IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC. and KINDEVA DRUG DELIVERY L.P.,

Defendants.

Civil Action No. **1:22-CV-35 (Kleeh)**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP (collectively, "Plaintiffs"), by their attorneys, file this Complaint against Defendants Mylan Pharmaceuticals Inc. ("Mylan") and Kindeva Drug Delivery L.P. ("Kindeva") (collectively, "Defendants"), and allege the following:

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(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 211699 filed by or for the benefit of Defendants with the United States Food and Drug Administration ("FDA"). Through this ANDA, Defendants seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of Plaintiffs' Symbicort® pharmaceutical products prior to the expiration of U.S. Patent No. 11,311,558 ("the '558 patent"). Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

THE PARTIES

Plaintiffs

2. Plaintiff AstraZeneca AB is a corporation organized and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP is the holder of approved New Drug Application No. 021929 for Symbicort.

Defendants

4. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a company organized and existing under the laws of the State of West Virginia, with a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

5. On information and belief, Defendant Kindeva is a company organized under and existing under the laws of the State of Delaware, with a place of business at 42 Water Street, Building 75, St. Paul, Minnesota 55170.

6. Defendants, working in collaboration with each other and with or through their subsidiaries, agents, and affiliates, are in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic versions of branded pharmaceutical products in the United States. As a part of this business, Defendants participate in operations related to preparing and filing ANDAs with FDA.

BACKGROUND

The NDA

7. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application ("NDA") No. 021929 for Symbicort (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol.

8. Each Symbicort canister is formulated as a pressurized metered dose inhaler ("inhaler"). Symbicort is a prescription drug approved for the treatment of asthma in patients 6 years of age and older and maintenance treatment in patients with chronic obstructive pulmonary disease ("COPD") including bronchitis and emphysema. Budesonide and formoterol fumarate dihydrate are the two active ingredients in Symbicort. Symbicort is available in an 80 mcg budesonide/4.5 mcg formoterol fumarate dihydrate dosage and a 160 mcg budesonide/4.5 mcg formoterol fumarate dihydrate dosage.

9. FDA approved NDA No. 021929 on July 21, 2006.

10. Plaintiff AstraZeneca Pharmaceuticals LP sells and distributes Symbicort throughout the United States pursuant to NDA No. 021929.

The Patent-in-Suit

11. The '558 patent, entitled "Composition for Inhalation," was issued by the United States Patent and Trademark Office ("the USPTO") on April 26, 2022, to AstraZeneca AB, upon assignment from the inventors Nayna Govind and Maria Marlow. The '558 patent claims, *inter alia*, a pharmaceutical composition comprising formoterol fumarate dihydrate, budesonide or an epimer thereof, 1,1,1,2,3,3,3-heptafluoropropane ("HFA227"), PVP K25 (polyvinyl pyrrolidone with a nominal K-value of 25) and PEG 1000 (polyethylene glycol with a polymer length resulting in an average molecular weight of 1000 daltons), wherein the PVP K25 and PEG are present at certain concentrations. Specifically, claim 3 recites a pharmaceutical composition comprising formoterol, budesonide or an epimer thereof, HFA 227, about 0.0005 to about 0.05% w/w PVP K25, and 0.3% w/w PEG 1000.

12. The '558 patent is related through continuation applications to U.S. Patent Nos. 7,759,328 ("the '328 patent"), 8,143,239 ("the '239 patent"), 8,575,137 ("the '137 patent"), and 10,166,247 ("the '247 patent"), which are also directed to pharmaceutical compositions of

formoterol, budesonide, HFA 227, PVP K25, and PEG 1000 similar to the '558 patent. The patents share a common specification.

13. A true and correct copy of the '558 patent is attached as Exhibit A.

14. Plaintiff AstraZeneca AB has been and still is the owner of the '558 patent.

ANDA No. 211699

15. On information and belief, 3M Company, through its 3M Drug Delivery Systems division, submitted ANDA No. 211699 to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale in the United States of Budesonide and Formoterol Fumarate Dihydrate Inhalation Aerosol, 80 mcg/4.5 mcg and 160 mcg/4.5 mcg ("Mylan's ANDA Products"), generic versions of the two dosage forms of Symbicort, prior to the expiration of the patent-in-suit.

16. On information and belief, FDA sent a Paragraph IV Acknowledgment Letter for ANDA No. 211699 to 3M on August 15, 2018.

17. On information and belief, 3M transferred certain interests in ANDA No. 211699 to Mylan on August 17, 2018.

18. On information and belief, on May 1, 2020, 3M closed on a transaction whereby 3M sold substantially all of its drug delivery systems business (f/k/a 3M Drug Delivery Systems) to an affiliate of Altaris Capital Partners, LLC ("Altaris").

19. On information and belief, following this transaction, Altaris launched Kindeva as an independent company, and all of 3M's activities relating to ANDA No. 211699 were transferred to Kindeva.

20. On information and belief, Mylan purports to be the current owner of ANDA No. 211699.

21. On information and belief, Kindeva, formerly 3M Drug Delivery Systems, will

manufacture Mylan's ANDA Products.

22. On information and belief, Defendants have assisted with and participated in the preparation and submission of ANDA No. 211699, have provided material support to the preparation and submission of ANDA No. 211699, and intend to support the further prosecution of ANDA No. 211699.

23. On information and belief, Defendants will manufacture, offer for sale, or sell Mylan's ANDA Products within the United States, including within West Virginia, or will import Mylan's ANDA Products into the United States, including West Virginia.

24. On information and belief, Defendants will actively induce or contribute to infringement by Mylan's ANDA Products.

25. On information and belief, ANDA No. 211699 was approved on March 16, 2022, and Defendants intend to support the further prosecution of ANDA No. 211699 before FDA and may only manufacture, offer for sale, or sell Mylan's ANDA Products within the United States, including within West Virginia; import Mylan's ANDA Products into the United States, including West Virginia; and actively induce or contribute to infringement by Mylan's ANDA Products subject to the maintenance of FDA's approval.

26. By letters dated August 30, 2018 ("First Notice Letter") and October 11, 2019 ("Second Notice Letter"), Mylan notified Plaintiffs that it had filed ANDA No. 211699 seeking approval to market Mylan's ANDA Products and that Mylan was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. §§ 314.94 and 314.95. The First and Second Notice Letters, sent by Mylan, represented that Mylan owned ANDA No. 211699 and that Mylan had submitted purported Paragraph IV certifications to obtain approval to engage in the commercial manufacture, use, or sale of the product described in ANDA No. 211699

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