IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ZS PHARMA, INC. and ASTRAZENECA PHARMACEUTICALS LP,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ZS Pharma, Inc. and AstraZeneca Pharmaceuticals LP, collectively, "AstraZeneca" or "Plaintiffs", bring this action for patent infringement against Macleods Pharmaceuticals Ltd. ("Macleods Ltd.") and Macleods Pharma USA, Inc. ("Macleods Inc."), collectively "Defendants" or "Macleods".

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 217541, filed by and for the benefit of Defendants with the United States Food and Drug Administration ("FDA"). Through ANDA No. 217541, Defendants seek approval to market generic versions of LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet (the "Proposed ANDA Product"), prior to the expiration of U.S. Patent Nos. 8,877,255 ("the '225 Patent"), 9,592,253

("the '253 Patent"), 9,913,860 ("the '860 Patent"), 10,300,087 ("the '087 Patent"), and 10,695,365 ("the '365 Patent") (collectively, "the Patents-in-Suit").

THE PARTIES

2. Plaintiff ZS Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business in Wilmington, Delaware.

3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of Delaware, having a principal place of business in Wilmington, Delaware.

4. On information and belief, Defendant Macleods Ltd. is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai 400059, Maharashtra, India.

5. On information and belief, Defendant Macleods Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 103 College Road East (2nd Floor), Princeton, New Jersey, 08540.

JURISDICTION AND VENUE

6. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of the submission of Defendants' ANDA No. 217541 to the FDA.

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 1 et seq.

8. This Court has personal jurisdiction over Macleods Ltd. because, inter alia, it has maintained continuous and systematic contacts with this District and availed itself of the privilege of doing business in this District. On information and belief, Macleods Ltd. has: (1) acted in

concert with Macleods Inc. to file ANDA No. 217541 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product in the United States, including in this District; (2) regularly and continuously transacted business within this District, including by selling pharmaceutical products in this District either on its own or through its affiliates; and (3) derived substantial revenue from the sale of those products in this District. Alternatively, this Court has personal jurisdiction over Macleods Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2).

9. This Court has personal jurisdiction over Macleods Inc. because, on information and belief, Macleods Inc. is a corporation organized and existing under the laws of Delaware.

10. On information and belief, if ANDA No. 217541 is approved, the Proposed ANDA Product accused of infringing the Patents-in-Suit will be marketed, distributed, offered for sale, and/or sold in this District, prescribed by physicians practicing in this District, dispensed by pharmacies located within this District, and/or used by patients in this District, all of which would have a substantial effect on this District.

11. This Court also has personal jurisdiction over Defendants because they have affirmatively availed themselves of the jurisdiction of this Court through the assertion of counterclaims in suits brought in this District and/or by being sued in this District without challenging personal jurisdiction. *See, e.g., Anacor Pharmaceuticals, Inc. et al. v. Macleods Pharmaceuticals Ltd.*, 21-1350 (D. Del.); *Merck Sharp & Dohme Corp. v. Macleods Pharmaceuticals Ltd. et al.*, 19-316 (D. Del.); *Genentech, Inc. et al. v. Macleods Pharmaceuticals Ltd et al.*, 19-154 (D. Del.); *Boehringer Ingelheim Pharm. Inc. et al. v. Macleods Pharmaceuticals Ltd et al.*, 18-1764 (D. Del.).

12. For the reasons set forth above, and for additional reasons which will be supplied if Defendants challenge personal jurisdiction in this action, Defendants are subject to personal jurisdiction in this District.

13. Venue is proper in this District for Macleods Ltd. pursuant to 28 U.S.C. § 1391(c) because, *inter alia*, Macleods Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this District.

14. Venue is proper in this District for Macleods Inc. pursuant to 28 U.S.C. § 1400(b) because Macleods Inc. is a corporation organized and existing under the laws of Delaware.

THE PATENTS-IN-SUIT

15. The Patents-in-Suit are assigned to ZS Pharma, Inc.

16. The ’255 Patent, entitled “Microporous Zirconium Silicate for the Treatment of Hyperkalemia,” was duly and legally issued on November 4, 2014. A copy of the ’255 Patent is attached as Exhibit A.

17. The ’253 Patent, entitled “Extended Use Zirconium Silicate Compositions and Methods of Use Thereof,” was duly and legally issued on March 14, 2017. A copy of the ’253 Patent is attached as Exhibit B.

18. The ’860 Patent, entitled “Microporous Zirconium Silicate for the Treatment of Hyperkalemia,” was duly and legally issued on March 13, 2018. A copy of the ’860 Patent is attached as Exhibit C.

19. The ’087 Patent, entitled “Extended Use Zirconium Silicate Compositions and Methods of Use Thereof,” was duly and legally issued on May 28, 2019. A copy of the ’087 Patent is attached as Exhibit D.

20. The '365 Patent, entitled "Microporous Zirconium Silicate for the Treatment of Hyperkalemia," was duly and legally issued on June 30, 2020. A copy of the '365 Patent is attached as Exhibit E.

FACTUAL BACKGROUND

LOKELMA® (sodium zirconium cyclosilicate)

21. LOKELMA® (sodium zirconium cyclosilicate) is a drug used to treat hyperkalemia. Marked elevations in serum potassium can cause fatal heart arrhythmias and abnormalities in conduction (progression of electrical impulses through the heart) and muscle weakness and paralysis. LOKELMA® (sodium zirconium cyclosilicate) is a non-absorbed zirconium silicate that preferentially captures potassium in exchange for hydrogen and sodium, thereby lowering serum potassium levels.

22. AstraZeneca is the holder of approved New Drug Application ("NDA") No. 207078 for LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet. Pursuant to NDA No. 207078, AstraZeneca markets and distributes LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet in the United States.

23. LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet, the active pharmaceutical ingredient sodium zirconium cyclosilicate, the method of manufacture, and/or their use are covered by one or more claims of the Patents-in-Suit. The Patents-in-Suit have been listed for NDA No. 207078 in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is also known as the "Orange Book."

Defendants' ANDA No. 217541

24. In a letter dated July 14, 2022 (the "Notice Letter"), Defendants stated that they had submitted ANDA No. 217541 to the FDA seeking approval to commercially manufacture, use,

offer for sale, sell, and/or import the Proposed ANDA Product prior to the expiration of the Patents-in-Suit. The Notice Letter further stated that ANDA No. 217541 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product.

25. Defendants were aware of the Patents-in-Suit when they submitted ANDA No. 217541 with a Paragraph IV Certification.

26. On information and belief, sodium zirconium cyclosilicate is the active ingredient in the Proposed ANDA Product.

27. On information and belief, the Proposed ANDA Product exhibits sodium zirconium cyclosilicate as patented by the Asserted Patents.

28. On information and belief, ANDA No. 217541 refers to and relies upon the NDA for LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and LOKELMA® (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet. *See* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

29. On information and belief, Defendants intend to have healthcare providers use the Proposed ANDA Product, if approved, as set forth in the Proposed ANDA Product label. On information and belief, Defendants' Proposed ANDA Product label will instruct healthcare providers to prescribe the Proposed ANDA Product in the manner set forth in the label.

30. On information and belief, the FDA has not yet approved ANDA No. 217541.

31. Plaintiffs commenced this action within 45 days of receipt of the Notice Letter.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,877,255

32. Plaintiffs hereby reallege and incorporate the allegations of paragraphs 1 – 31 of this Complaint.

33. On information and belief, the Proposed ANDA Product infringes one or more claims of the '255 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of a sodium zirconium silicate as covered by one or more of the claims of the '255 Patent.

34. Defendants' submission of ANDA No. 217541 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product before the expiration of the '255 Patent constitutes infringement of the '255 Patent under 35 U.S.C. § 271(e)(2).

35. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217541 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

36. On information and belief, upon FDA approval of ANDA No. 217541, Defendants will infringe the '255 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

37. On information and belief, Defendants had knowledge of the '255 Patent when they submitted ANDA No. 217541 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '255 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '255 Patent.

38. To date, Plaintiffs have not received sufficient information, materials, and things from Defendants to enable Plaintiffs to meaningfully evaluate the bases for Defendants' assertion of non-infringement of the '255 Patent.

39. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 217541, Plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Defendants infringe one or more claims of the '255 Patent.

40. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 9,592,253

41. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 40 of this Complaint.

42. On information and belief, the Proposed ANDA Product infringes one or more claims of the '253 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of a sodium zirconium silicate as covered by one or more of the claims of the '253 Patent.

43. Defendants' submission of ANDA No. 217541 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product before the expiration of the '253 Patent constitutes infringement of the '253 Patent under 35 U.S.C. § 271(e)(2).

44. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217541 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

45. On information and belief, upon FDA approval of ANDA No. 217541, Defendants will infringe the '253 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

46. On information and belief, Defendants had knowledge of the '253 Patent when they submitted ANDA No. 217541 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '253 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '253 Patent.

47. To date, Plaintiffs have not received sufficient information, materials, and things from Defendants to enable Plaintiffs to meaningfully evaluate the bases for Defendants' assertion of non-infringement of the '253 Patent.

48. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 217541, Plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Defendants infringe one or more claims of the '253 Patent.

49. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 9,913,860

50. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 49 of this Complaint.

51. On information and belief, the Proposed ANDA Product infringes one or more claims of the ’860 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of a sodium zirconium silicate as covered by one or more of the claims of the ’860 Patent.

52. Defendants’ submission of ANDA No. 217541 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product before the expiration of the ’860 Patent constitutes infringement of the ’860 Patent under 35 U.S.C. § 271(e)(2).

53. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217541 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

54. On information and belief, upon FDA approval of ANDA No. 217541, Defendants will infringe the ’860 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

55. On information and belief, Defendants had knowledge of the ’860 Patent when they submitted ANDA No. 217541 to the FDA, Defendants knew or should have known that they will induce or contribute to another’s direct infringement of the ’860 Patent, and Defendants acted with the specific intent to induce or contribute to another’s direct infringement of the ’860 Patent.

56. To date, Plaintiffs have not received sufficient information, materials, and things from Defendants to enable Plaintiffs to meaningfully evaluate the bases for Defendants' assertion of non-infringement of the '860 Patent.

57. In the absence of the ability to meaningfully evaluate information related to Defendants' ANDA No. 217541, Plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Defendants infringe one or more claims of the '860 Patent.

58. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 10,300,087

59. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 58 of this Complaint.

60. On information and belief, the Proposed ANDA Product infringes one or more claims of the '087 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of a sodium zirconium silicate as covered by one or more of the claims of the '087 Patent.

61. Defendants' submission of ANDA No. 217541 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product before the expiration of the '087 Patent constitutes infringement of the '087 Patent under 35 U.S.C. § 271(e)(2).

62. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217541 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

63. On information and belief, upon FDA approval of ANDA No. 217541, Defendants will infringe the '087 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

64. On information and belief, Defendants had knowledge of the '087 Patent when they submitted ANDA No. 217541 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '087 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '087 Patent.

65. In the Notice Letter, Defendants do not dispute that the Proposed ANDA Product infringes one or more claims of the '087 Patent.

66. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 10,695,365

67. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1 – 66 of this Complaint.

68. On information and belief, the Proposed ANDA Product infringes one or more claims of the '365 Patent, either literally or under the doctrine of equivalents, by the use and/or

presence in the Proposed ANDA Product of a sodium zirconium silicate as covered by one or more of the claims of the '365 Patent.

69. Defendants' submission of ANDA No. 217541 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product before the expiration of the '365 Patent constitutes infringement of the '365 Patent under 35 U.S.C. § 271(e)(2).

70. On information and belief, Defendants plan to, intend to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217541 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

71. On information and belief, upon FDA approval of ANDA No. 217541, Defendants will infringe the '365 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

72. On information and belief, Defendants had knowledge of the '365 Patent when they submitted ANDA No. 217541 to the FDA, Defendants knew or should have known that they will induce or contribute to another's direct infringement of the '365 Patent, and Defendants acted with the specific intent to induce or contribute to another's direct infringement of the '365 Patent.

73. In the Notice Letter, Defendant does not dispute that the Proposed ANDA Product infringes one or more claims of the '365 Patent.

74. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

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

a) Judgment that Defendants' submission of ANDA No. 217541 to the FDA was an act of infringement of one or more claims of the '255, '253, '860, '087, and '365 Patents under 35 U.S.C. § 271(e)(2);

b) Judgment that Defendants' making, using, offering to sell, selling, or importing into the United States of the Proposed ANDA Product prior to the expiration of the '255, '253, '860, '087, and '365 Patents, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more claims of those Patents;

c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 217541 shall be a date that is not earlier than the expiration of the '255, '253, '860, '087, and '365 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

d) An Order permanently enjoining Defendants, Defendants' affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Defendants, from making, using, offering to sell, selling, or importing into the United States the Proposed ANDA Product until after the expiration of the '255, '253, '860, '087, and '365 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

e) A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, expenses, and disbursements of this action;

f) An award of Plaintiffs' reasonable costs and expenses in this action; and

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

DATED: August 22, 2022

MCCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiffs ZS Pharma, Inc. and AstraZeneca Pharmaceuticals LP

OF COUNSEL:

Lisa B. Pensabene
Hassen Sayeed
Daniel O'Boyle
James Li
O'MELVENY & MYERS LLP
7 Times Square
New York, New York 10036
(212) 326-2000