IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., and TEVA PHARMACEUTICALS USA, INC.,	)	
Plaintiffs,	)	C.A. No.
v.	)	**JURY TRIAL DEMANDED**
ARMSTRONG PHARMACEUTICALS, INC. and AMPHASTAR PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva Branded"), Norton (Waterford) Ltd. ("Norton"), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Armstrong Pharmaceuticals, Inc. ("Armstrong") and Amphastar Pharmaceuticals, Inc. ("Amphastar") (collectively, "Defendants"), and allege as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment of patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 212447 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol prior to the expiration of U.S. Patent No. 9,463,289 ("the '289 patent").

THE PARTIES

Plaintiffs

2. Plaintiff Teva Branded is a company organized under the laws of the State of Delaware, with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380.

3. Plaintiff Norton is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland. Norton trades, *i.e.*, does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

4. Plaintiff Teva USA is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

Defendants

5. On information and belief, Defendant Armstrong is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 25 John Road, Canton, Massachusetts 02021.

6. On information and belief, Defendant Amphastar is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 11570 6th Street, Rancho Cucamonga, California 91730.

7. On information and belief, Defendant Armstrong is a subsidiary of Defendant Amphastar.

8. On information and belief, Defendants collaborate on the regulatory approval, manufacturing, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in this District. *See* Exhibit A, Amphastar Pharmaceuticals, Inc., Form

10-K for 2023 Fiscal Year, https://ir.amphastar.com/websites/amphastar/English/3210/us-sec-filing.html?format=convpdf&secFilingId=86259bf0-66bf-4a42-869e-a3c82f393360&shortDesc=Annual%20Report.

9. Defendant Armstrong notified Plaintiffs by letter ("Armstrong Notice Letter") that Armstrong had submitted to FDA ANDA No. 212447 ("Armstrong ANDA") for a purported generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol, 90 mcg per actuation ("Armstrong ANDA Product"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Armstrong ANDA Product in and/or into the United States, including Delaware, prior to the expiration of the '289 patent.

10. On information and belief, Defendants acted collaboratively in the preparation of the Armstrong ANDA, in pursuing FDA approval of the Armstrong ANDA, and in seeking to market the Armstrong ANDA Product. *See* Exhibit B, News Detail, Amphastar Receives FDA Approval for Albuterol Sulfate Inhalation Aerosol (May 22, 2024) https://ir.amphastar.com/websites/amphastar/English/2110/newsdetail.html?airportNewsID=52a21c4e-48ff-463d-a4ed-3052c81b0b8d ("Amphastar Pharmaceuticals, Inc. . . . today announced that the U.S. Food and Drug Administration ('FDA') has granted approval for the Company's Abbreviated New Drug Application ('ANDA') for Albuterol Sulfate Inhalation Aerosol, previously known as AMP-008.").

11. On information and belief, the Armstrong ANDA was approved by FDA on May 21, 2024.

12. On information and belief, Defendants plan to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Armstrong ANDA Product in and/or into the United States, including Delaware, imminently starting in the third quarter of

2024. *See* Exhibit B, News Detail, Amphastar Receives FDA Approval for Albuterol Sulfate Inhalation Aerosol (May 22, 2024) https://ir.amphastar.com/websites/amphastar/English/2110/newsdetail.html?airportNewsID=52a21c4e-48ff-463d-a4ed-3052c81b0b8d ("Amphastar plans to launch its Albuterol Sulfate Inhalation Aerosol in the third quarter of 2024."); Exhibit C, Amphastar Pharmaceuticals, Corporate Presentation June 2024, at 14 https://ir-api.eqs.com/media/document/81cdac59-ecc8-4144-9bb1-c53e3952e045/assets/Corp%20Pres%20June.pdf?disposition=inline ("Albuterol . . . Launch planned Q3 2024.").

13. On information and belief, Defendants have made offers to sell the Armstrong ANDA Product in the United States.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

14. Plaintiffs incorporate each of the preceding paragraphs 1–13 as if fully set forth herein.

15. This is a civil action for declaratory judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

16. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Personal Jurisdiction

17. Plaintiffs incorporate each of the preceding paragraphs 1–16 as if fully set forth herein.

18. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Defendants.

19. This Court has personal jurisdiction over Defendants because, among other things, Defendants have purposefully availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. On information and belief, Defendants develop, manufacture, import, market, offer to sell, sell, and/or import generic drugs throughout the United States, including in Delaware, and therefore transact business within Delaware, and/or have engaged in systematic and continuous business contacts within Delaware.

20. This Court also has personal jurisdiction over Defendant Armstrong because, on information and belief, it is incorporated in the State of Delaware.

21. This Court also has personal jurisdiction over Defendant Amphastar because, on information and belief, it is incorporated in the State of Delaware.

22. In addition, this Court has personal jurisdiction over Defendants because, among other things, on information and belief: (1) Defendants filed the Armstrong ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Armstrong ANDA Product in the United States, including in Delaware; and (2) Defendants, individually and/or in concert, will market, distribute, offer for sale, sell, and/or import the Armstrong ANDA Product imminently starting in the third quarter of 2024 in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the Armstrong ANDA Product in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, starting in

the third quarter of 2024, the Armstrong ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

23. In addition, this Court has personal jurisdiction over Defendants Amphastar and Armstrong because, on information and belief, Amphastar, the parent of Armstrong, (1) engages in patent litigation concerning its ANDA products in this District; (2) does not contest personal jurisdiction in this District; and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, Answer (Dkt. 6) ¶¶ 6-8, Counterclaims, *Par Pharm., Inc. et al. v. Amphastar Pharm., Inc.*, Civil Action No. 18-2032-CFC (D. Del. Feb. 19, 2019) (not contesting personal jurisdiction in this District and asserting counterclaims); *id.* ¶ 8 ("To the extent that an answer is required, for purposes of this case only, Amphastar does not contest personal jurisdiction in this Court.").

24. For the above reasons, it would not be unfair or unreasonable for Defendants to litigate this action in this District, and the Court has personal jurisdiction over Defendants here.

Venue

25. Plaintiffs incorporate each of the preceding paragraphs 1–24 as if fully set forth herein.

26. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

27. Venue is proper in this Judicial District because, on information and belief, Defendants Armstrong and Amphastar are incorporated in the State of Delaware and reside in Delaware for purposes of venue under 28 U.S.C. § 1400(b).

28. On information and belief, Defendants have committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '289 patent

by, among other things, seeking to market the Armstrong ANDA Product throughout the United States, including within Delaware. On information and belief, Defendants conduct business in Delaware by, among other things, marketing, selling, and distributing pharmaceutical products throughout the United States, including in Delaware.

29. On information and belief, Defendant Amphastar, the parent of Defendant Armstrong, (1) engages in patent litigation concerning its ANDA products in this District, and (2) does not contest venue in this District. *See, e.g.*, Answer (Dkt. 6) ¶¶ 6-8, Counterclaims, *Par Pharm., Inc. et al. v. Amphastar Pharm., Inc.*, Civil Action No. 18-2032-CFC (D. Del. Feb. 19, 2019) (not contesting venue in this District and asserting counterclaims); *id.* ¶ 7 ("To the extent that an answer is required, for purposes of this case only, Amphastar does not contest venue in this judicial district.").

BACKGROUND

NDA No. 021457

30. Teva Branded is the holder of New Drug Application ("NDA") No. 021457, under which FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol on October 29, 2004. ProAir® HFA (albuterol sulfate) Inhalation Aerosol is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

31. On October 1, 2022, the manufacturing of branded ProAir® HFA (albuterol sulfate) Inhalation Aerosol was discontinued. Teva USA exclusively distributes an authorized generic of ProAir® HFA (albuterol sulfate) Inhalation Aerosol under NDA No. 021457 in the United States.

The '289 Patent

32. The '289 patent, titled "Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof," duly and legally issued on October 11, 2016. A true and correct copy of the '289 patent is attached hereto as Exhibit D.

33. Norton is the owner and assignee of the '289 patent.

34. The '289 patent is listed in connection with ProAir® HFA (NDA No. 021457) in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

35. The Orange Book currently lists the expiration of the '289 patent as May 18, 2031.

Defendants' ANDA and Notice of Paragraph IV Certification

36. Plaintiffs incorporate each of the preceding paragraphs 1–35 as if fully set forth herein.

37. On information and belief, Defendants have submitted or caused the submission of the Armstrong ANDA to FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Armstrong ANDA Product prior to the expiration of the '289 patent.

38. In the Armstrong Notice Letter, Defendant Armstrong notified Plaintiffs of the submission of the Armstrong ANDA to FDA.

39. In the Armstrong Notice Letter, Defendant Armstrong notified Plaintiffs that Armstrong had filed a Paragraph IV Certification with respect to the '289 patent and was seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Armstrong ANDA Product prior to the expiration of the '289 patent.

40. On information and belief, Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted the Armstrong

ANDA. On information and belief, starting in the third quarter of 2024, Defendants will manufacture, use, offer for sale, or sell the Armstrong ANDA Product within the United States, or will import the Armstrong ANDA Product into the United States. On information and belief, starting in the third quarter of 2024, Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Armstrong ANDA Product in or into the United States.

41. In the Armstrong Notice Letter, Defendant Armstrong stated that Armstrong's Proposed ANDA Product is formulated as 90 mcg/inh of albuterol sulfate as an aerosol in a metered dose inhaler for inhalation.

42. In the Armstrong Notice Letter, Defendant Armstrong stated that the active ingredient of the Armstrong ANDA Product is albuterol sulfate.

43. On information and belief, the Armstrong ANDA contains a Paragraph IV Certification with respect to the '289 patent asserting that the '289 patent is unenforceable, invalid, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the Armstrong ANDA Product ("Armstrong's Paragraph IV Certification"). Defendant Armstrong notified Plaintiffs of Armstrong's Paragraph IV Certification in the Armstrong Notice Letter.

44. The Armstrong Notice Letter appends a document titled "Detailed Statement of the Factual and Legal Bases for Armstrong Pharmaceuticals, Inc.'s Paragraph IV Certification" asserting that the commercial manufacture, use, offer for sale, sale, or importation of the Armstrong ANDA Product will not infringe any claim of the '289 patent ("Detailed Statement").

45. In the Armstrong Notice Letter and Detailed Statement, Armstrong asserts that the Armstrong ANDA Product would not infringe any claim of the '289 patent based upon a narrow, incorrect claim construction for the term "lying in a common plane" in claim 1 of the '289 patent that is different than the construction adopted for that term by the United States District Court for the District of New Jersey in *Teva Branded Pharm. Prods. R&D, Inc. v. Cipla Ltd.*, No. 20-10172 (D.N.J.). *See* Markman Opinion, ECF No. 217 (Nov. 11, 2022), at 6-8 (the Court construing the term "lying in a common plane coincident with the longitudinal axis X" in claim 1 of the '289 patent to mean "aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, the canister support formation, and the actuation member"); Markman Order, ECF No. 218 (Nov. 11, 2022), at 2. On information and belief, applying the construction adopted by the Court in *Teva Branded Pharm. Prods. R&D, Inc. v. Cipla Ltd.*, the Armstrong ANDA Product meets each and every limitation of at least one or more claims of the '289 patent.

46. Plaintiffs have been in contact with counsel for Armstrong, seeking information concerning Armstrong's product to allow further assessment of infringement. On July 17, 2024, the parties executed an Offer of Confidential Access, under which Armstrong agreed to provide Plaintiffs' counsel access to portions of the Armstrong ANDA and a sample of the Armstrong ANDA Product.

47. On July 24, 2024, Plaintiffs' counsel received limited portions of the Armstrong ANDA from Armstrong's counsel.

48. On July 25, 2024, Plaintiffs' counsel received samples of only portions of the Armstrong ANDA Product from Armstrong's counsel.

49. On information and belief, the Armstrong ANDA Product meets each and every limitation of at least one or more claims of the ’289 patent, including at least claim 1.

50. As of the filing of this Complaint, Armstrong has only provided Plaintiffs with limited documents from the Armstrong ANDA and samples of an incomplete Armstrong ANDA Product.

51. The Armstrong ANDA and samples of the Armstrong ANDA Product are not publicly available. The Armstrong ANDA and samples of the Armstrong ANDA Product are peculiarly within the Defendants’ possession.

52. On information and belief, Defendants have now begun to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Armstrong ANDA Product, but Plaintiffs do not have access to the complete Armstrong ANDA Product. Plaintiffs turn to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to further confirm their allegations of infringement.

COUNT I – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEFENDANTS OF U.S. PATENT NO. 9,463,289

53. Plaintiffs incorporate each of the preceding paragraphs 1–52 as if fully set forth herein.

54. Defendants have knowledge of the ’289 patent.

55. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Armstrong ANDA Product would infringe one or more claims of the ’289 patent, including at least claim 1, either literally or under the doctrine of equivalents.

56. On information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Armstrong ANDA Product imminently starting in the third quarter of 2024.

57. On information and belief, the use of the Armstrong ANDA Product in accordance with and as directed by Defendants' proposed labeling for the Armstrong ANDA Product would infringe one or more claims of the '289 patent, including at least claim 1.

58. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '289 patent imminently starting in the third quarter of 2024.

59. On information and belief, Defendants know that the Armstrong ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '289 patent and that the Armstrong ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Defendants plan and intend to, and will, contribute to infringement of the '289 patent imminently starting in the third quarter of 2024.

60. The foregoing actions by Defendants constitute and/or will constitute infringement of the '289 patent, active inducement of infringement of the '289 patent, and contribution to the infringement by others of the '289 patent.

61. On information and belief, Defendants have acted with full knowledge of the '289 patent and without a reasonable basis for believing that they would not be liable for infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent.

62. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Defendants regarding whether Defendants' manufacture, use, sale, offer for sale, or importation into the United States of the Armstrong ANDA Product with its proposed

labeling according to the Armstrong ANDA will infringe one or more claims of the ’289 patent, including at least claim 1, and whether said claims of the ’289 patent are valid.

63. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Armstrong ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’289 patent and that the claims of the ’289 patent are valid.

64. Plaintiffs will suffer, and will continue to suffer, economic harm as a result of Defendants’ infringing activities in an amount to be proven at trial.

65. Defendants should be enjoined from infringing the ’289 patent, actively inducing infringement of the ’289 patent, and contributing to the infringement by others of the ’289 patent.

JURY DEMAND

Plaintiffs demand a jury trial on all issues and claims so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment that the ’289 patent is valid and enforceable;

(b) A judgment declaring that making, using, offering for sale, selling, marketing, distributing, or importing the Armstrong ANDA Product, or any other product, the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the ’289 patent prior to its expiration date will infringe, actively induce infringement of, and/or contribute to the infringement by others of the ’289 patent under 35 U.S.C. §§ 271(a)-(c);

(c) An award of Plaintiffs’ damages or other monetary relief pursuant to, among other things, 35 U.S.C. § 284, to compensate Plaintiffs if any Defendant, their officers, agents, servants, employees and attorneys, or any person acting in concert with them, engages in the

manufacture, use, offer for sale, sale, marketing, distribution, or importation of the Armstrong ANDA Product, or any other product, the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '289 patent, or the inducement of or the contribution to the foregoing, prior to the expiration date of the '289 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A permanent injunction pursuant to, among other things, 35 U.S.C. § 283 enjoining Defendants, their officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, offering for sale, selling, marketing, distributing, or importing the Armstrong ANDA Product, or any other product, the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '289 patent, or the inducement of or the contribution to the foregoing, prior to the expiration date of the '289 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment that Defendants willfully and deliberately infringed the '289 patent.

(f) A declaration that this case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(g) An award of Plaintiffs' costs and expenses in this action; and

(h) Such further and other relief as this Court may deem just and proper.

/s/ Karen E. Keller

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