IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ZS PHARMA, INC. and ASTRAZENECA PHARMACEUTICALS LP,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ALKEM LABORATORIES LTD.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ZS Pharma, Inc. and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca" or "Plaintiffs") bring this action for patent infringement against Alkem Laboratories Ltd. ("Alkem" or "Defendant").

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. 217558, filed by and for the benefit of Defendant with the United States Food and Drug Administration ("FDA"). Through ANDA No. 217558, Defendant seeks 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 No. 11,738,044 ("the '044 Patent").

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 Alkem is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, India 400 013.

JURISDICTION AND VENUE

5. 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 Defendant's ANDA No. 217558 to the FDA.

6. 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.

7. This Court has personal jurisdiction over Alkem 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, Alkem has (1) filed ANDA No. 217558 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 Alkem pursuant to Federal Rule of Civil Procedure 4(k)(2).

8. On information and belief, if ANDA No. 217558 is approved, the Proposed ANDA Product accused of infringing the '044 Patent 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.

9. This Court also has personal jurisdiction over Alkem because it has affirmatively availed itself 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. For example, Alkem did not contest this Court's jurisdiction in Plaintiffs' previously-filed civil action regarding Defendants' ANDA No. 217558, Civil Action No. 22-1096-GBW. *See ZS Pharma, Inc. et al. v. Alkem Laboratories Ltd.*, Civil Action No. 22-1096-GBW, D.I. 17 at ¶¶ 7–10 (D. Del).

10. For the reasons set forth above, and for additional reasons which will be supplied if Defendant challenges personal jurisdiction in this action, Defendant is subject to personal jurisdiction in this District.

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

THE '044 PATENT

12. The '044 Patent is assigned to ZS Pharma, Inc.

13. The '044 Patent, entitled "Extended Use Zirconium Silicate Compositions and Methods of Use Thereof," was duly and legally issued on August 29, 2023. A copy of the '044 Patent is attached as Exhibit A.

FACTUAL BACKGROUND

LOKELMA® (sodium zirconium cyclosilicate)

14. 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.

15. 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.

16. 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 '044 Patent. The '044 Patent has 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."

Defendant's ANDA No. 217558

17. In a letter dated July 14, 2022 (the "Notice Letter"), Defendant stated that it had submitted ANDA No. 217558 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product. The Notice Letter further stated that ANDA No. 217558 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") that U.S. Patent Nos. 8,877,255 ("the '255 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") 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. Plaintiffs timely filed suit with respect to those patents on August 22, 2022. *See ZS Pharma, Inc. et al. v. Alkem Laboratories Ltd.*, Civil Action No. 22-1096-GBW, D.I. 1 (D. Del).

18. On information and belief, Defendants have amended or will amend ANDA No. 217558 to include a Paragraph IV Certification that the '044 Patent is 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.

19. Defendants' submission of ANDA No. 217558 to the FDA constitutes infringement of one or more claims of the '044 Patent under 35 U.S.C. § 271(e)(2)(A). Although the '044 Patent did not issue until after ANDA No. 217558 was filed, this does not preclude Defendants from infringement liability under 35 U.S.C. § 271(e)(2). *See Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1127 (Fed. Cir. 2018).

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

21. On information and belief, the Proposed ANDA Product exhibits sodium zirconium cyclosilicate as patented by the '044 Patent.

22. On information and belief, ANDA No. 217558 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 Defendant, 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).

23. On information and belief, Defendant intends to have healthcare providers use its Proposed ANDA Product, if approved, as set forth in the Proposed ANDA Product label.

24. On information and belief, Defendant's Proposed ANDA Product label will instruct healthcare providers to prescribe the Proposed ANDA Product in the manner set forth in the label.

25. On information and belief, the FDA has not yet approved ANDA No. 217558.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,738,044

26. Plaintiffs hereby reallege and incorporate the allegations of paragraphs 1 – 25 of this Complaint.

27. On information and belief, the Proposed ANDA Product infringes one or more claims of the '044 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 '044 Patent.

28. Defendant's submission of ANDA No. 217558 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 '044 Patent constitutes infringement of the '044 Patent under 35 U.S.C. § 271(e)(2).

29. On information and belief, Defendant plans to, intends to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217558 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

30. On information and belief, upon FDA approval of ANDA No. 217558, Defendant will infringe the '044 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).

31. On information and belief, Defendants have or will have knowledge that if they were to receive approval from the FDA to market the Proposed ANDA Product described in ANDA No. 217558 and make the Proposed ANDA Product available for sale and/or use by others, e.g., by doctors, pharmacists, healthcare providers and patients, according to the package insert and prescribing information during the proposed shelf life of the products before expiration of the '044 Patent, such activities would result in the sale and/or use of a product that itself infringes and/or is especially made for an infringing use. Upon information and belief, Defendants have or will have knowledge of such infringement and/or such infringing use and also knows or will know that the Proposed ANDA Product described in ANDA No. 217558 are not a staple article or commodity of commerce suitable for substantial non-infringing use, but rather are especially made to infringe and/or are especially adapted for use in the direct infringement of the '044 Patent.

32. 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 Defendant's submission of ANDA No. 217558 to the FDA was an act of infringement of one or more claims of the '044 Patent under 35 U.S.C. § 271(e)(2);

b) Judgment that Defendant's making, using, offering to sell, selling, or importing into the United States of the Proposed ANDA Product prior to the expiration of the '044 Patent, will

infringe, will actively induce infringement, and/or will contribute to the infringement of one or more claims of the '044 Patent;

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. 217558 shall be a date that is not earlier than the expiration of the '044 Patent plus any other exclusivity to which Plaintiffs are or become entitled;

d) An Order permanently enjoining Defendant, Defendant's affiliates and subsidiaries, each of its officers, agents, servants and employees, and any person acting in concert with Defendant, from making, using, offering to sell, selling, or importing into the United States the Proposed ANDA Product until after the expiration of the '044 Patent 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: October 20, 2023

MCCARTER & ENGLISH, LLP

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