

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

)	
ZS PHARMA, INC. and)	
ASTRAZENECA PHARMACEUTICALS)	
LP,)	
)	
Plaintiffs,)	C.A. No. _____
)	
v.)	
)	
ASCENT PHARMACEUTICALS INC.)	
AND HETERO DRUGS LTD.,)	
)	
Defendants.)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ZS Pharma, Inc. and AstraZeneca Pharmaceuticals LP, collectively, “AstraZeneca” or “Plaintiffs”, bring this action for patent infringement against Ascent Pharmaceuticals Inc. (“Ascent”) and Hetero Drugs Ltd. (“Hetero”), collectively, “Defendants”.

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. 217578, filed by and for the benefit of Defendants with the United States Food and Drug Administration (“FDA”). Through ANDA No. 217578, 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. 8,802,152 (“the ’152 Patent”), 8,808,750 (“the ’750 Patent”), 8,877,255 (“the ’255 Patent”), 9,592,253 (“the ’253 Patent”), 9,844,567 (“the ’567 Patent”), 9,861,658 (“the ’658 Patent”), 9,913,860 (“the ’860 Patent”), 10,300,087 (“the ’087

Patent”), 10,335,432 (“the ’432 Patent”), 10,398,730 (“the ’730 Patent”), 10,413,569 (“the ’569 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 Ascent is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 400 South Technology Drive, Central Islip, New York.

5. On information and belief, Defendant Hetero is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Telangana, India.

6. On information and belief, Defendants collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group.

7. On information and belief, Defendants acted in concert to develop the Proposed ANDA Product that is the subject of ANDA No. 217578 and to seek regulatory approval from the FDA to market and sell the Proposed ANDA Product throughout the United States, including within this District.

8. Defendants' ANDA No. 217578 seeks approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of AstraZeneca's LOKELMA[®] (sodium zirconium cyclosilicate) for oral suspension 5 g per packet and 10 g per packet prior to the expiration of the Patents-in-Suit.

9. On information and belief, Defendants' ANDA No. 217578 references a Drug Master File for sodium zirconium cyclosilicate held by Hetero Drugs Ltd.

10. On information and belief, Defendants intend to act collaboratively to obtain approval for Defendants' ANDA No. 217578, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product.

JURISDICTION AND VENUE

11. 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. 217578 to the FDA.

12. 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.

13. This Court has personal jurisdiction over Defendants because, inter alia, they have maintained continuous and systematic contacts with this District and availed themselves of the privilege of doing business in this District. On information and belief, Defendants: (1) acted in concert to file ANDA No. 217578 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 their own or through their affiliates; and

(3) derived substantial revenue from the sale of those products in this District. Alternatively, this Court has personal jurisdiction over Hetero pursuant to Federal Rule of Civil Procedure 4(k)(2).

14. On information and belief, if ANDA No. 217578 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.

15. 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., Vifor Pharma, Inc. et al. v. Alkem Laboratories Ltd. et al.*, 20-106 (D. Del.); *Anacor Pharmaceuticals, Inc. v. Ascent Pharmaceuticals, Inc., et al.*, 18-1673 (D. Del.); *Duchesnay Inc. et al. v. Hetero Labs Limited*, 21-1130 (D. Del.); *Otsuka Pharmaceutical Co., Ltd. et al. v. Hetero Labs, Ltd.*, 20-cv-1531 (D. Del.).

16. This Court also has personal jurisdiction over Ascent at least because Ascent has confirmed that it will not contest personal jurisdiction in this District for purposes of litigation involving ANDA No. 217578.

17. 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.

18. Venue is proper in this District for Ascent at least because Ascent has confirmed that it will not contest venue in this District for purposes of litigation involving ANDA No. 217578.

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

THE PATENTS-IN-SUIT

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

21. The '152 Patent, entitled "Microporous Zirconium Silicate for the Treatment of Hyperkalemia," was duly and legally issued on August 12, 2014. A copy of the '152 Patent is attached as Exhibit A.

22. The '750 Patent, entitled "Microporous Zirconium Silicate for the Treatment of Hyperkalemia," was duly and legally issued on August 19, 2014. A copy of the '750 Patent is attached as Exhibit B.

23. 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 C.

24. 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 D.

25. The '567 Patent, entitled "Microporous Zirconium Silicate for the Treatment of Hyperkalemia," was duly and legally issued on December 19, 2017. A copy of the '567 Patent is attached as Exhibit E.

26. The '658 Patent, entitled "Microporous Zirconium Silicate for the Treatment of Hyperkalemia," was duly and legally issued on January 9, 2018. A copy of the '658 Patent is attached as Exhibit F.

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