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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. AMNEAL PHARMACEUTICALS LLC Defendant.	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 Amneal Pharmaceuticals LLC ("Amneal"), allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 5,661,136 ("'136 patent," a true and accurate copy of which is attached hereto as Exhibit A) 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. 208857, filed by Amneal with the United States Food and Drug Administration ("FDA") for approval to market a proposed generic version of the Clolar® (clofarabine) injection drug product.

THE PARTIES

2. Genzyme is a corporation organized and existing under the laws of the State 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 the State 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 with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

5. On information and belief, Amneal is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807-2863.

JURISDICTION AND VENUE

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

7. On information and belief, Amneal 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. On information and belief, Amneal regularly does or solicits business, engages in a persistent course of conduct, and derives substantial revenue from things used or consumed in New Jersey.

8. On information and belief and as stated in the letter dated May 17, 2016, and received by Plaintiffs on or about May 18, 2016, purporting to be a notice pursuant to Section 505(j)(2)(B)(ii) and (iv) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)) and 21 C.F.R. § 314.95(c) (the "Notice Letter"), Amneal submitted ANDA No. 208857 to the FDA under Section 505(j) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, importation, use, and/or 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.

9. On information and belief, Amneal developed a generic copy of Clolar®.

10. On information and belief, Amneal prepared and/or filed ANDA No. 208857 seeking approval from the FDA to sell the Clofarabine ANDA Injection throughout the United States, including within the State of New Jersey.

11. This Court has personal jurisdiction over Amneal because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271 (e)(2), and intends 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 in New Jersey. For example, on information and belief, following approval of ANDA No. 208857, Amneal will 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.

12. This Court also has personal jurisdiction over Amneal because, *inter alia*, Amneal, on information and belief: (1) maintains substantial, systematic, and continuous contacts with the State of New Jersey; (2) 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. 0600211542 and has appointed a registered agent in New Jersey; (4) is registered with the state of New Jersey's Department of Health as a drug manufacturer and wholesaler; (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.

13. Additionally, personal jurisdiction over Amneal is also proper because Amneal 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., BTG International Limited v. Amneal Pharmaceuticals LLC,* Civil Action No. 15-cv-05909-KM-JBC (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Amneal Pharmaceuticals LLC. et al.*, Civil Action No. 15-cv-001585-JBS-KMW (D.N.J.).

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

THE PATENT

15. 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

16. 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®.

17. Clolar® is indicated for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens ("Approved Indication"). Usage of Clolar® and the Approved Indication are described in the Clolar® Prescribing Information, which also states that a mechanism of action of the clofarabine in Clolar® is inhibiting DNA synthesis through an inhibitory action on ribonucleotide reductase and by competitive inhibition of DNA polymerases.

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

19. The '136 patent covers the use of Clolar® according to its Approved Indication, which occurs via a mechanism of action as described in the Clolar® Prescribing Information.

20. Amneal has knowledge of the '136 patent.

21. By the Notice Letter, Amneal notified Plaintiffs that Amneal had submitted ANDA No. 208857 to the FDA seeking approval to engage in the commercial manufacture, importation, use, and/or sale of the Clofarabine ANDA Injection prior to the expiration of the '136 patent.

22. Amneal's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, importation, use, and/or sale of Amneal's Clofarabine ANDA Injection prior to the expiration of the '136 patent.

23. On information and belief, Amneal intends to engage in the commercial manufacture, importation, use, and/or sale of its Clofarabine ANDA Injection in/into the United States and/or induce or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the '136 patent.

24. In the Notice Letter, Amneal notified Plaintiffs that ANDA No. 208857 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Amneal's opinion, the '136 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of the Clofarabine ANDA Injection in/into the United States ("Paragraph IV Certification").

25. 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 used in the methods of one or more claims of the '136 patent, including but not limited to Claims 1 and 5.

26. On information and belief, Amneal asserted in ANDA No. 208857 that the Clofarabine ANDA Injection is bioequivalent to Clolar®.

27. On information and belief, Amneal's ANDA No. 208857 refers to and relies upon the Clolar® NDA and contains data that, according to Amneal, demonstrate the bioequivalence of the Clofarabine ANDA Injection and Clolar®.

28. On information and belief, Amneal is seeking approval to market its Clofarabine ANDA Injection for the same Approved Indication as Clolar®.

29. On information and belief, Amneal will knowingly accompany the Clofarabine ANDA Injection with prescribing information that will contain 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 Claims 1 and 5.

30. Upon information and belief, Amneal's prescribing information for its Clofarabine ANDA Injection will instruct users to administer Amneal's Clofarabine ANDA Injection to bring about a cytotoxic effect in a mammalian cancerous cell.

31. Upon information and belief, Amneal's prescribing information for its Clofarabine ANDA Injection will instruct users to administer Amneal's Clofarabine ANDA Injection to inhibit ribonucleotide reductase and DNA polymerase α in a mammalian cell.

32. Upon information and belief, Amneal has knowledge and/or an expectation that its Clofarabine ANDA Injection will be used in accordance with its prescribing information.

33. On information and belief, Amneal knows that the prescribing information 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 prescribing information.

34. 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 1 and

5, by using the Clofarabine ANDA Injection in accordance with the prescribing information provided by Amneal after the FDA approves ANDA No. 208857.

35. On information and belief, Amneal specifically intends that physicians, health care providers, and/or patients will use the Clofarabine ANDA Injection in accordance with the prescribing information provided by Amneal to directly infringe one or more claims of the '136 patent, including but not limited to Claims 1 and 5.

36. On information and belief, Amneal 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.

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

38. On information and belief, Amneal knowingly has taken and intends 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 prescribing information with instructions for administering the Clofarabine ANDA Injection as claimed in one or more claims of the '136 patent, including but not limited to Claims 1 and 5.

39. Amneal is aware of the decision issued on August 22, 2013 in *Southern Research Institute et al. v. Abon Pharmaceuticals LLC*, 1:12-cv-04709, construing phrases from the claims of the '136 patent to include "cells in, or derived from, a mammal (such as a human)."

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

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

41. Plaintiffs repeat and reallege the allegations of paragraphs 1-40 as if fully set forth herein.

42. Amneal's submission of ANDA No. 208857 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 in/into the United States 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 1 and 5, under 35 U.S.C. § 271 (e)(2)(A).

43. Amneal had notice of the '136 patent at the time of its infringement. Amneal's infringement has been, and continues to be, deliberate.

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

45. 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

46. Plaintiffs repeat and reallege the allegations of paragraphs 1-45 as if fully set forth herein.

47. 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. Amneal has taken immediate and active steps, through its submission of its ANDA No. 208857, 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.

48. Upon FDA approval of ANDA No. 208857, Amneal will infringe one or more of the claims of the '136 patent, including but not limited to Claims 1 and 5, under §§ 271 (a), (b), or (c) by making, using, selling, offering for sale, or importing the Clofarabine ANDA Injection in/into the United States prior to the expiration of '136 patent, 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).

49. Upon FDA approval of ANDA No. 208857, use of the Clofarabine ANDA Injection 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 1 and 5, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (a), unless enjoined by this Court.

50. Amneal has taken and intends 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 1 and 5, under 35 U.S.C. § 271 (b) and/or § 271 (c) after ANDA No. 208857 is approved, unless enjoined by this Court.

51. Amneal has knowledge of the '136 patent and, by the prescribing information it will include with its Clofarabine ANDA Injection, knows or should know that it 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 1 and 5, either literally or under the doctrine of equivalents.

52. Amneal's offering for sale, sale, and/or importation of the Clofarabine ANDA Injection in/into the United States with the prescribing information 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 1 and 5, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b).

53. The use of the Clofarabine ANDA Injection constitutes a material part of at least one of the claims of the '136 patent; Amneal knows 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 1 and 5, either literally or under the doctrine of equivalents; and Amneal knows that the Clofarabine ANDA Injection is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

54. Amneal's manufacture, use, offering for sale, sale, and/or importation of the Clofarabine ANDA Injection in/into the United States will contributorily infringe at least one of the claims of the '136 patent, including but not limited to Claims 1 and 5, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (c).

55. Amneal will have notice of the '136 patent at the time of its infringement. Amneal's infringement will be deliberate.

56. Plaintiffs will be substantially and irreparably harmed if Amneal's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that Amneal has infringed one or more claims of the '136 patent by the filing of ANDA No. 208857;

(b) A judgment declaring that Amneal's 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. 208857 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date no earlier than July 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 Amneal 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 Amneal 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 Amneal 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: June 29, 2016

WALSH PIZZI O'REILLY FALANGA 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: June 29, 2016

WALSH PIZZI O'REILLY FALANGA 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: June 29, 2016

WALSH PIZZI O'REILLY FALANGA LLP

s/ Liza M. Walsh

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