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

before the expiration of the patents listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book, for Symbicort.

27. In its First Notice Letter, Mylan alleged that the '328, '239, and '137 patents are invalid, not infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products, and/or unenforceable. In its Second Notice Letter, Mylan alleged that the '247 patent is invalid, not infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products, and/or unenforceable.

28. The parties proceeded to trial on the '328, '239, and '137 patents (the "Trial Patents") in October 2020. Prior to trial, Defendants stipulated to infringement of the asserted claims of the Trial Patents, which are similar to those of the '558 patent and likewise recite pharmaceutical compositions of formoterol, budesonide or an epimer thereof, HFA 227, PVP K25, and PEG 1000. For example, claim 13 of the '328 patent recites "[a] pharmaceutical composition comprising formoterol fumarate dihydrate, budesonide, HFA227, PVP K25, and PEG-1000, wherein the formoterol fumarate dihydrate is present at a concentration of 0.09 mg/ml, the budesonide is present at a concentration of 2 mg/ml, the PVP K25 is present at a concentration of 0.001% w/w, and the PEG-1000 is present at a concentration of 0.3% w/w."

29. After a five-day trial, the Court entered judgment of nonobviousness as to each asserted claim. The Court held that the person of ordinary skill in the art ("POSA") would not have been motivated to make the multiple independent selections from the prior art required to arrive at the asserted claims, including the propellant HFA227, the excipient PVP K25, the excipient PEG-1000, and the concentration of PEG-1000. *AstraZeneca AB v. Mylan Pharm. Inc.*, 522 F. Supp. 3d 200, 216–19 (N.D. W. Va. 2021). Furthermore, the Court found that the prior art "teaches away and does not render the claims obvious," because it "cut against the very

goal a POSA would have been trying to achieve—a stable product with a consistent dose." *Id.* at 219–20. The Court likewise found that "a POSA would not have had a reasonable expectation of success in creating a stable budesonide pMDI using HFA 227, PVP K25, and PEG-1000, much less when these ingredients were combined with formoterol," *id.* at 220, and that the claimed compositions demonstrated unexpected properties, *id.* at 220-21.

30. Mylan appealed, and the Federal Circuit affirmed the Court's judgment of nonobviousness, specifically upholding the Court's finding that the prior art taught away from the claimed invention. *AstraZeneca AB v. Mylan Pharm. Inc.*, 19 F.4th 1325, 1337–38 (Fed. Cir. 2021). The Federal Circuit disagreed with the Court's construction of a term not at issue in most claims of the '558 patent ("0.001%"), and vacated for further proceedings, *id.* at 1338, which are currently underway in this District with respect to the '247 patent.

31. By letter dated March 8, 2022, Plaintiffs notified Mylan through its counsel that the USPTO allowed the pending claims of U.S. Patent Application No. 16/832,590 ("the '590 application"), which issued as the '558 patent on April 26, 2022. AstraZeneca's letter notified Mylan that its proposed generic Symbicort products infringe every limitation of the allowed claims. AstraZeneca's letter also notified Mylan that the allowed claims were substantially identical to the invention claimed in U.S. Patent Application Publication No. 2021/0069215 ("the '215 publication").

32. A copy of AstraZeneca's letter, which includes the '215 publication, is attached here as Exhibit B.

JURISDICTION

33. Plaintiffs incorporate each of the preceding paragraphs as though fully set forth herein.

34. Subject matter jurisdiction over this action is proper pursuant to 28 U.S.C.

§§ 1331 and 1338.

Personal Jurisdiction over Mylan Pharmaceuticals Inc.

35. On information and belief, Defendant Mylan 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.

36. On information and belief, Defendant Mylan has extensive contacts with the State of West Virginia, regularly conducts business in the State of West Virginia, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of West Virginia, and intends to sell in the State of West Virginia the products described in ANDA No. 211699. Furthermore, on information and belief, Mylan has a regular and established place of business in this judicial district.

37. On information and belief, Defendant Mylan is engaged in the business of challenging patents held by branded pharmaceutical companies, including in this judicial district. Mylan has consented to jurisdiction and venue in this Court, and availed itself of the protections afforded by this Court, including by asserting counterclaims in this Court.

38. This Court has personal jurisdiction over Defendant Mylan by virtue of the fact that Mylan has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in the State of West Virginia, including acts of patent infringement with respect to Mylan's ANDA Products. These acts have led and will lead to foreseeable harm and injury to AstraZeneca AB and AstraZeneca Pharmaceuticals LP in this judicial district. For example, on information and belief, Mylan will make, use, import, sell, and/or offer for sale Mylan's ANDA Products throughout the United States, including in the

State of West Virginia, prior to the expiration of the patent-in-suit.

39. On information and belief, Defendant Mylan, and/or its subsidiaries, affiliates or agents, intends to engage in the commercial manufacture and sale of Mylan's ANDA Products, before the expiration of the patent-in-suit throughout the United States, including in this judicial district, and to derive substantial revenue therefrom.

40. On information and belief, Defendant Mylan, and/or its subsidiaries, affiliates or agents, intends to place Mylan's ANDA Products into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this judicial district.

41. On information and belief, Defendant Mylan regularly solicits business in the State of West Virginia, engages in other persistent courses of conduct in this State, and/or derives substantial revenues from the services or products used or consumed in the State of West Virginia.

Personal Jurisdiction over Kindeva Drug Delivery L.P.

42. This Court has personal jurisdiction over Defendant Kindeva by virtue of the fact that Kindeva has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in the State of West Virginia, including acts of patent infringement with respect to Mylan's ANDA Products. These acts have led and will lead to foreseeable harm and injury to AstraZeneca AB and AstraZeneca Pharmaceuticals LP in this judicial district. For example, on information and belief, Kindeva will make, use, import, sell, and/or offer for sale Mylan's ANDA Products, throughout the United States, including in the State of West Virginia, prior to the expiration of the patent-in-suit.

43. On information and belief, Defendant Kindeva and/or its subsidiaries, affiliates or

agents, intends to engage in the commercial manufacture and/or sale of Mylan's ANDA Products, before the expiration of the patent-in-suit throughout the United States, including in this judicial district, and to derive substantial revenue therefrom.

44. On information and belief, Defendant Kindeva regularly conducts and/or solicits business in the State of West Virginia, engages in other persistent courses of conduct in this State, and/or derives substantial revenues from the services or products used or consumed in the State of West Virginia.

45. On information and belief, Defendants participated in the preparation, development, and filing of ANDA No. 211699, and its underlying subject matter, with the intent to market, sell, and/or distribute Mylan's ANDA Products to the residents of the State of West Virginia. Plaintiffs' cause of action arose from Defendants' contact with the State of West Virginia.

46. This Court therefore has personal jurisdiction over all Defendants.

VENUE

47. Plaintiffs incorporate each of the preceding paragraphs as though fully set forth herein.

48. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

49. Venue is proper as to Defendant Mylan because Mylan resides in this judicial district, has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, intends a future course of conduct that includes acts of patent infringement in the State of West Virginia, and has a regular and established place of business in this judicial district. On information and belief, Defendants will make, use, import, sell, and/or offer for sale Mylan's ANDA Products throughout the United States, including in the

State of West Virginia, prior to the expiration of the patent-in-suit.

50. Venue is proper as to Defendant Kindeva because Kindeva has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, intends a future course of conduct that includes acts of patent infringement in the State of West Virginia. These acts have led and will lead to foreseeable harm and injury to AstraZeneca AB and AstraZeneca Pharmaceuticals LP in this judicial district. For example, on information and belief, Defendant Kindeva will make, use, import, sell, and/or offer for sale Mylan's ANDA Products throughout the United States, including in the State of West Virginia, prior to the expiration of the patent-in-suit.

51. On information and belief, Kindeva has consented to venue in West Virginia for purposes of this litigation.

52. Venue is proper as to all Defendants.

COUNT 1
INFRINGEMENT OF THE '558 PATENT

53. Plaintiffs incorporate by reference the preceding paragraphs as though fully set forth herein.

54. On information and belief, Defendants submitted or caused the submission of ANDA No. 211699 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Mylan's ANDA Products in the United States before the expiration of the '558 patent.

55. Under 35 U.S.C. § 271(e)(2)(A), the submission of ANDA No. 211699 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products before the expiration of the '558 patent constitutes infringement of one or more claims of the '558 patent, either literally or under the doctrine of equivalents.

56. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products would infringe the '558 patent and/or actively induce and/or contribute to infringement of the '558 patent. Accordingly, unless enjoined by this Court, Defendants will make, use, offer to sell, or sell Mylan's ANDA Products within the United States, or will import Mylan's ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '558 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

57. On information and belief, Defendants will market and distribute Mylan's ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users. On information and belief, Defendants will also knowingly and intentionally accompany Mylan's ANDA Products with a product label and product insert that will include instructions for using and administering the ANDA Products. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of Mylan's ANDA Products to directly infringe one or more claims of the '558 patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '558 patent and knowledge that they are encouraging infringement.

58. Defendants have actual and constructive notice of the '558 patent by at least April 26, 2022 through the filing of this Complaint. Based on this disclosure, Defendants have had further knowledge of, or were willfully blind to, the '558 patent and that Mylan's ANDA Products would infringe one or more claims of the '558 patent.

59. Defendants have no reasonable basis to assert that the commercial manufacture, use, offer for sale, or sale of Mylan's ANDA Products will not contribute to the infringement of and/or induce the infringement of the '558 patent.

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

COUNT 2
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '558 PATENT

61. Plaintiffs restate, reallege, and incorporate by reference the preceding paragraphs as though fully set forth herein.

62. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

63. On information and belief, Mylan's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of West Virginia, by or through Defendants and their affiliates.

64. On information and belief, Defendants know that health care professionals or patients will use Mylan's ANDA Products in accordance with the labeling sought by ANDA No. 211699 and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '558 patent under one or more of 35 U.S.C. §§ 271(b), (c), (f) and/or (g).

65. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Mylan's ANDA Product complained of herein will begin imminently. Any such conduct before the '558 patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '558 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and/or (g).

66. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the

infringement of the '558 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

67. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

68. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211699 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's ANDA Products before the expiration of the '558 patent was an act of infringement of one or more claims of the '558 patent;

B. A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and/or (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '558 patent;

C. The entry of a permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and/or § 283, enjoining Defendants, their affiliates and subsidiaries, and all persons and entities acting in concert with Defendants from commercially manufacturing, using, offering for sale, or selling Mylan's ANDA Products within the United States, or importing Mylan's ANDA Products into the United States, until the expiration of the '558 patent;

D. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 211699 shall be no earlier than the expiration date of the

'558 patent, or any later expiration of exclusivity for the '558 patent, including any extensions or regulatory exclusivities;

E. An award of damages or other relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and/or 284, if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Products, or any product that infringes the '558 patent, or induces or contributes to such conduct, prior to the expiration of the '558 patent;

F. The entry of judgment declaring that Defendants' acts render this case an exceptional case, and awarding Plaintiffs attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

G. An award to Plaintiffs of their costs and expenses in this action; and

H. Such further relief as this Court may deem just and proper.

Dated: April 26, 2022

Respectfully submitted,

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/s/ Sandra K. Law

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