IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and KAI PHARMACEUTICALS, INC., Plaintiffs, v. USV PRIVATE LIMITED, Defendant.	))))))))))	C.A. No. _____

COMPLAINT

Plaintiffs Amgen Inc. ("Amgen") and KAI Pharmaceuticals, Inc. ("KAI") (collectively "Plaintiffs") by their attorneys, hereby allege as follows:

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 submission by defendant USV Private Limited ("USV") of Abbreviated New Drug Application ("ANDA") No. 216930 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Parsabiv® (etelcalcetide) injection for intravenous use at strengths of 2.5 mg/0.5 mL, 5 mg/mL, and 10 mg/2 mL ("USV's Proposed ANDA Product") prior to the expiration of U.S. Patent Nos. 9,820,938 ("the '938 patent"), 10,344,765 ("the '765 patent"), and 11,162,500 ("the '500 patent") (collectively "the Asserted Patents"). USV notified Plaintiffs that it had submitted this ANDA by a letter received February 28, 2022 ("Notice Letter"). Upon information and belief, USV's Proposed ANDA Product will be marketed as a competing product to Parsabiv® (etelcalcetide), a product developed by Plaintiffs for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

PARTIES

2. Plaintiff Amgen is a corporation organized and existing under the laws of Delaware, having its corporate offices and a place of business at One Amgen Center Drive, Thousand Oaks, CA 91320.

3. Plaintiff KAI is a corporation organized and existing under the laws of Delaware, having a place of business at One Amgen Center Drive, Thousand Oaks, CA 91320. KAI is a wholly owned subsidiary of Amgen.

4. Upon information and belief, Defendant USV is a corporation organized and existing under the laws of India, having a place of business at Arvind Vithal Gandhi Chowk, B.S.D. Marg, Station Road, Govandi East, Mumbai, Maharashtra, 400088 India. Upon information and belief, USV is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs, throughout the United States, including in Delaware.

JURISDICTION AND VENUE

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

6. On information and belief, USV develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

7. In addition, this Court has personal jurisdiction over USV because, among other things, on information and belief: (1) USV filed USV's ANDA for the purpose of seeking approval

to engage in the commercial manufacture, use, sale, or offer for sale of USV's Proposed ANDA Product in the United States, including in Delaware; and (2) upon approval of USV's ANDA, USV will market, distribute, offer for sale, sell, and/or import USV's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of USV's Proposed ANDA Product in Delaware. On information and belief, upon approval of USV's ANDA, USV's Proposed 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 substantial effects on Delaware.

8. In addition, this Court has personal jurisdiction over USV because it has committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Amgen and KAI, both Delaware corporations.

9. In addition, this Court has personal jurisdiction over USV because it regularly engages in patent litigation concerning USV's ANDA products in this District and does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by contesting claims in this District. *See, e.g.*, *Astellas US LLC, et al. v. USV Private Ltd.*, C.A. No. 20-00793 (D. Del.).

10. In addition, to the extent personal jurisdiction does not exist over USV in Delaware, this Court has personal jurisdiction over it under Federal Rule of Civil Procedure 4(k)(2) because USV is not subject to jurisdiction in any state's courts of general jurisdiction and exercising jurisdiction over it is consistent with the United States Constitution and laws.

11. For at least the above reasons, it would not be unfair or unreasonable for USV to litigate this action in this District, and USV is subject to personal jurisdiction in this District.

12. Venue is proper in this Court under 28 U.S.C. § 1391(c) with respect to USV at least because, on information and belief, USV is a foreign corporation that may be sued in any judicial district.

BACKGROUND

PARSABIV® (ETELCALCETIDE)

13. On February 7, 2017, the FDA granted approval to market Parsabiv® (etelcalcetide) for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

14. The active pharmaceutical ingredient in Parsabiv® is etelcalcetide, which was invented by scientists at KAI and developed by KAI and Amgen. Etelcalcetide is a synthetic peptide calcium-sensing receptor agonist. It is a calcimimetic agent that allosterically modulates the calcium-sensing receptor ("CaSR"). Etelcalcetide binds to the CaSR and enhances activation of the receptor by extracellular calcium. Activation of the CaSR on parathyroid chief cells decreases parathyroid hormone ("PTH") secretion.

15. Parsabiv® (etelcalcetide) is FDA approved for intravenous injection. It is FDA approved as a sterile, preservative-free, ready-to-use clear and colorless solution in a single-dose vial containing 5 mg/mL of etelcalcetide. Each vial contains 2.5, 5, or 10 mg etelcalcetide. Each vial is formulated with 0.85% weight/volume sodium chloride, 10 mM succinic acid, and adjusted to pH 3.3 with sodium hydroxide and/or hydrochloric acid.

16. Amgen, itself or through a subsidiary, markets Parsabiv® (etelcalcetide) in the United States pursuant to approved New Drug Application ("NDA") No. 208325.

17. KAI, a wholly owned subsidiary of Amgen, is the holder of approved NDA No. 208325 for Parsabiv® (etelcalcetide).

18. The '938, '765, and '500 patents are listed for NDA No. 208325 for Parsabiv® (etelcalcetide) in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

19. The '938 patent, titled "Stable Liquid Formulation of AMG 416 (Etelcalcetide)," was duly and legally issued on November 21, 2017. A copy of the '938 patent is attached as Exhibit A.

20. Plaintiffs own and have rights to the '938 patent.

21. There is an actual case or controversy between the parties regarding USV's liability for its infringement of the '938 patent.

22. The '765 patent, titled "Stable Liquid Formulation of AMG 416 (Etelcalcetide)," was duly and legally issued on July 9, 2019. A copy of the '765 patent is attached as Exhibit B.

23. Plaintiffs own and have rights to the '765 patent.

24. There is an actual case or controversy between the parties regarding USV's liability for its infringement of the '765 patent.

25. The '500 patent, titled "Stable Liquid Formulation of AMG 416 (Etelcalcetide)," was duly and legally issued on November 2, 2021. A copy of the '500 patent is attached as Exhibit C.

26. Plaintiffs own and have rights to the '500 patent.

27. There is an actual case or controversy between the parties regarding USV's liability for its infringement of the '500 patent.

USV'S ANDA

28. On February 28, 2022, Plaintiffs received USV's Notice Letter, which informed Plaintiffs that USV seeks through ANDA No. 216930 approval to engage in the commercial manufacture, use, sale, or offer for sale of USV's Proposed ANDA Product prior to the expiration of the Asserted Patents. According to the Notice Letter, included within ANDA No. 216930 is a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of USV's Proposed ANDA Product.

29. On information and belief, USV included within ANDA No. 216930 a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification") that USV is not seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of USV's Proposed ANDA Product prior to the expiration of U.S. Patent Nos. 8,377,880, 8,999,932, 9,278,995, and 9,701,712, which are also listed in the Orange Book for NDA No. 208325 for Parsabiv® (etelcalcetide).

30. This action is being filed within 45 days of Plaintiffs' receipt of USV's Notice Letter.

31. USV was aware of the Asserted Patents when ANDA No. 216930 was filed with a Paragraph IV Certification.

32. On information and belief, etelcalcetide is the active ingredient in USV's Proposed ANDA Product. On information and belief, USV's Proposed ANDA Product is a pharmaceutical formulation comprising etelcalcetide in an aqueous solution having a pH of 2.0 to 5.0 and an etelcalcetide concentration of between 0.5 mg/mL to 15 mg/mL.

33. On information and belief, ANDA No. 216930 refers to and relies upon the NDA for Parsabiv® (etelcalcetide) and contains data that, according to USV, demonstrate bioequivalence of USV's Proposed ANDA Product and Parsabiv® (etelcalcetide), *see* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7), or USV has sought a waiver of the requirement to demonstrate bioequivalence of its Proposed ANDA Product and Parsabiv® (etelcalcetide).

34. On information and belief, USV intends to have healthcare providers use its Proposed ANDA Product, if approved, as set forth in its Proposed ANDA Product label. On information and belief, USV's Proposed ANDA Product label will instruct healthcare providers to prescribe USV's Proposed ANDA Product in the manner set forth in the label.

COUNT I
(Infringement of the '938 Patent)

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

36. Claim 1 of the '938 patent covers "[a] pharmaceutical formulation comprising AMG 416 [etelcalcetide] in aqueous solution, wherein the formulation has a pH of 2.0 to 5.0."

37. Upon information and belief, USV's Proposed ANDA Product is covered by one or more claims of the '938 patent, including at least claim 1, because it is a pharmaceutical formulation comprising etelcalcetide in an aqueous solution having a pH of 2.0 to 5.0.

38. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of USV's Proposed ANDA Product, or the use of USV's Proposed ANDA Product in accordance with and as directed by USV's proposed labeling for that product, will infringe one or more claims of the '938 patent, including at least claim 1, either literally or under the doctrine of equivalents.

39. Upon information and belief, USV filed as part of ANDA No. 216930 a Paragraph IV Certification, asserting that the claims of the '938 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of USV's Proposed ANDA Product.

40. USV did not contend in its Notice Letter that USV's Proposed ANDA Product, or the use of USV's Proposed ANDA Product in accordance with and as directed by USV's proposed labeling for that product, would not infringe claims 1-5 and 7-14 of the '938 patent.

41. USV has no reasonable basis to believe that USV's Proposed ANDA Product, or the use of USV's Proposed ANDA Product in accordance with and as directed by USV's proposed labeling for that product, would not infringe one or more valid claims of the '938 patent.

42. The purpose of filing ANDA No. 216930 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of USV's Proposed ANDA Product prior to the expiration of the '938 patent.

43. USV's submission of ANDA No. 216930 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of USV's Proposed ANDA Product prior to the expiration of the '938 patent is an act of infringement of the '938 patent under 35 U.S.C. § 271(e)(2)(A).

44. Upon information and belief, USV intends to engage in the commercial manufacture, use, sale and/or offer for sale of USV's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 216930 and any amendments thereto, *i.e.*, prior to the expiration of the '938 patent.

45. Upon information and belief, USV has knowledge of the '938 patent at least because the '938 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Amgen's Parsabiv® (etelcalcetide) drug product.

Notwithstanding this knowledge, USV continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of USV's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 216930 and any amendments thereto.

46. Upon information and belief, USV plans and intends to, and will, actively induce infringement of the '938 patent when ANDA No. 216930 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '938 patent. Further, upon information and belief, USV plans and intends to, and will, do so immediately and imminently upon approval.

47. The foregoing actions by USV constitute and/or will constitute infringement of the '938 patent and active inducement of infringement of the '938 patent, either literally or under the doctrine of equivalents.

48. Unless USV is enjoined from infringing the '938 patent and actively inducing infringement of the '938 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '765 Patent)

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

50. Claim 1 of the '765 patent covers "[a] pharmaceutical formulation comprising AMG 416 [etelcalcetide] hydrochloride in aqueous solution, wherein the formulation has a pH of 2.0 to 5.0."

51. Upon information and belief, USV's Proposed ANDA Product is covered by one or more claims of the '765 patent, including at least claim 1, because it is a pharmaceutical

formulation comprising etelcalcetide hydrochloride in an aqueous solution having a pH of 2.0 to 5.0.

52. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of USV's Proposed ANDA Product, or the use of USV's Proposed ANDA Product in accordance with and as directed by USV's proposed labeling for that product, will infringe one or more claims of the '765 patent, including at least claim 1, either literally or under the doctrine of equivalents.

53. Upon information and belief, USV filed as part of ANDA No. 216930 a Paragraph IV Certification, asserting that the claims of the '765 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of USV's Proposed ANDA Product.

54. USV did not contend in its Notice Letter that USV's Proposed ANDA Product, or the use of USV's Proposed ANDA Product in accordance with and as directed by USV's proposed labeling for that product, would not infringe claims 1-5 and 7-14 of the '765 patent.

55. USV has no reasonable basis to believe that USV's Proposed ANDA Product, or the use of USV's Proposed ANDA Product in accordance with and as directed by USV's proposed labeling for that product, would not infringe one or more valid claims of the '765 patent.

56. The purpose of filing ANDA No. 216930 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of USV's Proposed ANDA Product prior to the expiration of the '765 patent.

57. USV's submission of ANDA No. 216930 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of USV's Proposed ANDA Product prior to the expiration of the '765 patent is an act of infringement of the '765 patent under 35 U.S.C. § 271(e)(2)(A).

58. Upon information and belief, USV intends to engage in the commercial manufacture, use, sale and/or offer for sale of USV's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 216930 and any amendments thereto, *i.e.*, prior to the expiration of the '765 patent.

59. Upon information and belief, USV has knowledge of the '765 patent at least because the '765 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Amgen's Parsabiv® (etelcalcetide) drug product. Notwithstanding this knowledge, USV continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of USV's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 216930 and any amendments thereto.

60. Upon information and belief, USV plans and intends to, and will, actively induce infringement of the '765 patent when ANDA No. 216930 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '765 patent. Further upon information and belief, USV plans and intends to, and will, do so immediately and imminently upon approval.

61. The foregoing actions by USV constitute and/or will constitute infringement of the '765 patent and active inducement of infringement of the '765 patent, either literally or under the doctrine of equivalents.

62. Unless USV is enjoined from infringing the '765 patent and actively inducing infringement of the '765 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III
(Infringement of the '500 Patent)

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

64. Claim 1 of the '500 patent covers "[a] pharmaceutical formulation comprising etelcalcetide in aqueous solution, wherein the formulation has a pH of 2.0 to 5.0 and wherein the etelcalcetide is present at a concentration of between 0.5 mg/mL to 15 mg/mL."

65. Upon information and belief, USV's Proposed ANDA Product is covered by one or more claims of the '500 patent, including at least claim 1, because it is a pharmaceutical formulation comprising etelcalcetide in an aqueous solution having a pH of 2.0 to 5.0 and an etelcalcetide concentration of between 0.5 mg/mL to 15 mg/mL.

66. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of USV's Proposed ANDA Product, or the use of USV's Proposed ANDA Product in accordance with and as directed by USV's proposed labeling for that product, will infringe one or more claims of the '500 patent, including at least claim 1, either literally or under the doctrine of equivalents.

67. Upon information and belief, USV filed as part of ANDA No. 216930 a Paragraph IV Certification, asserting that the claims of the '500 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of USV's Proposed ANDA Product.

68. USV did not contend in its Notice Letter that USV's Proposed ANDA Product, or the use of USV's Proposed ANDA Product in accordance with and as directed by USV's proposed labeling for that product, would not infringe claims 1-4, 6-16, 19-24, 27-33, 35, 50, 52-57, 61-67, 69, 71, and 86 of the '500 patent.

69. USV has no reasonable basis to believe that USV's Proposed ANDA Product, or the use of USV's Proposed ANDA Product in accordance with and as directed by USV's proposed labeling for that product, would not infringe one or more valid claims of the '500 patent.

70. The purpose of filing ANDA No. 216930 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of USV's Proposed ANDA Product prior to the expiration of the '500 patent.

71. USV's submission of ANDA No. 216930 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of USV's Proposed ANDA Product prior to the expiration of the '500 patent is an act of infringement of the '500 patent under 35 U.S.C. § 271(e)(2)(A).

72. Upon information and belief, USV intends to engage in the commercial manufacture, use, sale and/or offer for sale of USV's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 216930 and any amendments thereto, *i.e.*, prior to the expiration of the '500 patent.

73. Upon information and belief, USV has knowledge of the '500 patent at least because the '500 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Amgen's Parsabiv® (etelcalcetide) drug product. Notwithstanding this knowledge, USV continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of USV's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 216930 and any amendments thereto.

74. Upon information and belief, USV plans and intends to, and will, actively induce infringement of the '500 patent when ANDA No. 216930 and any amendments thereto are

approved, and will do so with specific intent to induce infringement of the '500 patent. Further, upon information and belief, USV plans and intends to, and will, do so immediately and imminently upon approval.

75. The foregoing actions by USV constitute and/or will constitute infringement of the '500 patent and active inducement of infringement of the '500 patent, either literally or under the doctrine of equivalents.

76. Unless USV is enjoined from infringing the '500 patent and actively inducing infringement of the '500 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that USV's submission of ANDA No. 216930 to the FDA was an act of infringement of one or more claims of the Asserted Patents;

(b) A judgment that USV's making, using, offering to sell, selling, marketing, distributing, or importing into the United States USV's Proposed ANDA Product prior to the expiration of the Asserted Patents will infringe and/or will actively induce infringement of one or more claims of the Asserted Patents;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for USV to make, use, offer for sale, sell, market, distribute, or import USV's Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, be not earlier than the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) enjoining USV, USV's affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with USV, from making, using, selling, offering to sell, marketing, distributing, or importing USV's Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, or the inducement of any of the foregoing, prior to the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

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

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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