IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ORION CORPORATION, BAYER CONSUMER CARE AG, BAYER HEALTHCARE LLC, and BAYER HEALTHCARE PHARMACEUTICALS INC., Plaintiffs, v. ALEMBIC PHARMACEUTICALS LIMITED, Defendant.	C.A. No. 1:25-cv-00825 (JLH)

ALEMBIC PHARMACEUTICALS LIMITED AND ALEMBIC PHARMACEUTICALS, INC.'S ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant Alembic Pharmaceuticals Limited ("Defendant" or "Alembic"), by and through its attorneys, hereby provides the following Answer, Affirmative Defenses and Counterclaims to the Complaint filed by Plaintiffs Orion Corporation, Bayer Consumer Care AG, Bayer Healthcare LLC, and Bayer Healthcare Pharmaceuticals Inc. (collectively "Plaintiffs"). Unless otherwise specifically admitted below, Alembic denies all allegations in Plaintiffs' Complaint. *See* Fed. R. Civ. P. 8(b)(3).

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code that arises out of the filing by Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. (collectively, "Alembic") of Abbreviated New Drug Application No. 220499 ("Alembic's ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale,

and/or importation of a generic version of Plaintiffs' Nubeqa® (darolutamide) tablets ("Alembic's ANDA Product") prior to the expiration of U.S. Patent Nos. 10,010,530 ("the '530 patent"), 10,383,853 ("the '853 patent"), 10,835,515 ("the '515 patent"), and 11,168,058 ("the '058 patent"). These patents are referred to collectively herein as the "patents-in-suit."

ANSWER: Alembic admits that Plaintiffs' Complaint purports to bring this action as a result of Alembic filing its Abbreviated New Drug Application ("ANDA") No. 220499, for infringement of United States Patent Nos. 10,010,530, 10,383,853, 10,835,515, and 11,168,058. Alembic denies that Alembic Pharmaceuticals, Inc. filed any ANDA.

PARTIES

Plaintiffs

2. Plaintiff Orion is a corporation organized under the laws of Finland with a principal place of business at Orionintie IA, FI-02200 Espoo, Finland. Orion is the owner and assignee of the patents-in-suit.

ANSWER: Alembic is without knowledge or information at this time sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies all such allegations.

3. Plaintiff BCC is a Swiss corporation with its principal place of business at Peter Merian-Str. 84, Basel, Switzerland 4052. BCC is an exclusive licensee under the patents-in-suit.

ANSWER: Alembic is without knowledge or information at this time sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies all such allegations.

4. Plaintiff BHC is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey. BHC is an exclusive sublicensee under the patents-in-suit.

ANSWER: Alembic is without knowledge or information at this time sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies all such allegations.

5. Plaintiff BHCPI is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey. BHCPI is the holder of New Drug Application ("NDA") No. 212099 for Nubeqa® (darolutamide) tablets.

ANSWER: Alembic is without knowledge or information at this time sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies all such allegations.

Defendants

6. Upon information and belief, defendant Alembic Pharmaceuticals Limited is a company organized and existing under the laws of the Republic of India with a principal place of business at Alembic Road, 390 033 Vadodara, India. Upon information and belief, Alembic Pharmaceuticals Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Alembic Pharmaceuticals, Inc.

ANSWER: Alembic admits the allegations of Paragraph 6 with the exception that Alembic Pharmaceuticals Limited has its principal place of business at Alembic Road, Vadodara – 390 003, Gujarat India.

7. Upon information and belief, defendant Alembic Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 550 Hills Drive, Suite 104B, Bedminster, New Jersey 07921. Upon information and belief, Alembic Pharmaceuticals, Inc. is in the business of, among other things,

manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

ANSWER: Alembic denies that Alembic Pharmaceuticals Inc. is in the business of manufacturing generic versions of branded pharmaceutical products. Alembic admits the remainder of the allegations of Paragraph 7. Answering further, Alembic Pharmaceuticals Inc. has been dismissed from this case (D.I. 11).

8. Upon information and belief, Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. acted in concert to prepare and submit Alembic's ANDA to the FDA. Upon information and belief, Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. know and intend that upon approval of Alembic's ANDA, Alembic Pharmaceuticals Limited will manufacture Alembic's ANDA Product, and Alembic Pharmaceuticals, Inc. will directly or indirectly market, sell, and distribute Alembic's ANDA Product throughout the United States, including in Delaware.

ANSWER: Alembic denies that Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. acted in concert to prepare and submit Alembic's ANDA to the FDA. Alembic admits the remainder of the allegations of Paragraph 8.

9. Upon information and belief, Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Alembic's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Alembic Pharmaceuticals, Inc. participated in, assisted, and cooperated with Alembic Pharmaceuticals Limited in the acts complained of herein.

ANSWER: Alembic denies the allegations of Paragraph 9.

10. Upon information and belief, following any FDA approval of Alembic's ANDA, Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. will act in concert to distribute and sell Alembic's ANDA Product throughout the United States, including within Delaware.

ANSWER: Alembic admits the allegations of Paragraph 10.

JURISDICTION

11. Jurisdiction is proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

ANSWER: Paragraph 11 contains legal conclusions to which no response is required. To the extent a response is required, Alembic admits the allegations of Paragraph 11.

12. This Court has personal jurisdiction over each of Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc.

ANSWER: Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations. Answering further, Alembic is not challenging personal jurisdiction in this case.

13. Alembic Pharmaceuticals Limited is subject to personal jurisdiction in Delaware because, among other things, Alembic Pharmaceuticals Limited, itself and through its subsidiary Alembic Pharmaceuticals, Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Alembic Pharmaceuticals Limited, itself and through its subsidiary Alembic Pharmaceuticals, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Alembic Pharmaceuticals Limited

is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Alembic Pharmaceuticals, Inc. and therefore the activities of Alembic Pharmaceuticals, Inc. in this jurisdiction are attributed to Alembic Pharmaceuticals Limited.

ANSWER: Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations. Answering further, Alembic is not challenging personal jurisdiction in this case.

14. Alembic Pharmaceuticals, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Alembic Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, upon information and belief, Alembic Pharmaceuticals, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

ANSWER: Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, Alembic admits the allegations in Paragraph 14.

15. Alembic has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV),

serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

ANSWER: Alembic admits that Alembic Pharmaceuticals Limited has previously filed ANDA applications under the Hatch-Waxman Act with certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and served notice letters to companies and have been sued as a result of making such filings and serving such notice letters as contemplated by the Hatch-Waxman Act. Alembic denies all remaining allegations in Paragraph 15.

16. Upon information and belief, Alembic, with knowledge of the Hatch-Waxman Act process, directed Alembic's Notice Letter to BHCPI, an entity incorporated in Delaware. Upon information and belief, Alembic knew when it did so that it was triggering the forty-five-day period for BHCPI to bring an action for patent infringement under the Hatch-Waxman Act.

ANSWER: Alembic admits that Alembic Pharmaceuticals Limited served a notice letter on BHCPI as a Paragraph IV Patent Certification Notice regarding Alembic Pharmaceuticals Limited's ANDA No. 220499 for darolutamide tablets, 300 mg with knowledge of the Hatch-Waxman Act. Alembic is without knowledge of information at this time sufficient to form a belief as to the truth of the remaining allegations in Paragraph 16 and therefore denies all such remaining allegations.

17. Because BHCPI is incorporated in Delaware, BHCPI suffers injury and consequences from Alembic's filing of Alembic's ANDA, in Delaware. Alembic has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Alembic's Notice Letter to BHCPI, a Delaware corporation, that it would be sued in Delaware for patent infringement.

ANSWER: Paragraph 17 contains legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations. Alembic is also without knowledge of information at this time sufficient to form a belief as to the truth of the factual allegations in Paragraph 17 and therefore denies all such allegations. Answering further, Alembic is not challenging personal jurisdiction in this case.

18. Upon information and belief, if Alembic's ANDA is approved, Alembic will directly or indirectly manufacture, market, sell, and/or distribute Alembic's ANDA Product within the United States, including in Delaware, consistent with Alembic's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Alembic regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Alembic's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Alembic's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of the patents-in-suit in the event that Alembic's ANDA Product is approved before the patents expire.

ANSWER: Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations. Alembic is also without knowledge of information at this time sufficient to form a belief as to the truth of the factual allegations in Paragraph 18 and therefore denies all such allegations. Answering further, Alembic is not challenging personal jurisdiction in this case.

19. Upon information and belief, Alembic derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Alembic and/or Alembic Pharmaceuticals Limited or Alembic Pharmaceuticals, Inc. Upon information and belief, various products for which Alembic Pharmaceuticals Limited or Alembic Pharmaceuticals, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

ANSWER: Paragraph 19 contains legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations. Alembic is also without knowledge of information at this time sufficient to form a belief as to the truth of the factual allegations in Paragraph 19 and therefore denies all such allegations. Answering further, Alembic is not challenging personal jurisdiction in this case.

VENUE

20. Venue is proper in this district as to Alembic Pharmaceuticals, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Alembic Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

ANSWER: Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations. Answering further, Alembic Pharmaceuticals Inc. has been dismissed from this case (D.I. 11).

21. Venue is proper in this district as to Alembic Pharmaceuticals Limited pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Alembic Pharmaceuticals Limited is a company organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

ANSWER: Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations. Answering further, Alembic is not challenging venue in this case.

FACTUAL BACKGROUND

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

ANSWER: Alembic incorporates by reference its answers to Paragraphs 1-22 as if set forth herein.

The '530 Patent

23. The '530 patent, entitled "Carboxamide Derivative and Its Diastereomers in Stable Crystalline Form," (Exhibit A hereto), was duly and legally issued on July 3, 2018.

ANSWER: Alembic admits that Exhibit A purports to be a copy of the '530 patent and that, on its face Exhibit A is titled, "Carboxamide Derivative and its Diastereomers in Stable Crystalline Form." Alembic also admits that Exhibit A, on its face, indicates that the '530 patent was issued on July 3, 2018. The remaining allegations in Paragraph 23 contain legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

24. The '530 patent lists as inventors Olli Törmäkangas and Terhi Heikkinen.

ANSWER: Alembic admits that Exhibit A, on its face, lists the inventors as Olli Törmäkangas and Terhi Heikkinen.

25. The '530 patent is listed in connection with Nubeqa® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

ANSWER: Alembic admits that the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") lists the '530 patent in connection with Nubeqa®.

26. Claim 1 of the '530 patent recites:

> Crystalline form I of N-((S)-1-(3-(3-chloro-4-cyanophenyl)-lHpyrazol-1-yl) propan-2-yl)-5-(1-hydroxyethyl)-1 H-pyrazole-3-carboxamide (I) having an X-ray powder diffraction pattern comprising characteristic peaks at about 8.5, 10.4, 16.6, 16.9, and 24.3 degrees 2-theta.

ANSWER: Alembic admits that Exhibit A, at column 16, lines 49-53 recites the paragraph above. The remaining allegations in Paragraph 26 contain legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

27. Plaintiffs will be substantially and irreparably damaged by infringement of the '530 patent.

ANSWER: Alembic denies the allegations in Paragraph 27.

The '853 Patent

28. The '853 patent, entitled "Carboxamide Derivative and Its Diastereomers in Stable Crystalline Form," (Exhibit B hereto), was duly and legally issued on August 20, 2019.

ANSWER: Alembic admits that Exhibit B purports to be a copy of the '853 patent and that, on its face Exhibit B is titled, "Carboxamide Derivative and its Diastereomers in Stable Crystalline Form." Alembic also admits that Exhibit B, on its face, indicates that the '853 patent was issued on August 29, 2019. The remaining allegations in Paragraph 28 contain legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

29. The '853 patent lists as inventors Olli Törmäkangas and Terhi Heikkinen.

ANSWER: Alembic admits that Exhibit B, on its face, lists the inventors as Olli Törmäkangas and Terhi Heikkinen.

30. The ’853 patent is listed in connection with Nubeqa® in the FDA's Orange Book.

ANSWER: Alembic admits that the Orange Book lists the ’853 patent in connection with Nubeqa®.

31. Claim 1 of the ’853 patent recites:

> Crystalline form I of N-((S)-1-(3-(3-chloro-4-cyanophenyl)-lHpyrazol-1-yl)propan-2-yl)-5-(1-hydroxyethyl)-1 H-pyrazole-3-carboxamide (I) having an X-ray powder diffraction pattern comprising characteristic peaks at about 8.5, 10.4, 16.6, and 24.3 degrees 2-theta, wherein the crystalline form I is substantially free of any other crystalline form of N-((S)-1-(3-(3-chloro-4-cyanophenyl)-lH-pyrazol-1-yl)propan-2-yl)-5-(1-hydroxyethyl)lH-pyrazole-3-carboxamide (1).

ANSWER: Alembic admits that Exhibit B, at column 16, lines 52-60 recites the paragraph above. The remaining allegations in Paragraph 31 contain legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

32. Plaintiffs will be substantially and irreparably damaged by infringement of the ’853 patent.

ANSWER: Alembic denies the allegations in Paragraph 27.

The ’515 Patent

33. The ’515 patent, entitled “Carboxamide Derivative and Its Diastereomers in Stable Crystalline Form,” (Exhibit C hereto), was duly and legally issued on November 17, 2020.

ANSWER: Alembic admits that Exhibit C purports to be a copy of the ’515 patent and that, on its face Exhibit C is titled, “Carboxamide Derivative and its Diastereomers in Stable Crystalline Form.” Alembic also admits that Exhibit C, on its face, indicates that the ’515 patent

was issued on November 17, 2020. The remaining allegations in Paragraph 33 contain legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

34. The ’515 patent lists as inventors Olli Törmäkangas and Terhi Heikkinen.

ANSWER: Alembic admits that Exhibit C, on its face, lists the inventors as Olli Törmäkangas and Terhi Heikkinen.

35. The ’515 patent is listed in connection with Nubeqa® in the FDA's Orange Book.

ANSWER: Alembic admits that the Orange Book lists the ’515 patent in connection with Nubeqa®.

36. Claim 1 of the ’515 patent recites:

> A pharmaceutical dosage form in the form of a tablet or a capsule for oral administration comprising crystalline form I of N-((S)-1-(3-(3-chloro-4-cyanophenyl)-lH-pyrazol-1-yl) propan-2-yl)-5-(1-hydroxyethyl)-lH-pyrazole-3-carboxamide (I) having an X-ray powder diffraction pattern comprising characteristic peaks at about 8.5, 10.4, 16.6, 16.9 and 24.3 degrees 2-theta, together with a pharmaceutical excipient.

ANSWER: Alembic admits that Exhibit C, at column 16, lines 32-38 recites the paragraph above. The remaining allegations in Paragraph 36 contain legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

37. Plaintiffs will be substantially and irreparably damaged by infringement of the ’515 patent.

ANSWER: Alembic denies the allegations in Paragraph 37.

The ’058 Patent

38. The ’058 patent, entitled ’Manufacture of a Crystalline Pharmaceutical Product,’ (Exhibit D hereto), was duly and legally issued on November 9, 2021.

ANSWER: Alembic admits that Exhibit D purports to be a copy of the '058 patent and that, on its face Exhibit D is titled, "Manufacture of a Crystalline Pharmaceutical Product," Alembic also admits that Exhibit D, on its face, indicates that the '058 patent was issued on November 9, 2021. The remaining allegations in Paragraph 38 contain legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

39. The '058 patent lists as inventors Merja Reunanen and Anna Staffans.

ANSWER: Alembic admits that Exhibit D, on its face, lists the inventors as Merja Reunanen and Anna Staffans.

40. The '058 patent is listed in connection with Nubeqa® in the FDA's Orange Book.

ANSWER: Alembic admits that the Orange Book lists the '058 patent in connection with Nubeqa®.

41. Claim 1 of the '058 patent recites:

> Crystalline particles of N-((S)-1-(3-(3-chloro-4-cyano-phenyl)lH-pyrazol-1-yl)-propan-2-yl)-5-(1-hydroxyethyl)-lH-pyrazole-3-carboxamide (I) having a specific surface area (SSA) in a range from about 8 to about 16 m^2/g.

ANSWER: Alembic admits that Exhibit D, at column 10, lines 10-14 recites the paragraph above. The remaining allegations in Paragraph 41 contain legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

42. Claim 10 of the '058 patent recites:

> Crystalline particles of N-((S)-1-(3-(3-chloro-4-cyanophenyl)-1 Hpyrazol-1-yl)-propan-2-yl)-5-(1-hydroxyethyl)-lH-pyrazole-3-carboxamide (I) having a rounded particle shape and a volume median diameter (Dv50) ranging from

between 100 μm and 1000 μm.

ANSWER: Alembic admits that Exhibit D, at column 10, lines 37-41 recites the paragraph above. The remaining allegations in Paragraph 41 contain legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

43. Plaintiffs will be substantially and irreparably damaged by infringement of the '058 patent.

ANSWER: Alembic denies the allegations in Paragraph 43.

Infringement by Alembic

44. By letter dated May 20, 2025 ("Alembic's Notice Letter"), Alembic notified Plaintiffs that it had submitted to the FDA ANDA No. 220499, seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of Alembic's ANDA Product prior to the expiration of the patents-in-suit. On information and belief, the purpose of the submission of ANDA No. 220499 was to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Alembic's ANDA Product prior to the expiration of the patents-in-suit.

ANSWER: Alembic admits that on May 20, 2025, Alembic Pharmaceuticals Limited sent Plaintiffs a so-called notice letter informing them that the United States Food and Drug Administration ("FDA") had deemed Alembic Pharmaceuticals Limited's ANDA No. 220499 for darolutamide tables, 300 mg, suitable for filing. Alembic denies all remaining allegations in Paragraph 44.

45. In Alembic's Notice Letter, Alembic also notified Plaintiffs that, as part of ANDA No. 220499, Alembic had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the

patents-in-suit. On information and belief, Alembic submitted ANDA No. 220499 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Product.

ANSWER: Alembic admits Alembic's Notice Letter notified Plaintiffs that Alembic Pharmaceuticals Limited filed so-called Paragraph IV certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the patents-in-suit. Alembic further admits that Alembic Pharmaceuticals Limited's ANDA No. 220449 contains such so-called Paragraph IV certifications.

46. According to information in Alembic's Notice Letter, Alembic's ANDA Product is a generic version of Nubeqa® tablets.

ANSWER: Alembic admits the allegations of Paragraph 46.

47. According to information in Alembic's Notice Letter, the dosage form of Alembic's ANDA Product is a tablet.

ANSWER: Alembic admits the allegations of Paragraph 47.

48. According to information in Alembic's Notice Letter, the proposed dosage strength of Alembic's ANDA Product is 300 mg.

ANSWER: Alembic admits the allegations of Paragraph 48.

49. On information and belief, Alembic's ANDA Product is not publicly available, nor is ANDA No. 220499 accessible to the public.

ANSWER: Alembic admits the allegations of Paragraph 49.

50. Alembic's Notice Letter was accompanied by an Offer of Confidential Access to portions of ANDA No. 220499. However, the Offer of Confidential Access was subject to

unreasonably restrictive confidentiality provisions. In addition, Alembic's Notice Letter did not offer to provide additional information beyond portions of ANDA No. 220499, such as samples of Alembic's ANDA Product, which on information and belief is not accessible to the public.

ANSWER: Alembic admits that Alembic Pharmaceuticals Limited Notice Letter included an Offer of Confidential Access to Alembic Pharmaceuticals Limited ANDA No. 220499 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), which Plaintiffs refused to respond to. Alembic further admits that samples of the product subject to ANDA No. 220499 are not public. Alembic denies the remainder of the allegations in Paragraph 50.

51. Plaintiffs are filing this Complaint within forty-five days of receipt of Alembic's Notice Letter.

ANSWER: Alembic admits the allegations of Paragraph 51.

COUNT I - INFRINGEMENT BY ALEMBIC
OF THE '530 PATENT UNDER 35 U.S.C. § 271(e)(2)

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

ANSWER: Alembic incorporates by reference its answers to Paragraphs 1-51 as if set forth herein.

53. Alembic's submission of Alembic's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Product prior to the expiration of the '530 patent was an act of infringement of the '530 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Alembic denies the allegations of Paragraph 53.

54. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product would infringe at least claim 1 of the '530 patent, recited above, literally and/or under the doctrine of equivalents. In Alembic's

Notice Letter, Alembic did not contest that Alembic's ANDA Product infringes claim 1 of the ’530 patent.

ANSWER: Alembic denies the allegations of Paragraph 54.

55. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product immediately and imminently upon FDA approval of Alembic's ANDA.

ANSWER: Alembic admits that it plans to engage in the manufacture, offering for sale, sale, marketing, distribution and importation of Alembic’s ANDA Product when allowed by FDA.

56. On information and belief, the use of Alembic's ANDA Product in accordance with and as directed by Alembic’s proposed labeling for that product would infringe at least claim 1 of the ’530 patent, recited above.

ANSWER: Alembic denies the allegations of Paragraph 56.

57. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the ’530 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Alembic denies the allegations of Paragraph 57.

58. On information and belief, Alembic knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’530 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the ’530 patent after approval of Alembic's ANDA.

ANSWER: Alembic denies the allegations of Paragraph 58.

59. The foregoing actions by Alembic constitute and/or will constitute infringement of the ’530 patent, active inducement of infringement of the ’530 patent, and contribution to the infringement by others of the ’530 patent.

ANSWER: Alembic denies the allegations of Paragraph 59.

60. Unless Alembic is enjoined from infringing the ’530 patent, actively inducing infringement of the ’530 patent, and contributing to the infringement by others of the ’530 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Alembic denies the allegations of Paragraph 60.

COUNT II - INFRINGEMENT BY ALEMBIC OF THE ’853 PATENT UNDER 35 U.S.C. § 271(e)(2)

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

ANSWER: Alembic incorporates by reference its answers to Paragraphs 1-60 as if set forth herein.

62. Alembic’s submission of Alembic’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Product prior to the expiration of the ’853 patent was an act of infringement of the ’853 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Alembic denies the allegations of Paragraph 62.

63. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product would infringe at least claim 1 of the ’853 patent, recited above, literally and/or under the doctrine of equivalents.

ANSWER: Alembic denies the allegations of Paragraph 63.

64. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product immediately

and imminently upon FDA approval of Alembic's ANDA.

ANSWER: Alembic admits that it plans to engage in the manufacture, offering for sale, sale, marketing, distribution and importation of Alembic's ANDA Product when allowed by FDA.

65. On information and belief, the use of Alembic's ANDA Product in accordance with and as directed by Alembic's proposed labeling for that product would infringe at least claim 1 of the '853 patent, recited above. In Alembic's Notice Letter, Alembic did not context that Alembic's ANDA product infringes claim 1 of the '853 patent.

ANSWER: Alembic denies the allegations of Paragraph 65.

66. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the '853 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Alembic denies the allegations of Paragraph 66.

67. On information and belief, Alembic knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '853 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the '853 patent after approval of Alembic's ANDA.

ANSWER: Alembic denies the allegations of Paragraph 67.

68. The foregoing actions by Alembic constitute and/or will constitute infringement of the '853 patent, active inducement of infringement of the '853 patent, and contribution to the infringement by others of the '853 patent.

ANSWER: Alembic denies the allegations of Paragraph 68.

69. Unless Alembic is enjoined from infringing the ’853 patent, actively inducing infringement of the ’853 patent, and contributing to the infringement by others of the ’853 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Alembic denies the allegations of Paragraph 69.

COUNT III - INFRINGEMENT BY ALEMBIC OF THE ’515 PATENT UNDER 35 U.S.C. § 271(e)(2)

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

ANSWER: Alembic incorporates by reference its answers to Paragraphs 1-69 as if set forth herein.

71. Alembic’s submission of Alembic’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Product prior to the expiration of the ’515 patent was an act of infringement of the ’515 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Alembic denies the allegations of Paragraph 71.

72. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product would infringe at least claim 1 of the ’515 patent, recited above, literally and/or under the doctrine of equivalents.

ANSWER: Alembic denies the allegations of Paragraph 72.

73. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product immediately and imminently upon FDA approval of Alembic's ANDA.

ANSWER: Alembic admits that it plans to engage in the manufacture, offering for sale, sale, marketing, distribution and importation of Alembic’s ANDA Product when allowed by FDA.

74. On information and belief, the use of Alembic's ANDA Product in accordance with and as directed by Alembic's proposed labeling for that product would infringe at least claim 1 of the '515 patent, recited above. In Alembic's Notice Letter, Alembic did not context that Alembic's ANDA product infringes claim 1 of the '515 patent.

ANSWER: Alembic denies the allegations of Paragraph 74.

75. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the '515 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Alembic denies the allegations of Paragraph 75.

76. On information and belief, Alembic knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '515 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the '515 patent after approval of Alembic's ANDA.

ANSWER: Alembic denies the allegations of Paragraph 76.

77. The foregoing actions by Alembic constitute and/or will constitute infringement of the '515 patent, active inducement of infringement of the '515 patent, and contribution to the infringement by others of the '515 patent.

ANSWER: Alembic denies the allegations of Paragraph 77.

78. Unless Alembic is enjoined from infringing the '515 patent, actively inducing infringement of the '515 patent, and contributing to the infringement by others of the '853 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Alembic denies the allegations of Paragraph 78.

COUNT IV - INFRINGEMENT BY ALEMBIC
OF THE '058 PATENT UNDER 35 U.S.C. § 271(e)(2)

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

ANSWER: Alembic incorporates by reference its answers to Paragraphs 1-78 as if set forth herein.

80. Alembic's submission of Alembic's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Product prior to the expiration of the '058 patent was an act of infringement of the '058 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Alembic denies the allegations of Paragraph 80.

81. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product would infringe at least claim 1 and/or claim 10 of the '058 patent, recited above, literally and/or under the doctrine of equivalents.

ANSWER: Alembic denies the allegations of Paragraph 81.

82. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product immediately and imminently upon FDA approval of Alembic's ANDA.

ANSWER: Alembic admits that it plans to engage in the manufacture, offering for sale, sale, marketing, distribution and importation of Alembic's ANDA Product when allowed by FDA.

83. On information and belief, the use of Alembic's ANDA Product in accordance with and as directed by Alembic's proposed labeling for that product would infringe at least claim 1 and/or claim 10 of the '058 patent, recited above.

ANSWER: Alembic denies the allegations of Paragraph 83.

84. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the ’058 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Alembic denies the allegations of Paragraph 84.

85. On information and belief, Alembic knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’058 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the ’058 patent after approval of Alembic's ANDA.

ANSWER: Alembic denies the allegations of Paragraph 85.

86. The foregoing actions by Alembic constitute and/or will constitute infringement of the ’058 patent, active inducement of infringement of the ’058 patent, and contribution to the infringement by others of the ’058 patent.

ANSWER: Alembic denies the allegations of Paragraph 86.

87. Unless Alembic is enjoined from infringing the ’058 patent, actively inducing infringement of the ’058 patent, and contributing to the infringement by others of the ’058 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Alembic denies the allegations of Paragraph 87.

COUNT V - DECLARATORY JUDGMENT OF INFRINGEMENT BY ALEMBIC OF THE ’530 PATENT

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

ANSWER: Alembic incorporates by reference its answers to Paragraphs 1-87 as if set forth herein.

89. Alembic has knowledge of the ’530 patent.

ANSWER: Alembic admits the allegations of Paragraph 89.

90. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product would infringe at least claim 1 of the ’530 patent, recited above, literally and/or under the doctrine of equivalents.

ANSWER: Paragraph 90 contains legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

91. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product with its proposed labeling upon FDA approval of Alembic's ANDA.

ANSWER: Alembic admits the allegations of Paragraph 91.

92. On information and belief, the use of Alembic's ANDA Product in accordance with and as directed by Alembic's proposed labeling for that product would infringe at least claim 1 of the ’530 patent, recited above.

ANSWER: Alembic denies the allegations of Paragraph 92.

93. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the ’530 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Alembic denies the allegations of Paragraph 93.

94. On information and belief, Alembic knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’530 patent and that

its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the '530 patent after approval of Alembic's ANDA.

ANSWER: Alembic denies the allegations of Paragraph 93.

95. The foregoing actions by Alembic constitute and/or will constitute infringement of the ’530 patent, active inducement of infringement of the ’530 patent, and contribution to the infringement by others of the ’530 patent.

ANSWER: Alembic denies the allegations of Paragraph 95.

96. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Alembic regarding whether Alembic's manufacture, use, sale, offer for sale, or importation into the United States of Alembic's ANDA Product with its proposed labeling according to Alembic's ANDA will infringe at least claim 1 of the ’530 patent, recited above.

ANSWER: Alembic denies the allegations of Paragraph 96.

97. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Alembic's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’530 patent and that the claims of the ’530 patent are valid.

ANSWER: Alembic denies the allegations of Paragraph 97.

98. Alembic should be enjoined from infringing the ’530 patent, actively inducing infringement of the ’530 patent, and contributing to the infringement by others of the ’530 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Alembic denies the allegations of Paragraph 98.

COUNT VI - DECLARATORY JUDGMENT OF INFRINGEMENT BY ALEMBIC OF THE '853 PATENT

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

ANSWER: Alembic incorporates by reference its answers to Paragraphs 1-98 as if set forth herein.

100. Alembic has knowledge of the '853 patent.

ANSWER: Alembic admits the allegations of Paragraph 100.

101. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product would infringe at least claim 1 of the '853 patent, recited above, literally and/or under the doctrine of equivalents.

ANSWER: Paragraph 101 contains legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

102. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product with its proposed labeling upon FDA approval of Alembic's ANDA.

ANSWER: Alembic admits the allegations of Paragraph 102.

103. On information and belief, the use of Alembic's ANDA Product in accordance with and as directed by Alembic's proposed labeling for that product would infringe at least claim 1 of the '853 patent, recited above.

ANSWER: Alembic denies the allegations of Paragraph 103.

104. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the '853 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Alembic denies the allegations of Paragraph 104.

105. On information and belief, Alembic knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’853 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the '853 patent after approval of Alembic's ANDA.

ANSWER: Alembic denies the allegations of Paragraph 105.

106. The foregoing actions by Alembic constitute and/or will constitute infringement of the ’853 patent, active inducement of infringement of the ’853 patent, and contribution to the infringement by others of the ’853 patent.

ANSWER: Alembic denies the allegations of Paragraph 106.

107. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Alembic regarding whether Alembic's manufacture, use, sale, offer for sale, or importation into the United States of Alembic's ANDA Product with its proposed labeling according to Alembic's ANDA will infringe at least claim 1 of the ’853 patent, recited above.

ANSWER: Alembic denies the allegations of Paragraph 107.

108. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Alembic's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’853 patent and that the claims of the ’853 patent are valid.

ANSWER: Alembic denies the allegations of Paragraph 108.

109. Alembic should be enjoined from infringing the ’853 patent, actively inducing infringement of the ’853 patent, and contributing to the infringement by others of the ’853 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Alembic denies the allegations of Paragraph 109.

COUNT VII - DECLARATORY JUDGMENT OF INFRINGEMENT BY ALEMBIC OF THE ’515 PATENT

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

ANSWER: Alembic incorporates by reference its answers to Paragraphs 1-109 as if set forth herein.

111. Alembic has knowledge of the ’515 patent.

ANSWER: Alembic admits the allegations of Paragraph 111.

112. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product would infringe at least claim 1 of the ’515 patent, recited above, literally and/or under the doctrine of equivalents.

ANSWER: Paragraph 112 contains legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

113. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product with its proposed labeling upon FDA approval of Alembic's ANDA.

ANSWER: Alembic admits the allegations of Paragraph 113.

114. On information and belief, the use of Alembic's ANDA Product in accordance with and as directed by Alembic's proposed labeling for that product would infringe at least claim 1 of the ’515 patent, recited above.

ANSWER: Alembic denies the allegations of Paragraph 114.

115. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the ’515 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Alembic denies the allegations of Paragraph 115.

116. On information and belief, Alembic knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’515 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the '515 patent after approval of Alembic's ANDA.

ANSWER: Alembic denies the allegations of Paragraph 116.

117. The foregoing actions by Alembic constitute and/or will constitute infringement of the ’515 patent, active inducement of infringement of the ’515 patent, and contribution to the infringement by others of the ’515 patent.

ANSWER: Alembic denies the allegations of Paragraph 117.

118. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Alembic regarding whether Alembic's manufacture, use, sale, offer for sale, or importation into the United States of Alembic's ANDA Product with its proposed labeling according to Alembic's ANDA will infringe at least claim 1 of the ’515 patent, recited above.

ANSWER: Alembic denies the allegations of Paragraph 118.

119. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Alembic's ANDA Product with its

proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’515 patent and that the claims of the ’515 patent are valid.

ANSWER: Alembic denies the allegations of Paragraph 119.

120. Alembic should be enjoined from infringing the ’515 patent, actively inducing infringement of the ’515 patent, and contributing to the infringement by others of the ’515 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Alembic denies the allegations of Paragraph 120.

COUNT VIII - DECLARATORY JUDGMENT OF INFRINGEMENT BY ALEMBIC OF THE ’058 PATENT

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

ANSWER: Alembic incorporates by reference its answers to Paragraphs 1-120 as if set forth herein.

122. Alembic has knowledge of the ’058 patent.

ANSWER: Alembic admits the allegations of Paragraph 122.

123. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product would infringe at least claim 1 and/or claim 10 of the ’058 patent, recited above, literally and/or under the doctrine of equivalents.

ANSWER: Paragraph 123 contains legal conclusions to which no response is required. To the extent a response is required, Alembic denies all such allegations.

124. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product with its proposed labeling upon FDA approval of Alembic's ANDA.

ANSWER: Alembic admits the allegations of Paragraph 124.

125. On information and belief, the use of Alembic's ANDA Product in accordance with and as directed by Alembic's proposed labeling for that product would infringe at least claim 1 of the ’058 patent, recited above.

ANSWER: Alembic denies the allegations of Paragraph 125.

126. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the ’058 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Alembic denies the allegations of Paragraph 126.

127. On information and belief, Alembic knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’058 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the '058 patent after approval of Alembic's ANDA.

ANSWER: Alembic denies the allegations of Paragraph 127.

128. The foregoing actions by Alembic constitute and/or will constitute infringement of the ’058 patent, active inducement of infringement of the ’058 patent, and contribution to the infringement by others of the ’058 patent.

ANSWER: Alembic denies the allegations of Paragraph 128.

129. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Alembic regarding whether Alembic's manufacture, use, sale, offer for sale, or importation into the United States of Alembic's ANDA Product with its proposed labeling according to Alembic's ANDA will infringe at least claim 1 of the ’058 patent, recited

above.

ANSWER: Alembic denies the allegations of Paragraph 129.

130. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Alembic's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '058 patent and that the claims of the '058 patent are valid.

ANSWER: Alembic denies the allegations of Paragraph 130.

131. Alembic should be enjoined from infringing the '058 patent, actively inducing infringement of the '058 patent, and contributing to the infringement by others of the '058 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Alembic denies the allegations of Paragraph 131.

ALEMBIC'S AFFIRMATIVE DEFENSES

Alembic asserts the following affirmative defenses without prejudice to the responses set forth in its Answer and without making any admission or implication as to the burden of proof for these defenses. Alembic reserves the right to assert other defenses and/or counterclaims if discovery merits such action.

FIRST DEFENSE
(Failure to State a Claim)

Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE
(Non-Infringement Under 35 U.S.C. § 271(a))

Alembic has not manufactured, used, offered to sell, sold, and/or imported Alembic's ANDA Product. Therefore, Alembic has not committed any acts of infringement under 35 U.S.C. § 271(a).

THIRD DEFENSE
(Non-Infringement Under 35 U.S.C. § 271(e)(2))

The manufacture, use, sale, offer for sale, and/or importation, of Alembic's ANDA Product has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid and enforceable claim of the patents-in-suit, either literally or under the doctrine of equivalents.

FOURTH DEFENSE
(Declaratory Judgment)

There are no real, substantial and continuing case or controversy regarding infringement of the patents-in-suit under 35 U.S.C. § 271(a) since Alembic has not committed any acts of infringement under 35 U.S.C. § 271(a).

FIFTH DEFENSE
(Invalidity)

One or more claims of the patents-in-suit are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112.

RESERVATION OF ALL DEFENSES

Alembic hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure, Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, and U.S. Patent Law, and any other defenses, at law or in equity, including unenforceability, that may exist or become available later as a result of discovery and further factual investigation during this litigation.

ALEMBIC'S COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Alembic Pharmaceuticals Limited ("Defendant" or "Alembic"), for its Counterclaims against Plaintiffs/Counterclaim-Defendants Orion Corporation ("Orion"), Bayer Consumer Care AG ("BCC"), Bayer Healthcare LLC ("BHC"), and Bayer Healthcare Pharmaceuticals Inc. ("BHCPI"), (collectively "Plaintiffs" or "Counterclaim-Defendants"), alleges as follows:

The Parties

1. Alembic is a corporation solely under the laws of India with its principal place of business at Alembic Road, Vadodara – 390 003, Gujarat India.

2. Orion purports to be a corporation organized and existing under the laws of Finland, with a principal place of business at Orionintie IA, FI-02200 Espoo, Finland.

3. BCC purports to be a corporation organized and existing under the laws of Switzerland, with a principal place of business at Peter Merian-Str. 84, Basel, Switzerland 4052.

4. BHC purports to be a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 100 Bayer Boulevard, Whippany, New Jersey.

5. BHCPI purports to be a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 100 Bayer Boulevard, Whippany, New Jersey.

Jurisdiction and Venue

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

8. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have purposefully availed themselves of the rights and privileges of this forum by suing Alembic in this District, and because on information and belief, Plaintiffs conduct substantial business in, and has regular and systematic contacts with, this District.

9. Venue for these Counterclaims is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

COUNT I
(Declaration of Non-Infringement of the ’530 Patent)

10. Alembic realleges and incorporates by reference the allegations of Paragraph 1-9.

11. A present, genuine, and justiciable controversy exists between Plaintiffs and Alembic regarding, inter alia, the non-infringement of the ’530 patent.

12. The manufacture, use, sale, offer for sale or importation of darolutamide tablets, 300 mg, that is the subject of Alembic’s ANDA No. 220499, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the ’530 patent.

13. Alembic is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of darolutamide tablets, 300 mg, that is the subject of Alembic’s ANDA No. 220499, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the ’530 patent.

COUNT II
(Declaration of Non-Infringement of the ’853 Patent)

14. Alembic realleges and incorporates by reference the allegations of Paragraph 1-13.

15. A present, genuine, and justiciable controversy exists between Plaintiffs and Alembic regarding, inter alia, the non-infringement of the ’853 patent.

16. The manufacture, use, sale, offer for sale or importation of darolutamide tablets, 300 mg, that is the subject of Alembic’s ANDA No. 220499, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the ’853 patent.

17. Alembic is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of darolutamide tablets, 300 mg, that is the subject of Alembic’s ANDA No. 220499, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the ’853 patent.

COUNT III
(Declaration of Non-Infringement of the ’515 Patent)

18. Alembic realleges and incorporates by reference the allegations of Paragraph 1-17.

19. A present, genuine, and justiciable controversy exists between Plaintiffs and Alembic regarding, inter alia, the non-infringement of the ’515 patent.

20. The manufacture, use, sale, offer for sale or importation of darolutamide tablets, 300 mg, that is the subject of Alembic’s ANDA No. 220499, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the ’515 patent.

21. Alembic is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of darolutamide tablets, 300 mg, that is the subject of Alembic’s ANDA No.

220499, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the ’515 patent.

COUNT IV
(Declaration of Non-Infringement of the ’058 Patent)

22. Alembic realleges and incorporates by reference the allegations of Paragraph 1-21.

23. A present, genuine, and justiciable controversy exists between Plaintiffs and Alembic regarding, inter alia, the non-infringement of the ’058 patent.

24. The manufacture, use, sale, offer for sale or importation of darolutamide tablets, 300 mg, that is the subject of Alembic’s ANDA No. 220499, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the ’058 patent.

25. Alembic is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of darolutamide tablets, 300 mg, that is the subject of Alembic’s ANDA No. 220499, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the ’058 patent.

COUNT V
(Declaration of Invalidity of the ’530 Patent)

26. Alembic realleges and incorporates by reference the allegations of Paragraph 1-25.

27. A present, genuine, and justiciable controversy exists between Plaintiffs and Alembic regarding, inter alia, the invalidity of the ’530 patent.

28. One or more claims of the ’530 are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112.

29. Alembic is entitled to a declaration that the ’530 patent is invalid for failing to comply with the conditions of patentability set forth in Title 35 of the United States Code.

COUNT VI
(Declaration of Invalidity of the ’853 Patent)

30. Alembic realleges and incorporates by reference the allegations of Paragraph 1-29.

31. A present, genuine, and justiciable controversy exists between Plaintiffs and Alembic regarding, inter alia, the invalidity of the ’853 patent.

32. One or more claims of the ’853 are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112.

33. Alembic is entitled to a declaration that the ’853 patent is invalid for failing to comply with the conditions of patentability set forth in Title 35 of the United States Code.

COUNT VII
(Declaration of Invalidity of the ’515 Patent)

34. Alembic realleges and incorporates by reference the allegations of Paragraph 1-33.

35. A present, genuine, and justiciable controversy exists between Plaintiffs and Alembic regarding, inter alia, the invalidity of the ’515 patent.

36. One or more claims of the ’515 are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112.

37. Alembic is entitled to a declaration that the ’515 patent is invalid for failing to comply with the conditions of patentability set forth in Title 35 of the United States Code.

COUNT VIII
(Declaration of Invalidity of the '058 Patent)

38. Alembic realleges and incorporates by reference the allegations of Paragraph 1-37.

39. A present, genuine, and justiciable controversy exists between Plaintiffs and Alembic regarding, inter alia, the invalidity of the '058 patent.

40. One or more claims of the '058 are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112.

41. Alembic is entitled to a declaration that the '058 patent is invalid for failing to comply with the conditions of patentability set forth in Title 35 of the United States Code.

PRAYER FOR RELIEF

WHEREFORE, Alembic demands judgment for itself and against Plaintiffs/Counterclaim Defendants as follows:

A. A declaration that the manufacture, use, sale, offer for sale or importation of darolutamide tablets, 300 mg, that is the subject of Alembic's ANDA No. 220499, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '530, '853, '515 and '058 patents.

B. A declaration that one or more claims of the '530, '853, '515 and '058 are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and 112.

C. An award to Alembic of such further relief at law or in equity as the Court deems just and proper.

Dated: September 8, 2025

DEVLIN LAW FIRM LLC

/s/ Timothy Devlin

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