

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

SUPERNUS PHARMACEUTICALS, INC.,

Plaintiff,

v.

ALKEM LABORATORIES LTD.,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Supernus Pharmaceuticals, Inc. (“Supernus” or “Plaintiff”), by its undersigned attorneys, for its Complaint against Defendant Alkem Laboratories Ltd. (“Alkem” or “Defendant”), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 (“the ’576 patent”), 8,298,580 (“the ’580 patent”), 8,663,683 (“the ’683 patent”), 8,877,248 (“the ’248 patent”), 8,889,191 (“the ’191 patent”), 8,992,989 (“the ’989 patent”), 9,549,940 (“the ’940 patent”), 9,555,004 (“the ’004 patent”), 9,622,983 (“the ’983 patent”), and 10,314,790 (“the ’790 patent”) attached hereto as Exhibits A–J (collectively, “the patents in suit”).

THE PARTIES

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

3. Upon information and belief, Alkem is a corporation operating and existing under the laws of India, with its principal place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (W), Mumbai – 400 013, Maharashtra, India.

4. Upon information and belief, Alkem filed an Abbreviated New Drug Application (“ANDA”) No. 217248 (“the Alkem ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of generic topiramate extended-release capsules, containing 25 mg, 50 mg, 100 mg, and 200 mg of topiramate (“the Alkem ANDA Products”).

5. On or about May 25, 2022, Alkem sent a letter purportedly pursuant to subsections 505(j)(2)(B) and 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) and 21 C.F.R. § 314.95 stating that it had submitted Abbreviated New Drug Application (ANDA) No. 217248 to FDA seeking approval to market the Alkem ANDA Products, and containing a paragraph IV certification under 35 U.S.C. § 355(j)(2)(B)(iv) concerning the ’576, ’580, ’683, ’248, ’191, ’989, ’940, ’004, ’983, and ’790 patents (the “May 25 Notice Letter”).

JURISDICTION AND VENUE

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

7. Alkem is subject to personal jurisdiction in the State of Illinois and this Judicial District because the May 25 Notice Letter identified an attorney located within this district as its agent for service with respect to this matter, stating that Manish K. Mehta, E-mail: mmehta@beneschlaw.com, Benesch Friedlander Coplan & Aronoff, 71 South Wacker Drive,

Suite 1600, Chicago, Illinois 60606, “is authorized to accept service of process on behalf of Alkem.”

8. Alkem is also subject to personal jurisdiction in the State of Illinois and this Judicial District because, among other reasons, Alkem, itself and through its affiliates, has purposefully availed itself of the benefits and protections of Illinois’s laws such that it should reasonably anticipate being sued here. On information and belief, Alkem, itself and through its affiliates, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Illinois and this Judicial District, and therefore transacts business within the State of Illinois and this Judicial District, and/or has engaged in systematic and continuous business contacts within the State of Illinois and this Judicial District.

9. Upon information and belief, Alkem is in the business of manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Illinois and this Judicial District. Upon information and belief, Alkem directly or through its affiliates and agents, formulates, manufactures, packages, markets, and/or sells pharmaceutical products throughout the United States, including in the State of Illinois and this Judicial District. Indeed, Alkem’s website states that the “United States is the focal point of international operations. In this stride, we have cumulatively filed more than 125 ANDAs with the US FDA.” Alkem Website, <https://www.alkemlabs.com/overview.php> (last visited July 6, 2022). Alkem’s website further states that “we manufacture and supply a wide-range of generics and branded formulations in the United States,” and “[o]ur products are available at major pharmacy chains, wholesalers, managed care companies, distributors and pharmaceutical retailers.” Alkem Website, <https://www.alkemlabs.com/us.php> (last visited July 6, 2022).

10. Upon information and belief, upon approval of the Alkem ANDA, Defendant and/or its affiliates or agents will distribute, market, and sell the Alkem ANDA Products in the State of Illinois and this Judicial District, and also throughout the United States, and Alkem will derive substantial revenue therefrom.

11. Upon information and belief, upon approval of Alkem's ANDA, Defendant and/or its affiliates or agents will place the Alkem ANDA Products into the stream of commerce with the reasonable expectation or knowledge and the intent that such products will ultimately be purchased and used by consumers in the State of Illinois and this Judicial District.

12. Upon information and belief, Defendant derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredients used in generic pharmaceutical products sold throughout the United States, including in the State of Illinois and this Judicial District.

13. Defendant has taken the significant step of applying to FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the State of Illinois and this Judicial District and elsewhere throughout the United States. Upon information and belief, Defendant intends to direct sales of its generic drugs in the State of Illinois and this Judicial District, among other places, once Defendant receives the requested FDA approval to market its generic products. Upon information and belief, Defendant will engage in marketing its proposed Alkem ANDA Products in the State of Illinois and this Judicial District if FDA approves the Alkem ANDA.

14. Defendant's tortious acts of (i) preparing and filing the Alkem ANDA with a paragraph IV certification to the patents in suit for the purpose of obtaining approval to engage in

the commercial manufacture, use, offer to sell, and/or sale within the United States, and/or importation into the United States, of the Alkem ANDA Products before the expiration of the patents in suit, and (ii) directing notice of its ANDA submission to Supernus, are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, offer to sell, and/or sale of the Alkem ANDA Products by Defendant before the expiration of the patents in suit throughout the United States, including in the State of Illinois and this Judicial District. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Defendant should reasonably anticipate being sued in the State of Illinois and this Judicial District.

15. Upon information and belief, Defendant intends to benefit directly if the Alkem ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of the Alkem ANDA.

16. This Court also has personal jurisdiction over Alkem because, among other reasons, Alkem has previously consented to personal jurisdiction in this Judicial District.¹

17. This Court has personal jurisdiction over Alkem under Federal Rule of Civil Procedure 4(k)(2) because, among other reasons, Alkem is organized under the laws of India.

¹ This Court also has personal jurisdiction over Alkem because it has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by asserting claims/counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Janssen Pharm., Inc. et al. v. Alkem Labs. Ltd.*, No. 13-9227 (N.D. Ill.), Dkt. 14; *Forest Labs., Inc. et al. v. Indchemie Health Specialties Pvt. Ltd. et al.*, No. 12-1855 (N.D. Ill.), Dkt. 22; *Shire Canada Inc., et al. v. Alkem Labs., Ltd.*, No. 11-206 (N.D. Ill.), Dkt. 11.

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