not establish personal jurisdiction over Sun Ltd., this Court may exercise jurisdiction over Sun Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Sun Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Sun Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing

and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun Ltd. satisfies due process.

28. On information and belief, Sun Global develops, manufactures, and/or distributes generic versions of branded pharmaceutical products for distribution in the United States, including in the State of New Jersey.

29. This Court has personal jurisdiction over Sun Global because, *inter alia*, Sun Global, on information and belief: (1) controls Defendant Sun FZE; (2) intends to market, sell, or distribute the Clofarabine ANDA Injection to residents of this State; (3) maintains a broad distributorship network within this State; (5) continuously and systematically places goods into the stream of commerce for distribution in the United States, including in the State of New Jersey; and (6) generates substantial revenue and income from sales of its generic pharmaceutical products throughout the United States, including within the State of New Jersey.

30. Additionally, on information and belief, Sun Global has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd. et al.*, Civil Action No. 14-cv-04307-JBS-KMW (D.N.J.); and *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd. et al.*, Civil Action No. 14-cv-06397-JBS-KMW (D.N.J.).

31. Alternatively, to the extent the above facts do not establish personal jurisdiction over Sun Global, this Court may exercise jurisdiction over Sun Global pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Sun Global would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Sun Global has sufficient contacts with the United States as a whole, including, but not limited to,

manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun Global satisfies due process.

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

THE PATENT

33. The '136 patent was duly and legally issued on August 26, 1997 to inventors Drs. John A. Montgomery and John A. Secrist, III. The '136 patent was assigned to Southern Research. With patent term extension, the '136 patent will expire on January 14, 2018. Pediatric exclusivity extends the expiration of the '136 patent by six months to July 14, 2018. At all times from the issuance of the '136 patent to the present, Southern Research has been the owner of the '136 patent. Genzyme is Southern Research's exclusive licensee under the '136 patent. Sanofi is Genzyme's exclusive sub-licensee under the '136 patent.

ACTS GIVING RISE TO THIS ACTION

34. Genzyme is the holder of the approved New Drug Application ("NDA") No. 021673 for the Clolar® (clofarabine) injection drug product ("Clolar NDA"). Southern Research, Genzyme, and Sanofi all share in the revenue generated from the sale of Clolar®.

35. The '136 patent is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the Orange Book) in connection with the Clolar® NDA as being applicable to Clolar®.

36. The '136 patent covers Clolar®.

37. On information and belief, the Sun Defendants have knowledge of the '136 patent.

38. By the Notice Letter, Sun FZE notified Plaintiffs that Sun FZE had submitted ANDA No. 208936 to the FDA seeking approval to engage in the commercial manufacture, importation, use, or sale of the Clofarabine ANDA Injection prior to the expiration of the '136 patent.

39. In the Notice Letter, Sun FZE notified Plaintiffs that ANDA No. 208936 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Sun FZE's opinion, the '136 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of the Clofarabine ANDA Injection in the United States ("Paragraph IV Certification").

40. On information and belief, the active ingredient of the Clofarabine ANDA Injection is clofarabine, which is the same active ingredient in Clolar® and the same active ingredient covered by one or more claims of the '136 patent.

41. On information and belief, Sun FZE asserted in ANDA No. 208936 that the Clofarabine ANDA Injection is bioequivalent to Clolar®.

42. On information and belief, Sun FZE's ANDA No. 208936 refers to and relies upon the Clolar® NDA and contains data that, according to Sun FZE, demonstrate the bioequivalence of the Clofarabine ANDA Injection and Clolar®.

43. On information and belief, Sun Ltd., Sun Global, and Sun Inc. were actively involved in the preparation and/or submission of ANDA No. 208936 including the Paragraph IV certification against the '136 patent.

44. On information and belief, Sun Ltd., Sun Global, and Sun Inc. actively and knowingly provided Sun FZE with material information and support in preparing and submitting ANDA No. 208936 and have therefore aided and/or abetted in the filing of ANDA No. 208936.

45. On information and belief, the Sun Defendants will work in concert with one another to commercially manufacture, use, offer for sale, and/or sell the Clofarabine ANDA Injection throughout the United States, import the Clofarabine ANDA Injection into the United States, and/or induce to such acts promptly upon receiving FDA approval to do so and during the term of the '136 patent.

46. On information and belief, the Sun Defendants will knowingly accompany the Clofarabine ANDA Injection with instructions for use that substantially copy the instructions for Clolar®, including instructions for administering the Clofarabine ANDA Injection as claimed in the '136 patent, including but not limited to in Claims 5 and 12.

47. On information and belief, the Sun Defendants know that the instructions that will accompany the Clofarabine ANDA Injection will induce and/or contribute to others using the Clofarabine ANDA Injection in the manner set forth in the instructions.

48. On information and belief, physicians, health care providers, and/or patients will directly infringe one or more claims of the '136 patent, including but not limited to Claims 5 and 12, by using the Clofarabine ANDA Injection in accordance with the instructions provided by the Sun Defendants after the FDA approves ANDA No. 208936.

49. On information and belief, the Sun Defendants specifically intend that physicians, health care providers, and/or patients will use the Clofarabine ANDA Injection in accordance with the instruction provided by the Sun Defendants to directly infringe one or more claims of the '136 patent, including but not limited to Claims 5 and 12.

50. On information and belief, the Sun Defendants designed the Clofarabine ANDA Injection for use in a way that would infringe the '136 patent and will instruct users of the

Clofarabine ANDA Injection to use the Clofarabine ANDA Injection in a way that would infringe one or more claims of the '136 patent.

51. On information and belief, the Clofarabine ANDA Injection is not a staple article or commodity of commerce suitable for substantial non-infringing use.

52. On information and belief, the Sun Defendants knowingly have taken and intend to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Clofarabine ANDA Injection in a manner that directly infringes one or more claims of the '136 patent, including but not limited to by providing instructions for administering the Clofarabine ANDA Injection as claimed in the '136 patent.

53. Plaintiffs commenced this action within 45 days of receiving the Notice Letter.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 5,661,136

54. Plaintiffs repeat and reallege the allegations of paragraphs 1-53 as if fully set forth herein.

55. Sun FZE's submission of ANDA No. 208936 containing the Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of the Clofarabine ANDA Injection prior to the expiration of the '136 patent constitutes infringement of at least one claim of the '136 patent, including but not limited to Claims 5 and 12, under 35 U.S.C. § 271(e)(2)(A).

56. Sun Ltd., Sun Global, and Sun Inc. actively and knowingly aided, abetted, and induced Sun FZE to submit ANDA No. 208936 containing the Paragraph IV Certification before the expiration of the '136 patent, which is an act of infringement under 35 U.S.C. § 271(b).

57. The Sun Defendants had notice of the '136 patent at the time of their infringement. The Sun Defendants' infringement has been, and continues to be, deliberate.

58. Plaintiffs will be substantially and irreparably harmed if the Sun Defendants' infringement of the '136 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

59. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT
OF U.S. PATENT NO. 5,661,136

60. Plaintiffs repeat and reallege the allegations of paragraphs 1-59 as if fully set forth herein.

61. This claim arises under the Patent Laws, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties. The Sun Defendants have taken immediate and active steps, through Sun FZE's submission of its ANDA, to obtain approval from the FDA to commercially manufacture, import, use, or sell the Clofarabine ANDA Injection prior to the expiration of the '136 patent.

62. After obtaining FDA approval, the Sun Defendants plan to act in concert with each other to commercially manufacture, use, offer for sale, and/or sell the Clofarabine ANDA Injection in the United States, import the Clofarabine ANDA Injection into the United States, and/or induce such acts prior to the expiration of the '136 patent.

63. Upon FDA approval of ANDA No. 208936, the Sun Defendants will infringe one or more of the claims of the '136 patent, including but not limited to Claims 5 and 12, under §§ 271 (a), (b), or (c) by making, using, selling, offering for sale, or importing the Clofarabine ANDA Injection in/into the United States, unless enjoined by this Court. Accordingly, an actual

and immediate controversy exists between the parties regarding infringement of the '136 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

64. Use of the Clofarabine ANDA Injection, when used as directed by the instructions to be included with the Clofarabine ANDA Injection, will directly infringe at least one of the claims of the '136 patent, including but not limited to Claims 5 and 12, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (a).

65. The Sun Defendants have taken and intend to take active steps to induce or contribute to the direct infringement of one or more claims of the '136 patent, including but not limited to Claims 5 and 12, under 35 U.S.C. § 271 (b) and/or § 271 (c) after ANDA No. 208936 is approved.

66. The Sun Defendants have knowledge of the '136 patent and, by the instructions for the Clofarabine ANDA Injection, know or should know that they will aid and abet another's direct infringement of at least one of the claims of the '136 patent, including but not limited to Claims 5 and 12, either literally or under the doctrine of equivalents.

67. The Sun Defendants' offering for sale, sale, and/or importation of the Clofarabine ANDA Injection with the instructions for the Clofarabine ANDA Injection will actively induce infringement of at least one of the claims of the '136 patent, including but not limited to Claims 5 and 12, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b).

68. The use of the Clofarabine ANDA Injection constitutes a material part of at least one of the claims of the '136 patent; the Sun Defendants know that the Clofarabine ANDA Injection is especially made or adapted for use in infringing at least one of the claims of the '136 patent, including but not limited to Claims 5 and 12, either literally or under the doctrine of

equivalents; and the Sun Defendants know that the Clofarabine ANDA Injection is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

69. The Sun Defendants' manufacture, use, offering for sale, sale, and/or importation of the Clofarabine ANDA Injection will contributorily infringe at least one of the claims of the '136 patent, including but not limited to Claims 5 and 12, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (c).

70. Plaintiffs will be substantially and irreparably harmed if the Sun Defendants' infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the Sun Defendants have infringed one or more claims of the '136 patent by the filing of ANDA No. 208936;

(b) A judgment declaring that the Sun Defendants' manufacturing, using, selling, offering for sale, or importing the Clofarabine ANDA Injection in/into the United States will infringe one or more claims of the '136 patent;

(c) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 208936 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date no earlier than January 14, 2018, the date on which the '136 patent expires, or the expiration of any other exclusivity to which Plaintiffs are or become entitled;

(d) Injunctive relief under 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining the Sun Defendants from making, using, selling, offering for sale, or

importing the Clofarabine ANDA Injection in/into the United States until after expiration of the '136 patent or the expiration of any other exclusivity to which Plaintiffs are or become entitled;

(e) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining the Sun Defendants from practicing any methods as claimed in the '136 patent, or from actively inducing or contributing to the infringement of any claim of the '136 patent, until after the expiration of the '136 patent or the expiration of any other exclusivity to which Plaintiffs are or become entitled;

(f) A Declaration that the commercial manufacture, use, sale, offer for sale, and importation in/into the United States of the Clofarabine ANDA Injection will directly infringe, induce, and/or contribute to infringement of the '136 patent;

(g) Damages under 35 U.S.C. § 271(e)(4)(C), which this Court should treble pursuant to 35 U.S.C. § 284, if any of the Sun Defendants infringes the '136 patent by engaging in the commercial manufacture, importation, use, sale, offer for sale, or import the Clofarabine ANDA Injection in/into the United States prior to the expiration of the '136 patent or the expiration of any other exclusivity to which Plaintiffs are or become entitled;

(h) An award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

DATED: March 24, 2016

CONNELL FOLEY LLP

s/Liza M. Walsh
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RULE 11.2 CERTIFICATION

I certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

DATED: March 24, 2016

CONNELL FOLEY LLP

s/Liza M. Walsh

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RULE 201.1 CERTIFICATION

We hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

DATED: March 24, 2016

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