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

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, MYLAN INC., and MYLAN N.V.,

Defendants.

Civil Action No. 1:18-CV-193

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, Mylan Inc., and Mylan N.V. (collectively, "Defendants" or "Mylan"), allege as follows:

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 ("the Mylan ANDA") 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 Nos. 7,759,328 ("the '328 patent"), 8,143,239 ("the '239 patent"), 8,575,137 ("the '137 patent"), and 7,967,011 ("the

'011 patent") (collectively, "the patents-in-suit"). 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 ("AstraZeneca AB") is a corporation operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

3. Plaintiff AstraZeneca Pharmaceuticals LP ("AstraZeneca Pharmaceuticals LP") is a limited partnership operating 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, Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Inc.

6. On information and belief, Defendant Mylan Laboratories Limited is a company organized and existing under the laws of India with its principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad 500034, India.

7. On information and belief, Mylan Laboratories Limited is a wholly-owned subsidiary of Mylan Inc.

8. On information and belief, Defendant Mylan Inc. is a company organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

9. On information and belief, Mylan Inc. is an indirectly wholly-owned subsidiary of Mylan N.V.

10. On information and belief, Defendant Mylan N.V. is a company organized and existing under the laws of the Netherlands, with its global headquarters and principal offices located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England.

11. On information and belief, Mylan N.V. is the ultimate corporate parent of Mylan Inc., Mylan Laboratories Limited, and Mylan Pharmaceuticals Inc.

12. 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 the FDA. As part of these ANDAs, Defendants file certifications pursuant to Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacturer, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such branded pharmaceutical products.

BACKGROUND

The NDA

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

14. The FDA approved NDA No. 021929 on July 21, 2006.

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

The Patents-in-Suit

16. United States Patent No. 7,759,328 ("the '328 patent"), entitled "Composition for Inhalation," was issued by the United States Patent and Trademark Office ("the USPTO") on July 20, 2010, to AstraZeneca AB, upon assignment from the inventors Nayna Govind and Maria Marlow. The '328 patent claims, *inter alia*, a pharmaceutical composition comprising formoterol fumarate dihydrate, budesonide, 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 an average molecular weight of 1,000), wherein the formoterol fumarate dihydrate, budesonide, PVP K25 and PEG-1000 are present in certain concentrations. A true and correct copy of the '328 patent is attached as Exhibit A.

17. Plaintiff AstraZeneca AB has been and still is the owner of the '328 patent.

18. United States Patent No. 8,143,239 ("the '239 patent"), entitled "Composition for inhalation," was issued by the USPTO on March 27, 2012 to AstraZeneca AB upon assignment

from inventors Nayna Govind and Maria Marlow. The claims of the '239 patent are directed to, *inter alia*, a pressurized metered dose inhaler containing a suspension composition comprising formoterol fumarate dihydrate, budesonide, HFA227, polyvinyl pyrrolidone ("PVP"), and polyethylene glycol ("PEG"), wherein the budesonide is present in a certain concentration and wherein an actuation of the inhaler delivers a certain dosage of formoterol fumarate dihydrate and budesonide. A true and correct copy of the '239 patent is attached as Exhibit B.

19. Plaintiff AstraZeneca AB has been and still is the owner of the '239 patent.

20. United States Patent No. 8,575,137 ("the '137 patent"), entitled "Composition for inhalation," was issued by the USPTO on November 5, 2013, to AstraZeneca AB upon assignment from inventors Nayna Govind and Maria Marlow. The claims of the '137 patent are directed to, *inter alia*, a pharmaceutical suspension composition comprising formoterol fumarate dihydrate, budesonide, HFA227, PVP, and PEG, wherein the budesonide, PVP, and PEG are present in certain concentrations. A true and correct copy of the '137 patent is attached as Exhibit C.

21. Plaintiff AstraZeneca AB has been and still is the owner of the '137 patent.

22. United States Patent No. 7,967,011 ("the '011 patent"), entitled "Inhalation device," was issued by the USPTO on June 28, 2011 to AstraZeneca AB upon assignment from inventors Darren Hodson and Jorgen Rasmussen. The claims of the '011 patent are directed to, *inter alia*, an actuator for an inhaler for delivering medicament by inhalation, the actuator comprising a main body tubular member; an ovoid, tubular mouthpiece; and a removable protection cap with release buttons. A true and correct copy of the '011 patent is attached as Exhibit D.

23. Plaintiff AstraZeneca AB has been and still is the owner of the '011 patent.

The ANDA

24. On information and belief, Defendants have submitted or caused to be 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 of 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 patents-in-suit.

25. By letter dated August 30, 2018 ("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 Notice Letter, sent by Mylan Pharmaceuticals Inc., represented that it had submitted to FDA ANDA No. 211699 and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the Mylan ANDA before the expiration of the patents listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book, for Symbicort.

26. In its Notice Letter, and through its Paragraph IV certification in the Mylan ANDA, Mylan alleges that the patents-in-suit are invalid, not infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products, and/or unenforceable.

27. Mylan's Notice Letter included an Offer of Confidential Access to the Mylan ANDA, subject to restrictions and terms set forth in the Notice Letter. The Offer of Confidential Access limited access to Mylan's ANDA to outside attorneys only.

28. After receiving the Notice Letter and accompanying Offer of Confidential Access, Plaintiffs attempted to negotiate reasonable terms of access to the Mylan ANDA. On September 17, 2018, after Mylan refused to make any modifications to its Offer of Confidential Access, Plaintiffs agreed to the original terms of the Offer of Confidential Access and requested prompt delivery of a copy of Mylan's ANDA as well as samples of Mylan's ANDA Products.

29. On October 1, 2018, Defendants produced in total 56 heavily redacted pages of Mylan's ANDA. None of the pages contained specifications of the inhaler(s) used in Mylan's ANDA Products. Due to the heavy redactions, none of the pages of Mylan's ANDA that Defendants produced identified any of the individuals or entities involved in developing, manufacturing or testing Mylan's ANDA Products or preparing Mylan's ANDA. Mylan refused to provide its complete, unredacted ANDA or samples of its ANDA Products.

30. On information and belief, Defendants have assisted with and participated in the preparation and submission of the Mylan ANDA, have provided material support to the preparation and submission of the Mylan ANDA, and intend to support the further prosecution of the Mylan ANDA.

31. On information and belief, if FDA approves the Mylan ANDA, 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.

32. On information and belief, if FDA approves the Mylan ANDA, Defendants will actively induce or contribute to infringement by Mylan's ANDA Products.

33. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiffs' receipt of the Notice Letter.

JURISDICTION

34. Plaintiffs incorporate each of the preceding paragraphs as if each fully set forth herein.

35. Subject matter jurisdiction over this action is proper pursuant to 28 U.S.C. §§ 1331 and 1338.

Personal Jurisdiction over Mylan Pharmaceuticals Inc.

36. On information and belief, Defendant Mylan Pharmaceuticals Inc. is incorporated in the State of West Virginia, with a regular and established place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

37. On information and belief, Mylan Pharmaceuticals Inc. is engaged in the business of challenging patents held by branded pharmaceutical companies, including in this judicial district. Mylan Pharmaceuticals Inc. 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. *See, e.g.*, *Bristol-Myers Squibb Co. et al. v. Mylan Pharmaceuticals Inc.*, 1:1 7-cv-00055 (N.D. W.Va.); *Gilead Sciences, Inc. v. Mylan Pharmaceuticals Inc.*, 1:17-cv-00036 (N.D. W.Va.); *Novartis Pharmaceuticals Corp. et al. v. Mylan Pharmaceuticals Inc.*, 1:1 7-cv-00054 (N.D. W.Va.).

38. On information and belief, Defendant Mylan Pharmaceuticals Inc. 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 product described in ANDA No. 211699 upon approval.

39. On information and belief, Defendant Mylan Pharmaceuticals Inc. is registered with the State of West Virginia Secretary of State as a Domestic Corporation, Business Purpose 3254 - Manufacturing - Chemical Manufacturing - Pharmaceutical and Medicine Manufacturing (in-Vitro diagnostic) and maintains Organization Number 20402.

Personal Jurisdiction over Mylan Laboratories Limited

40. On information and belief, Defendant Mylan Laboratories Limited is engaged in the business of challenging patents held by branded pharmaceutical companies, including in this judicial district. Defendant Mylan Laboratories Limited 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. *See, e.g.*, *Pfizer Inc. et al. v. Mylan Inc. et al.*, C.A. No. 1:15-cv-188-IMK (N.D. W.Va.); *Fresenius Kabi USA, LLC et al. v. Mylan Laboratories Ltd.*, C.A. No. 1:15-cv-185-IMK (N.D. W.Va.).

41. On information and belief, Defendant Mylan Laboratories Limited has substantial, continuous, and systematic contacts with the State of West Virginia including Defendant Mylan Laboratories Limited's engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of West Virginia.

42. This Court has personal jurisdiction over Defendant Mylan Laboratories Limited by virtue of the fact that Mylan Laboratories Limited 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, upon receiving approval from the FDA, Defendant Mylan Laboratories Limited 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 patents-in-suit.

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

44. On information and belief, Defendant Mylan Laboratories Limited 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.

45. On information and belief, Defendant Mylan Inc. 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. On information and belief, Defendant Mylan Laboratories Limited is registered to do business in this judicial district.

Personal Jurisdiction over Mylan Inc.

46. On information and belief, Defendant Mylan Inc. is engaged in the business of challenging patents held by branded pharmaceutical companies, including in this judicial district. Defendant Mylan Inc. 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. *See, e.g.*, *Sanofi-Aventis U.S. LLC et al. v. Mylan Pharmaceuticals Inc. et al.*, C.A. No. 1:17-cv-5-IMK (N.D. W.Va.); *Pfizer Inc. et al. v. Mylan Inc. et al.*, C.A. No. 1:15-cv-188-IMK (N.D.

W.Va.); *Fresenius Kabi USA, LLC et al. v. Mylan Laboratories Ltd.*, C.A. No. 1:15-cv-185-IMK (N.D. W.Va.).

47. On information and belief, Defendant Mylan Inc. has substantial, continuous, and systematic contacts with the State of West Virginia including Defendant Mylan Inc.'s engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of West Virginia.

48. This Court has personal jurisdiction over Defendant Mylan Inc. by virtue of the fact that Mylan Inc. 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, upon receiving approval from the FDA, Defendant Mylan Inc. 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 patents-in-suit.

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

50. On information and belief, Defendant Mylan Inc., 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.

51. On information and belief, Defendant Mylan Inc. 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. On information and belief, Defendant Mylan Inc. is registered to do business in this judicial district.

Personal Jurisdiction over Mylan N.V.

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

53. On information and belief, Defendant Mylan N.V. has substantial, continuous, and systematic contacts with the State of West Virginia including Defendant Mylan N.V.'s engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of West Virginia.

54. This Court has personal jurisdiction over Defendant Mylan N.V. by virtue of the fact that Mylan N.V. 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, upon receiving approval from the FDA,

Defendant Mylan N.V. 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 patents-in-suit.

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

56. On information and belief, Defendant Mylan N.V., 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.

57. On information and belief, Defendant Mylan N.V. 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.

58. On information and belief, Defendants Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, Mylan Inc., and Mylan N.V. are alter egos of each other. On information and belief, Defendants Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, Mylan Inc., and/or Mylan N.V. cooperate with each other in sale and marketing of generic pharmaceutical products and act as agents of one another.

59. 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.

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

VENUE

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

62. Venue is proper as to Defendant Mylan Pharmaceuticals Inc. because Mylan Pharmaceuticals Inc. 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, upon receiving approval from the FDA, Defendants will make, use, import, sell, and/or offer for sale the Mylan's ANDA Products, throughout the United States, including in the State of West Virginia, prior to the expiration of the patents-in-suit.

63. Venue is proper as to Defendant Mylan Laboratories Limited because Mylan Laboratories Limited 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 on information and belief has a regular and established place of business in the State of West Virginia, *inter alia*, through at least one or more affiliates, subsidiaries, parents, alter egos, agents and/or other entities in the Mylan corporate family who have a regular and established place of business in West Virginia. On information and belief, upon receiving approval from the FDA, Defendants will make, use,

import, sell, and/or offer for sale the Mylan's ANDA Products, throughout the United States, including in the State of West Virginia, prior to the expiration of the patents-in-suit.

64. Venue is proper as to Defendant Mylan Inc. because Mylan Inc. 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 on information and belief has a regular and established place of business in the State of West Virginia, *inter alia*, through at least one or more affiliates, subsidiaries, parents, alter egos, agents and/or other entities in the Mylan corporate family who have a regular and established place of business in West Virginia. On information and belief, upon receiving approval from the FDA, Defendants will make, use, import, sell, and/or offer for sale the Mylan's ANDA Products, throughout the United States, including in the State of West Virginia, prior to the expiration of the patents-in-suit.

65. Venue is proper as to Defendant Mylan N.V. because Mylan N.V. 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 on information and belief has a regular and established place of business in the State of West Virginia, *inter alia*, through at least one or more affiliates, subsidiaries, parents, alter egos, agents and/or other entities in the Mylan corporate family who have a regular and established place of business in West Virginia. On information and belief, upon receiving approval from the FDA, Defendants will make, use, import, sell, and/or offer for sale the Mylan's ANDA Products, throughout the United States, including in the State of West Virginia, prior to the expiration of the patents-in-suit.

66. Venue is also proper as to alien defendants Mylan Laboratories Limited and Mylan N.V. under 28 U.S.C. § 1391(c)(3).

67. Venue is proper as to all Defendants.

COUNT I
INFRINGEMENT OF THE '328 PATENT

68. Plaintiffs incorporate by reference paragraphs 1-67 of this Complaint as if fully set forth herein.

69. 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 '328 patent.

70. 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 '328 patent constitutes infringement of one or more claims of the '328 patent, either literally or under the doctrine of equivalents.

71. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products would infringe the '328 patent and/or actively induce and/or contribute to infringement of the '328 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 211699, 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 '328 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

72. On information and belief, upon FDA approval of ANDA No. 211699, 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 '328 patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '328 patent and knowledge that they are encouraging infringement.

73. Defendants had actual and constructive notice of the '328 patent prior to filing the Mylan ANDA, and were aware that the filing of the Mylan ANDA with the request for FDA approval prior to the expiration of the '328 patent would constitute an act of infringement of the '328 patent. Defendants have no reasonable basis for asserting 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 '328 patent.

74. In addition, Defendants filed the Mylan ANDA without adequate justification for asserting the '328 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Mylan's ANDA Products. Defendants' conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '328 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

75. 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 II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '328 PATENT

76. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1-75 as if fully set forth herein.

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

78. On information and belief, if the Mylan ANDA is approved, 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.

79. 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 the Mylan ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '328 patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and/or (g).

80. 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 immediately after the FDA approves the Mylan ANDA. Any such conduct before the '328 patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '328 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and/or (g).

81. 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 '328 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

82. 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.

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

COUNT III
INFRINGEMENT OF THE '239 PATENT

84. Plaintiffs incorporate by reference paragraphs 1-67 of this Complaint as if fully set forth herein.

85. 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 '239 patent.

86. The Notice Letter informed Plaintiffs that Mylan Pharmaceuticals Inc. had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '239 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products.

87. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA 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

'239 patent constitutes infringement of one or more claims of the '239 patent, either literally or under the doctrine of equivalents.

88. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products would infringe the '239 patent and/or actively induce and/or contribute to infringement of the '239 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 211699, 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 '239 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

89. On information and belief, upon FDA approval of ANDA No. 211699, Defendants will market and distribute Mylan's ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Mylan's ANDA Products. 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 '239 patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '239 patent and knowledge that they are encouraging infringement.

90. Defendants had actual and constructive notice of the '239 patent prior to filing the Mylan ANDA, and were aware that the filing of the Mylan ANDA with the request for FDA approval prior to the expiration of the '239 patent would constitute an act of infringement of the

'239 patent. Defendants have no reasonable basis for asserting 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 '239 patent.

91. In addition, Defendants filed the Mylan ANDA without adequate justification for asserting the '239 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Mylan's ANDA Products. Defendants' conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '239 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

92. 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 IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '239 PATENT

93. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1-67 and 84-92 as if fully set forth herein.

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

95. On information and belief, if the Mylan ANDA is approved, 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.

96. 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 the Mylan ANDA and Defendants will therefore contribute to the infringement of and/or induce the

infringement of one or more claims of the '239 patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and/or (g).

97. 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 immediately after the FDA approves the Mylan ANDA. Any such conduct before the '239 patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '239 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and/or (g).

98. 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 '239 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

99. 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.

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

COUNT V
INFRINGEMENT OF THE '137 PATENT

101. Plaintiffs incorporate by reference paragraphs 1-67 of this Complaint as if fully set forth herein.

102. 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 '137 patent.

103. The Notice Letter informed Plaintiffs that Mylan Pharmaceuticals Inc. had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '137 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products.

104. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA 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 '137 patent constitutes infringement of one or more claims of the '137 patent, either literally or under the doctrine of equivalents.

105. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products would infringe the '137 patent and/or actively induce and/or contribute to infringement of the '137 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 211699, 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 '137 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

106. On information and belief, upon FDA approval of ANDA No. 211699, Defendants will market and distribute Mylan's ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Mylan's ANDA Products. 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 '137 patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '137 patent and knowledge that they are encouraging infringement.

107. Defendants had actual and constructive notice of the '137 patent prior to filing the Mylan ANDA, and were aware that the filing of the Mylan ANDA with the request for FDA approval prior to the expiration of the '137 patent would constitute an act of infringement of the '137 patent. Defendants have no reasonable basis for asserting 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 '137 patent.

108. In addition, Defendants filed the Mylan ANDA without adequate justification for asserting the '137 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Mylan's ANDA Products. Defendants' conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '137 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

109. 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 VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '137 PATENT

110. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1-67 and 101-109 as if fully set forth herein.

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

112. On information and belief, if the Mylan ANDA is approved, 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.

113. 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 the Mylan ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '137 patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and/or (g).

114. 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 immediately after the FDA approves the Mylan ANDA. Any such conduct before the '137 patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '137 patent under one or more of 35 U.S.C. §§ 271(a) (b), (c), (f) and/or (g).

115. 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 '137 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

116. 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.

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

COUNT VII
INFRINGEMENT OF THE '011 PATENT

118. Plaintiffs incorporate by reference paragraphs 1-67 of this Complaint as if fully set forth herein.

119. 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 '011 patent.

120. The Notice Letter informed Plaintiffs that Mylan Pharmaceuticals Inc. had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '011 patent is will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products.

121. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA 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 '011 patent constitutes infringement of one or more claims of the '011 patent under at least the doctrine of equivalents.

122. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products would infringe the '011 patent and/or actively induce and/or contribute to infringement of the '011 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 211699, 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 '011 patent.

123. Defendants had actual and constructive notice of the '011 patent prior to filing the Mylan ANDA, and were aware that the filing of the Mylan ANDA with the request for FDA approval prior to the expiration of the '011 patent would constitute an act of infringement of the '011 patent. Defendants have no reasonable basis for asserting 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 '011 patent under 35 U.S.C. § 271(a), (b), (c), and/or (f).

124. In addition, Defendants filed the Mylan ANDA without adequate justification for asserting the '011 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Mylan's ANDA Products. Defendants' conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '011 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

125. 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 VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '011 PATENT

126. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1-67 and 118-125 as if fully set forth herein.

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

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

129. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Mylan's ANDA Products complained of herein will begin immediately after the FDA approves the Mylan ANDA. Any such conduct before the '011 patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '011 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

130. 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 '011 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

131. 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.

132. 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 '328 patent was an act of infringement of one or more claims of the '328 patent;

B. 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 '239 patent was an act of infringement of one or more claims of the '239 patent;

C. 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 '137 patent was an act of infringement of one or more claims of the '137 patent;

D. 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 '011 patent was an act of infringement of one or more claims of the '011 patent;

E. 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 '328 patent;

F. 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 '239 patent;

G. 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 '137 patent;

H. A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), and/or (f), 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 '011 patent;

I. The entry of a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), 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 '328, '239, '137, and '011 patents;

J. 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 last expiration date of any of the '328, '239, '137, and '011 patents, or any later expiration of exclusivity for any of the '328, '239, '137, and '011 patents, including any extensions or regulatory exclusivities;

K. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), 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 '328 patent, or induces or contributes to such conduct, prior to the expiration of the '328 patent;

L. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), 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 '239 patent, or induces or contributes to such conduct, prior to the expiration of the '239 patent;

A. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), 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 '137 patent, or induces or contributes to such conduct, prior to the expiration of the '137 patent;

M. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), 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 '011 patent, or induces or contributes to such conduct, prior to the expiration of the '011 patent;

N. 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;

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

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

Dated: October 12, 2018

Respectfully submitted,

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