IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORP. and THE REGENTS OF THE UNIVERSITY OF MICHIGAN, Plaintiffs, v. AIZANT DRUG RESEARCH SOLUTIONS PRIVATE LIMITED, Defendants.	)	C.A. No. 19-1734-CFC (CONSOLIDATED)

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF DEFENDANT

Plaintiffs Genzyme Corp. ("Genzyme") and The Regents of the University of Michigan ("U of M") (collectively, "Plaintiffs"), by way of their Complaint against Defendant Aizant Drug Research Solutions Private Limited ("Aizant" or "Defendant"), allege as follows:

NATURE OF THE ACTION

1. Defendant admits that this action purports to be an action for patent infringement, and that the recited ANDA application seeks FDA approval to market a generic version of CERDELGA®, but denies any patent infringement as alleged by Plaintiffs.

PARTIES

2. Admitted.

3. Admitted.

4. Admitted.

5. Admitted.

6. Defendant denies the allegations of Paragraph 6 of the Complaint as phrased, but does not contest venue in this Court solely for the purposes of this action.

JURISDICTION AND VENUE

7. Defendant does not dispute that this action purports to be an action arising under the patent laws of the United States of America, but denies any patent infringement as alleged by Plaintiffs.

8. Defendant does not dispute, for purposes of this action only, that this Court has personal jurisdiction over this matter, and otherwise denies the allegations of Paragraph 8 of the Complaint.

9. Defendant does not dispute, for purposes of this action only, that this Court has personal jurisdiction over Aizant, and otherwise denies the allegations of Paragraph 9 of the Complaint.

10. Defendant does not dispute, for purposes of this action only, that this Court has personal jurisdiction over Aizant, and otherwise denies the allegations of Paragraph 10 of the Complaint.

11. Defendant does not dispute that this Court has venue for purposes of this action only, and otherwise denies the allegations of Paragraph 11 of the Amended Complaint.

CERDELGA®

12. Admitted.

13. Admitted.

14. Defendant admits that eliglustat is the active ingredient in CERDELGA®, and that eliglustat is a small molecule inhibitor of glucosylceramide synthase, but denies that this compound is novel.

15. Admitted.

16. Admitted.

THE PATENTS-IN-SUIT

17. Defendant admits that, according to the first page of the '802 patent the USPTO issued it on July 12, 2005 and is entitled "Amino Ceramide-Like Compounds and Therapeutic Methods of Use." Defendant admits that what appears to be a true copy of the '802 patent is attached as Exhibit A. Defendant denies any inference that said patent was duly or legally issued.

18. Defendant admits that, according to the first page of the '185 patent the USPTO issued it on August 7, 2007 and is entitled "Amino Ceramide-Like Compounds and Therapeutic Methods of Use." Defendant admits that what appears to be a true copy of the '185 patent is attached as Exhibit B. Defendant denies any inference that said patent was duly or legally issued.

19. Defendant admits that, according to the first page of the '573 patent the USPTO issued it on November 10, 2009 and is entitled "Synthesis of UDP-Glucose: N-Acylsphingosine Glucosyltransferase Inhibitors." Defendant admits that what appears to be a true copy of the '573 patent is attached as Exhibit C. Defendant denies any inference that said patent was duly or legally issued.

20. Defendant denies that Eliglustat is covered by one or more claims of the '802, '185, and '573 patents. Defendant admits that the *Orange Book* presently lists the '802, '185, and '573 patents in relation to the CERDELGA® product.

21. Admitted.

AIZANT'S ANDA NO. 212463

22. Admitted.

23. Admitted.

24. Admitted.

25. Admitted.

26. Admitted.

COUNT I
INFRINGEMENT OF THE ’802 PATENT

27. Defendant incorporates its responses to paragraphs 1-26 as if fully set forth herein.

28. Admitted.

29. Defendant admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Products in the United States before expiration of the ’802 patent. Defendant denies the remaining allegations of Paragraph 29 of the Complaint as phrased, and affirmatively states that Defendant will decide whether to market its product only upon FDA approval.

30. Admitted.

31. Defendant admits that its August 12, 2019 letter identifies the established name of the drug product that is the subject of its ANDA is Eliglustat Tartrate, EQ 84gm base, oral capsule, and otherwise denies the allegations contained and inferred in Paragraph 31 of the Complaint.

32. Denied.

33. Admitted.

34. Defendant admits to filing its ANDA, and that filing its ANDA with a Paragraph IV certification to the ’802 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant denies the balance of the allegations of Paragraph 34 of the Complaint, and otherwise state that the remaining allegations set forth in paragraph 34 of the Complaint are legal conclusions to which no responsive pleading is necessary.

35. Denied.

36. Defendant admits actual knowledge of the ’802 patent prior to filing its ANDA, and that filing its ANDA with a Paragraph IV certification to the ’802 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant denies the balance of the allegations of Paragraph 36 of the Complaint, and otherwise states that the remaining allegations set forth in paragraph 36 of the Complaint are legal conclusions to which no responsive pleading is necessary.

37. Denied.

38. Denied.

39. Denied.

40. Denied.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’802 PATENT

41. Defendant incorporates its responses to paragraphs 1-40 as if fully set forth herein.

42. Defendant admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Products before expiration of the ’802 patent. Defendant denies the remaining allegations of Paragraph 42 of the Complaint as phrased, and affirmatively states that Defendant will decide whether to market its product only upon FDA approval.

43. Denied.

44. Denied.

45. Admitted.

46. Denied.

47. Denied.

COUNT III
INFRINGEMENT OF THE '185 PATENT

48. Defendant incorporates its responses to paragraphs 1-47 as if fully set forth herein.

49. Admitted.

50. Defendant admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Products in the United States before expiration of the '185 patent. Defendant denies the remaining allegations of Paragraph 50 of the Complaint as phrased, and affirmatively states that Defendant will decide whether to market its product only upon FDA approval.

51. Admitted.

52. Defendant admits that its August 12, 2019 letter identifies the established name of the drug product that is the subject of its ANDA is Eliglustat Tartrate, EQ 84gm base, oral capsule, and otherwise denies the allegations contained and inferred in Paragraph 52 of the Complaint.

53. Admitted.

54. Defendant admits to filing its ANDA, and that filing its ANDA with a Paragraph IV certification to the '185 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant denies the balance of the allegations of Paragraph 54 of the Complaint, and otherwise state that the remaining allegations set forth in paragraph 54 of the Complaint are legal conclusions to which no responsive pleading is necessary.

55. Denied.

56. Defendant admits actual knowledge of the '185 patent prior to filing its ANDA, and that filing its ANDA with a Paragraph IV certification to the '185 patent is a technical act of

infringement under 35 U.S.C. § 271(e). Defendant denies the balance of the allegations of Paragraph 56 of the Complaint, and otherwise state that the remaining allegations set forth in paragraph 56 of the Complaint are legal conclusions to which no responsive pleading is necessary.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '185 PATENT

61. Defendant incorporates its responses to paragraphs 1-60 as if fully set forth herein.

62. Defendant admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Products before expiration of the '185 patent. Defendant denies the remaining allegations of Paragraph 62 of the Complaint as phrased, and affirmatively states that Defendant will decide whether to market its product only upon FDA approval.

63. Denied.

64. Denied.

65. Admitted.

66. Denied.

67. Denied.

COUNT V
INFRINGEMENT OF THE '573 PATENT

68. Defendant incorporates its responses to paragraphs 1-67 as if fully set forth herein.

69. Admitted.

70. Defendant admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Products in the United States before expiration of the '573 patent. Defendant denies the remaining allegations of Paragraph 70 of the Complaint as phrased, and affirmatively states that Defendant will decide whether to market its product only upon FDA approval.

71. Admitted.

72. Defendant admits that its August 12, 2019 letter identifies the established name of the drug product that is the subject of its ANDA is Eliglustat Tartrate, EQ 84gm base, oral capsule, and otherwise denies the allegations contained and inferred in Paragraph 72 of the Complaint.

73. Denied.

74. Admitted.

75. Defendant admits to filing its ANDA, and that filing its ANDA with a Paragraph IV certification to the '573 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant denies the balance of the allegations of Paragraph 75 of the Complaint, and otherwise state that the remaining allegations set forth in paragraph 75 of the Complaint are legal conclusions to which no responsive pleading is necessary.

76. Denied.

77. Defendant admits actual knowledge of the ’573 patent prior to filing its ANDA, and that filing its ANDA with a Paragraph IV certification to the ’573 patent is a technical act of infringement under 35 U.S.C. § 271(e). Defendant denies the balance of the allegations of Paragraph 77 of the Complaint, and otherwise state that the remaining allegations set forth in paragraph 77 of the Complaint are legal conclusions to which no responsive pleading is necessary.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’573 PATENT

82. Defendant incorporates its responses to paragraphs 1-81 as if fully set forth herein.

83. Defendant admits that it filed its ANDA and Paragraph IV certifications to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Products before expiration of the ’573 patent. Defendant denies the remaining allegations of Paragraph 83 of the Complaint as phrased, and affirmatively states that Defendant will decide whether to market its product only upon FDA approval.

84. Denied.

85. Denied.

86. Admitted.

87. Denied.

88. Denied.

RESPONSE TO REQUEST FOR RELIEF

Defendant denies that Plaintiffs are entitled to any of the relief requested by the Complaint, or any other relief whatsoever.

AFFIRMATIVE DEFENSES

In further response to the Complaint, and as additional defenses thereto, Defendant assert the following affirmative defenses without prejudice to any denial in their Answer, and without admission to any allegation in the Complaint, unless otherwise explicitly admitted above. Defendant reserve the right to assert additional defenses in view of further information and/or analysis.

FIRST SEPARATE DEFENSE

(Non-Infringement)

The manufacture, use, sale, offer for sale, or importation of the ANDA products have not, do not and will not infringe any valid and enforceable claim of the ’802, ’185, and ’573 patents either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

SECOND SEPARATE DEFENSE

(Lack of Irreparable Harm)

Plaintiffs have planned for, and in fact anticipated, the filing of several ANDA applications with the FDA for the approval of generic forms of its CERDELGA® product for many years. Accordingly, should Aizant’s ANDA product be approved and should it further be sold in the United States market, Plaintiffs would not be irreparably harmed as a result of such anticipated competition. Further, should such sales occur, there are adequate remedies at law available, assuming such sales are found to infringe the ’802, ’185, and ’573 patents.

Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

THIRD SEPARATE DEFENSE

(Failure To State A Claim)

The Complaint is subject to dismissal for failure to state a claim upon which relief may be granted.

FOURTH SEPARATE DEFENSE

(Failure To State A Claim)

Each and every claim of the '802, '185, and '573 patents is invalid for failure to satisfy one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 103 and 112.

FIFTH SEPARATE DEFENSE

(Other Defenses)

Defendant reserve all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent laws and any additional defenses or counterclaims that discovery may reveal including that Plaintiffs have failed to avert any facts supporting the conclusion that this is an exceptional case and an award of attorney's fees under 35 U.S.C. § 285 is warranted.

COUNTERCLAIMS

In further response to the Complaint, Defendant allege the following counterclaims, without prejudice to any denial in their Answer, and without admission to any allegation in the Complaint, unless otherwise explicitly admitted above, and without assuming any burden when such burden would otherwise be Plaintiffs'.

PARTIES

1. Counterclaimant Aizant Drug Research Solutions Private Limited is a corporation organized and existing under the laws of India, with a principal place of business at Sy. No. 172 & 173, Apparel Park Road, Dulapally Village, Quthbullapur Mandal, Hyderabad, 500014 India.

2. Counterclaim Defendant Genzyme Corp. ("Genzyme") is a corporation organized and existing under the laws of Commonwealth of Massachusetts, having its principal place of business at 50 Binney Street, Cambridge, Massachusetts 02142. Genzyme is engaged in the business of research, development, manufacture, and sale of pharmaceutical products.

3. Counterclaim Defendant The Regents of the University of Michigan ("The Regents") is a constitutional corporation of the State of Michigan, having a principal place of business at 1600 Huron Parkway, 2nd Floor, Ann Arbor, MI 48109.

JURISDICTION AND VENUE

4. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) and by Counterclaim Defendants filing of its action against Aizant. This Court may declare the rights and legal relation of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5).

THE CONTROVERSY

5. Aizant holds Abbreviated New Drug Application ("ANDA") No. 212463 for eliglustat tablets.

6. On or about September 16, 2019, Counterclaim Defendants filed the present action against Aizant alleging infringement of U.S. Patent No. 6,916,802 (the "'802 patent"), U.S. Patent No. 7,253,185 (the "'185 patent"), and U.S. Patent No. 7,615,573 (the "'573 patent") (collectively the "patents-in-suit"), arising from Aizant submission of ANDA No. 212463. There

is a real, substantial, and continuing justiciable controversy between the parties because of the commencement by Counterclaim Defendants of their action and the filing by Aizant of ANDA No. 212463 with a certification that the ’802, ’185, and ’573 patents are invalid, unenforceable and/or will not be infringed by the manufacture, sale and use of the products of Aizant’s ANDA No. 212463.

7. The patents-in-suit effectively prevents approval of Aizant’s ANDA No. 212463 and the manufacture, sale and use of the products that are the subject of Aizant’s ANDA No. 212463. Aizant and Counter Defendants have adverse legal interests with respect to the patents-in-suit of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

COUNT I

DECLARATORY JUDGMENT OF INVALIDITY OF THE ’802 PATENT

8. Aizant repeats and incorporates by reference paragraphs 1-7 of its Counterclaim as if fully set forth herein.

9. A present, genuine, and justiciable controversy exists between Aizant and Counterclaim Defendants regarding, *inter alia*, the invalidity of the ’802 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgement.

10. The ’802 patent would be found anticipated and/or obvious to one of ordinary skill in the art in view of at least the prior art that is identified in the letter that is the subject of paragraphs 30-33 of the Complaint, as well as the prior art and argument identified in Defendants’ Joint Invalidity Contentions, served on June 12, 2019, in matter No. C.A. 18-1795-CFC.

11. Based at least upon on the prior art identified in said letter, one of ordinary skill in the art would have selected for development compounds known in the prior art as potent

inhibitors of glucosylceramide synthase and then would have been motivated to modify these compounds in obvious ways to arrive at the compounds claimed in the ’802 patent with a reasonable expectation of success.

12. The ’802 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code including without limitation, one or more of §§102, 103, and /or 112.

13. Aizant is entitled to a judicial declaration that the ’802 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT II

DECLARATORY JUDGMENT OF INVALIDITY OF THE ’185 PATENT

14. Aizant repeats and incorporates by reference paragraphs 1-13 of its Counterclaims as if fully set forth herein.

15. A present genuine, and justiciable controversy exists between Aizant and Counterclaim Defendants regarding, *inter alia*, the invalidity of the ’185 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgement.

16. The ’185 patent would be found obvious to one of ordinary skill in the art in view of at least the prior art that is identified in the letter that is the subject of paragraphs 51-54 of the Complaint, as well as the prior art and argument identified in Defendants’ Joint Invalidity Contentions, served on June 12, 2019, in matter No. C.A. 18-1795-CFC.

17. Based on the prior art identified in said letter, one of ordinary skill in the art would have selected for development compounds known in the prior art as potent inhibitors of glucosylceramide synthase and then would have been motivated to modify the compounds recited in the claims of the ‘185 in obvious ways to arrive at the compounds claimed in the ’185

patent with a reasonable expectation of success, and one of ordinary skill in the art would readily understand that pharmaceutical compositions with such compounds would contain one or more pharmaceutically acceptable carriers and/or excipients in order to treat patients having a glycosphingolipidosis disorder.

18. The ’185 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code including without limitation, one or more of §§103, and /or 112.

19. Aizant is entitled to a judicial declaration that the ’802 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT III

DECLARATORY JUDGMENT OF INVALIDITY OF THE ’573 PATENT

20. Aizant repeats and incorporates by reference paragraphs 1-19 of its Counterclaims as if fully set forth herein.

21. A present genuine, and justiciable controversy exists between Aizant and Counterclaim Defendants regarding, *inter alia*, the invalidity of the ’573 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgement.

22. The ’573 patent would be found obvious to one of ordinary skill in the art in view of at least the prior art that is identified in the letter that is the subject of paragraphs 71-74 of the Complaint, as well as the prior art and argument identified in Defendants’ Joint Invalidity Contentions, served on June 12, 2019, in matter No. C.A. 18-1795-CFC.

23. Based on the prior art identified in said letter, one of ordinary skill in the art would have selected for development compounds known in the prior art as potent inhibitors of glucosylceramide synthase and then would have been motivated to modify these compounds in

obvious ways to arrive at the compounds claimed in the '573 patent with a reasonable expectation of success, and it would have been obvious to one having ordinary skill in the art to administer the claimed compounds to a patient to treat the claimed disorders.

24. The '573 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code including without limitation, one or more of §§103, and /or 112.

25. Aizant is entitled to a judicial declaration that the '802 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

PRAYER FOR RELIEF

WHEREFORE, Aizant respectfully request the Court to enter judgment against Plaintiffs and Counterclaim-Defendant to include:

(a) Dismissing the Complaint with prejudice;

(b) Declaring that Aizant's submission of ANDA No. 212463 seeking FDA approval to market its ANDA products will not directly, indirectly, contributorily, and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '802, '185, and '573 patents under 35 U.S.C. § 271;

(c) Declaring that Aizant's commercial manufacture, use, offer for sale, sale, or importation of its ANDA products will not directly, indirectly, contributorily, and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '802, '185, and '573 patents under 35 U.S.C. § 271;

(d) Declaring that the claims of the patents-in-suit are invalid for failure to comply with one or more provisions of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103 and/or 112;

(e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Aizant its attorneys' fees, costs and expenses.

(f) Declaring that Plaintiff and Counterclaim Defendant are entitled to no damages, interest, costs, or other relief from or against Aizant; and

(g) Awarding Aizant such other further relief as the Court deems just and equitable.

/s/ Kelly E. Farnan

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