IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and NOVARTIS PHARMACEUTICALS CORP., Plaintiffs, v. KASHIV BIOSCIENCES, LLC, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS, INC., Defendants.	C.A. No. _____ JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs Genentech, Inc. ("Genentech") and Novartis Pharmaceuticals Corp. ("Novartis"), by and through their undersigned attorneys, for their Complaint against Defendants Kashiv BioSciences, LLC ("Kashiv"), Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals, Inc. (collectively, "Amneal") hereby allege as follows:

NATURE OF THE CASE

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("BPCIA"), and the Declaratory Judgment Act of 1934, 28 U.S.C. §§ 2201-2202.

2. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. 42 U.S.C. § 262(k). The abbreviated pathway (also known as the "subsection (k) pathway") allows a biosimilar applicant (here, Kashiv) to rely on the prior licensure

and approval status of the innovative biological product that the biosimilar purports to copy, known as the "reference product" (here, Genentech's and Novartis's XOLAIR® (omalizumab)). Genentech is the sponsor of XOLAIR® and therefore the "reference product sponsor" or "RPS" under the BPCIA. In the United States, Genentech and Novartis work together to develop and co-promote XOLAIR®.

3. XOLAIR® (omalizumab) targets and blocks immunoglobulin E (IgE). By reducing free IgE, down-regulating high-affinity IgE receptors and limiting mast cell degranulation, XOLAIR® minimizes the release of mediators throughout the allergic inflammatory cascade. XOLAIR® was first approved by the United States Food and Drug Administration ("FDA") in 2003 for the treatment of moderate-to-severe persistent asthma in certain adults and adolescents. FDA also has approved XOLAIR® for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in certain adult patients and the treatment of chronic spontaneous urticaria (CSU) in certain adults and adolescents. Most recently, FDA approved XOLAIR® in 2024 for IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. About 3.4 million children and 13.6 million adults in the U.S. have been diagnosed with IgE-mediated food allergies, based on estimates for 2024. Allergic reactions can range from mild to moderate, including hives and swelling, to severe and life-threatening, such as anaphylaxis. More than 40% of children and more than half of adults with food allergies have experienced a severe reaction at least once, and it is estimated that food-related anaphylaxis results in 30,000 medical events treated in emergency rooms in the U.S. each year.

4. Genentech and Novartis hold numerous patents related to XOLAIR® and the

manufacture and use of biologics like omalizumab.

5. On September 26, 2025, Amneal Pharmaceuticals, Inc. announced the submission of a Biologics License Application ("BLA") with FDA for a biosimilar copy of XOLAIR®, developed by Kashiv.[1] Defendants plan to sell ADL-018, the biosimilar product that is the subject of this BLA ("Proposed Kashiv Omalizumab Biosimilar"). Defendants' submission of this BLA constitutes an act of patent infringement under 35 U.S.C. § 271(e).

THE PARTIES, JURISDICTION, AND VENUE

6. Plaintiff Genentech is a corporation existing under the laws of the State of Delaware, with its corporate headquarters at 1 DNA Way, South San Francisco, California 94080. Genentech is a biotechnology company that develops, manufactures, and commercializes medicines to treat patients with serious and life-threatening medical conditions.

7. Plaintiff Novartis is a corporation organized and existing under the laws of Delaware, having a principal place of business at One Health Plaza, East Hanover, New Jersey 07936. Novartis is an innovative medicines company that works to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease.

8. On information and belief, Defendant Kashiv is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 20 New England Avenue, Piscataway, NJ 08854. Upon information and belief, Kashiv is in the business of, among other things, manufacturing and selling biosimilar versions of branded biologic drugs itself and through various operating subsidiaries throughout the United States,

[1] https://investors.amneal.com/news/press-releases/press-release-details/2025/Amneal-Announces-BLA-Submission-of-Biosimilar-Candidate-to-XOLAIR-omalizumab/default.aspx

including in Delaware. Upon information and belief, Kashiv is a wholly owned subsidiary of Amneal Pharmaceuticals, Inc.

9. On information and belief, Defendant Amneal Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Crossing Blvd., Bridgewater, NJ 08807. Upon information and belief, Amneal Pharmaceuticals LLC is a wholly owned subsidiary of Amneal Pharmaceuticals, Inc. Upon information and belief, Amneal Pharmaceuticals LLC is in the business of, among other things, manufacturing and selling biosimilar versions of branded biologic drugs itself and through various operating subsidiaries throughout the United States, including in Delaware.

10. On information and belief, Defendant Amneal Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Crossing Blvd., Bridgewater, NJ 08807. Upon information and belief, Amneal Pharmaceuticals, Inc. is in the business of, among other things, manufacturing and selling biosimilar versions of branded biologic drugs itself and through various operating subsidiaries throughout the United States, including in Delaware.

11. On information and belief, Defendants, acting in concert with each other, intend to develop, manufacture, market, distribute, offer for sale and/or sell in this Judicial District and throughout the United States the Proposed Kashiv Omalizumab Biosimilar following FDA approval of Defendants' BLA and, in doing so, will improperly exploit Genentech's and Novartis's intellectual property.

12. This is an action for patent infringement under the Patent Laws of the United States, Title 35 of the United States Code, Title 42 of the United States Code, and under the Declaratory

Judgment Act of 1934 (28 U.S.C. §§ 2201-2202), Title 28 of the United States Code.

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

14. This Court has personal jurisdiction over Kashiv because it is a limited liability company organized and existing under the laws of the State of Delaware, and also because it, directly and through its respective subsidiaries, affiliates, or agents, is in the business of manufacturing biosimilar drugs that it distributes or has distributed in the State of Delaware and throughout the United States, and has purposely availed itself of the rights and benefits of the State of Delaware, has engaged in systematic and continuous contacts with the State of Delaware, and regularly and continuously conducts business within this State, including by placing its products in the stream of commerce for distribution and consumption in Delaware. On information and belief, Kashiv derives substantial revenue from selling pharmaceutical products throughout the United States, including Delaware.

15. This Court has personal jurisdiction over Amneal Pharmaceuticals LLC because it is a limited liability company organized and existing under the laws of the State of Delaware, and also because it, directly and through its respective subsidiaries, affiliates, or agents, is in the business of manufacturing biosimilar drugs that it distributes or has distributed in the State of Delaware and throughout the United States, and has purposely availed itself of the rights and benefits of the State of Delaware, has engaged in systematic and continuous contacts with the State of Delaware, and regularly and continuously conducts business within this State, including by placing its products in the stream of commerce for distribution and consumption in Delaware. On information and belief, Amneal Pharmaceuticals LLC derives substantial revenue from selling pharmaceutical products throughout the United States, including Delaware.

16. This Court has personal jurisdiction over Amneal Pharmaceuticals, Inc. because it is a corporation organized and existing under the laws of the State of Delaware, and also because it, directly and through its respective subsidiaries, affiliates, or agents, is in the business of manufacturing biosimilar drugs that it distributes or has distributed in the State of Delaware and throughout the United States, and has purposely availed itself of the rights and benefits of the State of Delaware, has engaged in systematic and continuous contacts with the State of Delaware, and regularly and continuously conducts business within this State, including by placing its products in the stream of commerce for distribution and consumption in Delaware. On information and belief, Amneal Pharmaceuticals, Inc. derives substantial revenue from selling pharmaceutical products throughout the United States, including Delaware.

17. On information and belief, each of Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals, Inc. acted in collaboration and in concert with Kashiv to take substantial steps to prepare for and undertake the filing of Defendants' BLA and to file Defendants' BLA, seeking to market the Proposed Kashiv Omalizumab Biosimilar nationwide, including within this Judicial District.

18. This Court also has personal jurisdiction over each Defendant because this suit arises from and relates to their activities that are, and will be, directed to Delaware. On information and belief, following FDA approval of Defendants' BLA, Defendants, acting in collaboration and in concert, will market and sell the Proposed Kashiv Omalizumab Biosimilar, which is the subject of the infringement claims in this action, in the State of Delaware and throughout the United States, including in this Judicial District.

19. On information and belief, Defendants, acting in collaboration and in concert, have committed, or aided, abetted, induced, contributed to, and/or participated in the commission of the

tortious act of patent infringement that will lead to foreseeable harm and injury to Genentech and Novartis, which developed, obtained FDA approval for, manufactured, and/or distributed XOLAIR® for sale and use throughout the United States, including in this Judicial District.

20. Venue is proper in this Court under 28 U.S.C. § 1400(b) with respect to Defendants at least because, upon information and belief, Defendants are entities organized and existing under the laws of Delaware and therefore reside in Delaware for purposes of venue.

21. Genentech and/or Novartis owns each of the patents asserted in this Complaint (collectively, the "Asserted Patents"):

Patent	First Named Inventor	Assignee(s)
U.S. Patent No. 8,574,869	Yung-Hsiang Kao	Genentech, Inc.
U.S. Patent No. 8,986,957	Wolfgang Ernst Gustav Budach	Novartis Pharmaceuticals Corp.
U.S. Patent No. 9,243,224	Wolfgang Ernst Gustav Budach	Novartis Pharmaceuticals Corp.
U.S. Patent No. 11,078,294	Yung-Hsiang Kao	Genentech, Inc.
U.S. Patent No. 11,987,637	Yung-Hsiang Kao	Genentech, Inc.
U.S. Patent No. 12,030,959	Ryan Patrick Owen	Novartis Pharmaceuticals Corp. Genentech, Inc.
U.S. Patent No. 12,371,728	Inn Huam Yuk	Genentech, Inc.
U.S. Patent No. 12,371,510	Charles M. Winter	Novartis Pharmaceuticals Corp. Genentech, Inc.
U.S. Patent No. 12,492,265	Ryan Patrick Owen	Novartis Pharmaceuticals Corp. Genentech, Inc.

FACTUAL BASIS FOR RELIEF

22. The BPCIA provides a mechanism to obtain FDA approval for a biological product that is "biosimilar" to a previously licensed "reference product" such as XOLAIR®. 42 U.S.C. § 262(k). In order to be approved, biosimilars must be "highly similar to the reference product

notwithstanding minor differences in clinically inactive components," with "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." *Id.* § 262(i)(2)(A)-(B).

23. The BPCIA reduces substantially the time and expense otherwise required to gain FDA approval, by allowing biosimilar applicants like Kashiv to rely on most of the prior clinical testing that Genentech and Novartis conducted to establish the safety and efficacy of the reference product (XOLAIR®). Genentech and Novartis invested many years of effort into the development of XOLAIR® and received patents rewarding this research and their innovative work relating to methods of manufacturing biologic drugs.

24. In exchange for this accelerated and far less expensive application process, the BPCIA obligates a biosimilar applicant to address relevant patents in a manner that permits adjudication of patent rights before commercialization of the biosimilar product. The BPCIA does so, *inter alia*, through a set of pre-litigation exchanges or steps outlined in 42 U.S.C. § 262(*l*).

25. On September 18, 2026, Kashiv and Genentech, through their respective counsel, agreed pursuant to 42 U.S.C. § 262(*l*)(4)(A) that the Asserted Patents should be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6).

26. Genentech and Novartis filed this Complaint within the time required under 42 U.S.C. § 262(*l*)(6)—that is, within 30 days after Genentech and Kashiv reached agreement that the Asserted Patents would be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6).

CLAIMS FOR RELIEF

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 8,574,869 UNDER 35 U.S.C. § 271(e)

27. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

28. United States Patent No. 8,574,869 ("the '869 patent") (Exhibit 1 hereto), was duly and legally issued on November 5, 2013.

29. Genentech is the owner of all right, title, and interest in the '869 patent.

30. The '869 patent has not yet expired.

31. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of ADL-018 before the expiration of the '869 patent is an act of infringement of one or more claims of the '869 patent under 35 U.S.C. § 271(e)(2)(C)(i), including for the reasons set forth in Genentech's September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C).

32. For example, on information and belief, the manufacture, use, offer for sale, and/or sale of ADL-018 will infringe, *inter alia*, claim 8 of the '869 patent.

33. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '869 patent. Genentech is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from any further infringement. Genentech has no adequate remedy at law.

34. Defendants' commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the '869 patent will cause Genentech injury, entitling Genentech to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

35. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the '869 patent entitles Genentech to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 2: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '869 PATENT UNDER 35 U.S.C. § 271 (a), (b) AND/OR (c)

36. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

37. On information and belief, Kashiv submitted its BLA referencing Plaintiffs' XOLAIR® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of ADL-018 before the expiration of the '869 patent.

38. On information and belief, following FDA approval of their ADL-018, Defendants intend to infringe one or more claims of the '869 patent under 35 U.S.C. § 271(a) by making, offering to sell, selling, or using within the United States, directly or indirectly, ADL-018, which is manufactured using a method patented in one or more claims of the '869 patent. On information and belief, following FDA approval of their ADL-018, Defendants will induce and/or contribute to infringement of one or more claims of the '869 patent under 35 U.S.C. §§ 271(b-c) by actively inducing one or more of their subsidiaries, affiliates, or agents to make, sell, offer to sell, or use within the United States ADL-018, which is manufactured using a method patented in one or more claims of the '869 patent. Defendants have knowledge of and are aware of the '869 patent at least due to Genentech's September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

39. In view of Kashiv's submission of Defendants' BLA, an actual controversy has arisen and now exists between the parties concerning whether Defendants' manufacture, use, offer

to sell, and/or sale within the United States of ADL-018 has infringed and/or will infringe one or more claims of the ’869 patent. An actual controversy has also arisen and now exists between the parties concerning whether Defendants have infringed and/or will infringe one or more claims of the ’869 patent by actively inducing or contributing to the infringing manufacture of ADL-018 using a method patented in the ’869 patent.

40. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed and/or would infringe claims of the ’869 patent by making, using, offering to sell, and/or selling within the United States ADL-018, or by actively inducing and/or contributing to the infringement of one or more claims of the ’869 patent, before the expiration of the ’869 patent.

41. Genentech would be irreparably harmed if Defendants are not enjoined from infringing claims of the ’869 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, and/or selling within the United States ADL-018, or actively inducing and/or contributing to the infringement of one or more claims of the ’869 patent, before the expiration of the ’869 patent.

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 8,986,957 UNDER 35 U.S.C. § 271(e)

42. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

43. United States Patent No. 8,986,957 (“the ’957 patent”) (Exhibit 2 hereto), was duly and legally issued on March 24, 2015.

44. Novartis is the owner of all right, title, and interest in the ’957 patent.

45. The ’957 patent has not yet expired.

46. The submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of ADL-018 before the expiration of the

’957 patent is an act of infringement of one or more claims of the ’957 patent under 35 U.S.C. § 271(e)(2)(C)(i), including for the reasons set forth in Genentech’s September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C).

47. For example, on information and belief, the manufacture, use, offer for sale, and/or sale of ADL-018 will infringe, *inter alia*, claims 1-5 of the ’957 patent.

48. Novartis will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the ’957 patent. Novartis is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from any further infringement. Novartis has no adequate remedy at law.

49. Defendants’ commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the ’957 patent will cause Novartis injury, entitling Novartis to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

50. The submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the ’957 patent entitles Novartis to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 4: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’957 PATENT UNDER 35 U.S.C. § 271 (a), (b) AND/OR (c)

51. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

52. On information and belief, Kashiv submitted its BLA referencing Plaintiffs’ XOLAIR® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of ADL-018 before the expiration of the ’957 patent.

53. On information and belief, following FDA approval of their ADL-018, Defendants intend to infringe one or more claims of the ’957 patent under 35 U.S.C. § 271(a) by making, offering to sell, selling, or using within the United States, directly or indirectly, ADL-018, which is manufactured using a method patented in one or more claims of the ’957 patent. On information and belief, following FDA approval of their ADL-018, Defendants will induce and/or contribute to infringement of one or more claims of the ’957 patent under 35 U.S.C. §§ 271(b-c) by actively inducing one or more of their subsidiaries, affiliates, or agents to make, sell, offer to sell, or use within the United States ADL-018, which is manufactured using a method patented in one or more claims of the ’957 patent. Defendants have knowledge of and are aware of the ’957 patent at least due to Genentech’s September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

54. In view of Kashiv’s submission of Defendants’ BLA, an actual controversy has arisen and now exists between the parties concerning whether Defendants’ manufacture, use, offer to sell, and/or sale within the United States of ADL-018 has infringed and/or will infringe one or more claims of the ’957 patent. An actual controversy has also arisen and now exists between the parties concerning whether Defendants have infringed and/or will infringe one or more claims of the ’957 patent by actively inducing or contributing to the infringing manufacture of ADL-018 using a method patented in the ’957 patent.

55. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed and/or would infringe claims of the ’957 patent by making, using, offering to sell, and/or selling within the United States ADL-018, or by actively inducing and/or contributing to the infringement of one or more claims of the ’957 patent, before the expiration of the ’957 patent.

56. Novartis would be irreparably harmed if Defendants are not enjoined from infringing claims of the ’957 patent. Novartis does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, and/or selling within the United States ADL-018, or actively inducing and/or contributing to the infringement of one or more claims of the ’957 patent, before the expiration of the ’957 patent.

COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 9,243,224 UNDER 35 U.S.C. § 271(e)

57. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

58. United States Patent No. 9,243,224 (“the ’224 patent”) (Exhibit 3 hereto), was duly and legally issued on January 26, 2016.

59. Novartis is the owner of all right, title, and interest in the ’224 patent.

60. The ’224 patent has not yet expired.

61. The submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of ADL-018 before the expiration of the ’224 patent is an act of infringement of one or more claims of the ’224 patent under 35 U.S.C. § 271(e)(2)(C)(i), including for the reasons set forth in Genentech’s September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C).

62. For example, on information and belief, the manufacture, use, offer for sale, and/or sale of ADL-018 will infringe, *inter alia*, claims 1-7 of the ’224 patent.

63. Novartis will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the ’224 patent. Novartis is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from any further infringement. Novartis has no adequate remedy at law.

64. Defendants' commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the '224 patent will cause Novartis injury, entitling Novartis to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

65. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the '224 patent entitles Novartis to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '224 PATENT UNDER 35 U.S.C. § 271(a), (b) AND/OR (c)

66. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

67. On information and belief, Kashiv submitted its BLA referencing Plaintiffs' XOLAIR® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of ADL-018 before the expiration of the '224 patent.

68. On information and belief, following FDA approval of their ADL-018, Defendants intend to infringe one or more claims of the '224 patent under 35 U.S.C. § 271(a) by making, offering to sell, selling, or using within the United States, directly or indirectly, ADL-018, which is manufactured using a method patented in one or more claims of the '224 patent. On information and belief, following FDA approval of their ADL-018, Defendants will induce and/or contribute to infringement of one or more claims of the '224 patent under 35 U.S.C. §§ 271(b-c) by actively inducing one or more of their subsidiaries, affiliates, or agents to make, sell, offer to sell, or use within the United States ADL-018, which is manufactured using a method patented in one or more claims of the '224 patent. Defendants have knowledge of and are aware

of the ’224 patent at least due to Genentech’s September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

69. In view of Kashiv’s submission of Defendants’ BLA, an actual controversy has arisen and now exists between the parties concerning whether Defendants’ manufacture, use, offer to sell, and/or sale within the United States of ADL-018 has infringed and/or will infringe one or more claims of the ’224 patent. An actual controversy has also arisen and now exists between the parties concerning whether Defendants have infringed and/or will infringe one or more claims of the ’224 patent by actively inducing or contributing to the infringing manufacture of ADL-018 using a method patented in the ’224 patent.

70. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed and/or would infringe claims of the ’224 patent by making, using, offering to sell, and/or selling within the United States ADL-018, or by actively inducing and/or contributing to the infringement of one or more claims of the ’224 patent, before the expiration of the ’224 patent.

71. Novartis would be irreparably harmed if Defendants are not enjoined from infringing claims of the ’224 patent. Novartis does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, and/or selling within the United States ADL-018, or actively inducing and/or contributing to the infringement of one or more claims of the ’224 patent, before the expiration of the ’224 patent.

COUNT 7: INFRINGEMENT OF U.S. PATENT NO. 11,078,294 UNDER 35 U.S.C. § 271(e)

72. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

73. United States Patent No. 11,078,294 (“the ’294 patent”) (Exhibit 4 hereto) was duly and legally issued on August 3, 2021.

74. Genentech is the owner of all right, title, and interest in the ’294 patent.

75. The ’294 patent has not yet expired.

76. The submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of ADL-018 before the expiration of the ’294 patent is an act of infringement of one or more claims of the ’294 patent under 35 U.S.C. § 271(e)(2)(C)(i), including for the reasons set forth in Genentech’s September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C).

77. For example, on information and belief, the manufacture, use, offer for sale, and/or sale of ADL-018 will infringe, *inter alia*, claims 1, 7, and 8 of the ’294 patent.

78. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the ’294 patent. Genentech is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from any further infringement. Genentech has no adequate remedy at law.

79. Defendants’ commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the ’294 patent will cause Genentech injury, entitling Genentech to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

80. The submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the ’294 patent entitles Genentech to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 8: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’294 PATENT UNDER 35 U.S.C. § 271 (a), (b) AND/OR (c)

81. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

82. On information and belief, Kashiv submitted its BLA referencing Plaintiffs' XOLAIR® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of ADL-018 before the expiration of the '294 patent.

83. On information and belief, following FDA approval of their ADL-018, Defendants intend to infringe one or more claims of the '294 patent under 35 U.S.C. § 271(a) by making, offering to sell, selling, or using within the United States, directly or indirectly, ADL-018, which is manufactured using a method patented in one or more claims of the '294 patent. On information and belief, following FDA approval of their ADL-018, Defendants will induce and/or contribute to infringement of one or more claims of the '294 patent under 35 U.S.C. §§ 271(b-c) by actively inducing one or more of their subsidiaries, affiliates, or agents to make, sell, offer to sell, or use within the United States ADL-018, which is manufactured using a method patented in one or more claims of the '294 patent. Defendants have knowledge of and are aware of the '294 patent at least due to Genentech's September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

84. In view of Kashiv's submission of Defendants' BLA, an actual controversy has arisen and now exists between the parties concerning whether Defendants' manufacture, use, offer to sell, and/or sale within the United States of ADL-018 has infringed and/or will infringe one or more claims of the '294 patent. An actual controversy has also arisen and now exists between the parties concerning whether Defendants have infringed and/or will infringe one or more claims of the '294 patent by actively inducing or contributing to the infringing manufacture of ADL-018 using a method patented in the '294 patent.

85. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed and/or would infringe claims of the '294 patent by making, using, offering to sell, and/or selling

within the United States ADL-018, or by actively inducing and/or contributing to the infringement of one or more claims of the ’294 patent, before the expiration of the ’294 patent.

86. Genentech would be irreparably harmed if Defendants are not enjoined from infringing claims of the ’294 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, and/or selling within the United States ADL-018, or actively inducing and/or contributing to the infringement of one or more claims of the ’294 patent, before the expiration of the ’294 patent.

COUNT 9: INFRINGEMENT OF U.S. PATENT NO. 11,987,637 UNDER 35 U.S.C. § 271(e)

87. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

88. United States Patent No. 11,987,637 (“the ’637 patent”) (Exhibit 5 hereto), was duly and legally issued on May 21, 2024.

89. Genentech is the owner of all right, title, and interest in the ’637 patent.

90. The ’637 patent has not yet expired.

91. The submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of ADL-018 before the expiration of the ’637 patent is an act of infringement of one or more claims of the ’637 patent under 35 U.S.C. § 271(e)(2)(C)(i), including for the reasons set forth in Genentech’s September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C).

92. For example, on information and belief, the manufacture, use, offer for sale, and/or sale of ADL-018 will infringe, *inter alia*, claims 1, 4, 10, 11, 12, 14, 16, 19, 25, 26, 27, and 29 of the ’637 patent.

93. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the ’637 patent. Genentech is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from any further infringement. Genentech has no adequate remedy at law.

94. Defendants’ commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the ’637 patent will cause Genentech injury, entitling Genentech to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

95. The submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the ’637 patent entitles Genentech to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’637 PATENT UNDER 35 U.S.C. § 271 (a), (b) AND/OR (c)

96. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

97. On information and belief, Kashiv submitted its BLA referencing Plaintiffs’ XOLAIR® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of ADL-018 before the expiration of the ’637 patent.

98. On information and belief, following FDA approval of their ADL-018, Defendants intend to infringe one or more claims of the ’637 patent under 35 U.S.C. § 271(a) by making, offering to sell, selling, or using within the United States, directly or indirectly, ADL-018, which is manufactured using a method patented in one or more claims of the ’637 patent. On information and belief, following FDA approval of their ADL-018, Defendants will induce and/or contribute to infringement of one or more claims of the ’637 patent under 35 U.S.C. §§ 271(b-c) by actively

inducing one or more of their subsidiaries, affiliates, or agents to make, sell, offer to sell, or use within the United States ADL-018, which is manufactured using a method patented in one or more claims of the ’637 patent. Defendants have knowledge of and are aware of the ’637 patent at least due to Genentech’s September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

99. In view of Kashiv’s submission of Defendants’ BLA, an actual controversy has arisen and now exists between the parties concerning whether Defendants’ manufacture, use, offer to sell, and/or sale within the United States of ADL-018 has infringed and/or will infringe one or more claims of the ’637 patent. An actual controversy has also arisen and now exists between the parties concerning whether Defendants have infringed and/or will infringe one or more claims of the ’637 patent by actively inducing or contributing to the infringing manufacture of ADL-018 using a method patented in the ’637 patent.

100. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed and/or would infringe claims of the ’637 patent by making, using, offering to sell, and/or selling within the United States ADL-018, or by actively inducing and/or contributing to the infringement of one or more claims of the ’637 patent, before the expiration of the ’637 patent.

101. Genentech would be irreparably harmed if Defendants are not enjoined from infringing claims of the ’637 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, and/or selling within the United States ADL-018, or actively inducing and/or contributing to the infringement of one or more claims of the ’637 patent, before the expiration of the ’637 patent.

COUNT 11: INFRINGEMENT OF U.S. PATENT NO. 12,030,959 UNDER 35 U.S.C. § 271(e)

102. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

103. United States Patent No. 12,030,959 ("the '959 patent") (Exhibit 6 hereto), was duly and legally issued on July 9, 2024.

104. Plaintiffs are the owners of all right, title, and interest in the '959 patent.

105. The '959 patent has not yet expired.

106. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of ADL-018 before the expiration of the '959 patent is an act of infringement of one or more claims of the '959 patent under 35 U.S.C. § 271(e)(2)(C)(i), including for the reasons set forth in Genentech's September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C).

107. For example, the marketing of ADL-018 will induce and/or contribute to the infringement of claims 1-29 of the '959 patent.

108. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '959 patent. Plaintiffs are entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from any further infringement. Plaintiffs have no adequate remedy at law.

109. Defendants' commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the '959 patent will cause Plaintiffs injury, entitling Plaintiffs to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

110. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018

before the expiration of the ’959 patent entitles Plaintiffs to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 12: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’959 PATENT UNDER 35 U.S.C. § 271 (b) AND/OR (c)

111. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

112. On information and belief, Kashiv submitted its BLA referencing Plaintiffs’ XOLAIR® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of ADL-018 before the expiration of the ’959 patent.

113. On information and belief, following FDA approval of their ADL-018, Defendants will induce and/or contribute to infringement of one or more claims of the ’959 patent under 35 U.S.C. §§ 271(b-c) by actively instructing, encouraging, recommending, and/or promoting healthcare providers and patients to take actions with respect to ADL-018 that will directly infringe claims of the ’959 patent. Defendants have knowledge of and are aware of the ’959 patent at least due to Genentech’s September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

114. Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the ’959 patent at least because Kashiv filed a BLA that includes a proposed label having directions that instruct medical practitioners to administer and/or patients to use ADL-018 in a manner that infringes one or more claims of the ’959 patent.

115. On information and belief, Defendants know and/or are willfully blind to the fact that medical practitioners will administer and/or patients will use ADL-018 according to the proposed label, which administration and/or use will directly infringe one or more claims of the ’959 patent.

116. On information and belief, Defendants know or are willfully blind to the fact that they will aid and abet another's direct infringement of at least one of the claims of the '959 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in such proposed label.

117. In view of Kashiv's submission of Defendants' BLA, an actual controversy has arisen and now exists between the parties concerning whether Defendants have infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '959 patent.

118. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed and/or would infringe claims of the '959 patent by actively inducing and/or contributing to the infringement of one or more claims of the '959 patent, before the expiration of the '959 patent.

119. Plaintiffs would be irreparably harmed if Defendants are not enjoined from infringing claims of the '959 patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, and/or selling within the United States ADL-018, or actively inducing and/or contributing to the infringement of one or more claims of the '959 patent, before the expiration of the '959 patent.

COUNT 13: INFRINGEMENT OF U.S. PATENT NO. 12,371,728 UNDER 35 U.S.C. § 271(e)

120. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

121. United States Patent No. 12,371,728 ("the '728 patent") (Exhibit 7 hereto), was duly and legally issued on July 29, 2025.

122. Genentech is the owner of all right, title, and interest in the '728 patent.

123. The '728 patent has not yet expired.

124. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of ADL-018 before the expiration of the '728 patent is an act of infringement of one or more claims of the '728 patent under 35 U.S.C. § 271(e)(2)(C)(i), including for the reasons set forth in Genentech's September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C).

125. For example, on information and belief, the manufacture, use, offer for sale, and/or sale of ADL-018 will infringe, *inter alia*, claim 10 of the '728 patent.

126. Genentech will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '728 patent. Genentech is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from any further infringement. Genentech has no adequate remedy at law.

127. Defendants' commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the '728 patent will cause Genentech injury, entitling Genentech to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

128. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the '728 patent entitles Genentech to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 14: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '728 PATENT UNDER 35 U.S.C. § 271(a), (b) AND/OR (c)

129. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

130. On information and belief, Kashiv submitted its BLA referencing Plaintiffs' XOLAIR® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of ADL-018 before the expiration of the '728 patent.

131. On information and belief, following FDA approval of their ADL-018, Defendants intend to infringe one or more claims of the '728 patent under 35 U.S.C. § 271(a) by making, offering to sell, selling, or using within the United States, directly or indirectly, ADL-018, which is manufactured using a method patented in one or more claims of the '728 patent. On information and belief, following FDA approval of their ADL-018, Defendants will induce and/or contribute to infringement of one or more claims of the '728 patent under 35 U.S.C. §§ 271(b-c) by actively inducing one or more of their subsidiaries, affiliates, or agents to make, sell, offer to sell, or use within the United States ADL-018, which is manufactured using a method patented in one or more claims of the '728 patent. Defendants have knowledge of and are aware of the '728 patent at least due to Genentech's September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

132. In view of Kashiv's submission of Defendants' BLA, an actual controversy has arisen and now exists between the parties concerning whether Defendants' manufacture, use, offer to sell, and/or sale within the United States of ADL-018 has infringed and/or will infringe one or more claims of the '728 patent. An actual controversy has also arisen and now exists between the parties concerning whether Defendants have infringed and/or will infringe one or more claims of the '728 patent by actively inducing or contributing to the infringing manufacture of ADL-018 using a method patented in the '728 patent.

133. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed and/or would infringe claims of the '728 patent by making, using, offering to sell, and/or selling

within the United States ADL-018, or by actively inducing and/or contributing to the infringement of one or more claims of the ’728 patent, before the expiration of the ’728 patent.

134. Genentech would be irreparably harmed if Defendants are not enjoined from infringing claims of the ’728 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, and/or selling within the United States ADL-018, or actively inducing and/or contributing to the infringement of one or more claims of the ’728 patent, before the expiration of the ’728 patent.

COUNT 15: INFRINGEMENT OF U.S. PATENT NO. 12,371,510 UNDER 35 U.S.C. § 271(e)

135. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

136. United States Patent No. 12,371,510 (“the ’510 patent”) (Exhibit 8 hereto), was duly and legally issued on July 29, 2025.

137. Plaintiffs are the owners of all right, title, and interest in the ’510 patent.

138. The ’510 patent has not yet expired.

139. The submission of Defendants’ BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of ADL-018 before the expiration of the ’510 patent is an act of infringement of one or more claims of the ’510 patent under 35 U.S.C. § 271(e)(2)(C)(i), including for the reasons set forth in Genentech’s September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C).

140. For example, on information and belief, the manufacture, use, offer for sale, and/or sale of ADL-018 will infringe, *inter alia*, claims 1 and 3-5 of the ’510 patent.

141. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the ’510 patent. Plaintiffs are entitled to injunctive relief at

least under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from any further infringement. Plaintiffs have no adequate remedy at law.

142. Defendants' commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the '510 patent will cause Plaintiffs injury, entitling Plaintiffs to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

143. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the '510 patent entitles Plaintiffs to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 16: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '510 PATENT UNDER 35 U.S.C. § 271 (a), (b) AND/OR (c)

144. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

145. On information and belief, Kashiv submitted its BLA referencing Plaintiffs' XOLAIR® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of ADL-018 before the expiration of the '510 patent.

146. On information and belief, following FDA approval of their ADL-018, Defendants intend to infringe one or more claims of the '510 patent under 35 U.S.C. § 271(a) by making, offering to sell, selling, or using within the United States, directly or indirectly, ADL-018 drug product, which is an ultrafiltration retentate within the scope of one or more claims of the '510 patent. On information and belief, following FDA approval of their ADL-018, Defendants will induce and/or contribute to infringement of one or more claims of the '510 patent under 35 U.S.C. §§ 271(b-c) by actively inducing one or more of their subsidiaries, affiliates, or agents to make, sell, offer to sell, or use within the United States ADL-018 drug

product, which is an ultrafiltration retentate within the scope of one or more claims of the ’510 patent. Defendants have knowledge of and are aware of the ’510 patent at least due to Genentech’s September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

147. In view of Kashiv’s submission of Defendants’ BLA, an actual controversy has arisen and now exists between the parties concerning whether Defendants’ manufacture, use, offer to sell, and/or sale within the United States of ADL-018 has infringed and/or will infringe one or more claims of the ’510 patent. An actual controversy has also arisen and now exists between the parties concerning whether Defendants have infringed and/or will infringe one or more claims of the ’510 patent by actively inducing or contributing to the manufacture, use, offer to sell, and/or sale within the United States of ADL-018, which is an ultrafiltration retentate within the scope of one or more claims of the ’510 patent.

148. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed and/or would infringe claims of the ’510 patent by making, using, offering to sell, and/or selling within the United States ADL-018, or by actively inducing and/or contributing to the infringement of one or more claims of the ’510 patent, before the expiration of the ’510 patent.

149. Plaintiffs would be irreparably harmed if Defendants are not enjoined from infringing claims of the ’510 patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, and/or selling within the United States ADL-018, or actively inducing and/or contributing to the infringement of one or more claims of the ’510 patent, before the expiration of the ’510 patent.

COUNT 17: INFRINGEMENT OF U.S. PATENT NO. 12,492,265 UNDER 35 U.S.C. § 271(e)

150. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

151. United States Patent No. 12,492,265 ("the '265 patent") (Exhibit 9 hereto), was duly and legally issued on December 9, 2025.

152. Plaintiffs are the owners of all right, title, and interest in the '265 patent.

153. The '265 patent has not yet expired.

154. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of ADL-018 before the expiration of the '265 patent is an act of infringement of one or more claims of the '265 patent under 35 U.S.C. § 271(e)(2)(C)(i), including for the reasons set forth in Genentech's September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C).

155. For example, the marketing of ADL-018 will induce and/or contribute to the infringement of claims 1-30 of the '265 patent.

156. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '265 patent. Plaintiffs are entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from any further infringement. Plaintiffs have no adequate remedy at law.

157. Defendants' commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018 before the expiration of the '265 patent will cause Plaintiffs injury, entitling Plaintiffs to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

158. The submission of Defendants' BLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States of ADL-018

before the expiration of the ’265 patent entitles Plaintiffs to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 18: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’265 PATENT UNDER 35 U.S.C. § 271(b) AND/OR (c)

159. Plaintiffs incorporate by reference all of the allegations set forth above as if fully set forth below.

160. On information and belief, Kashiv submitted its BLA referencing Plaintiffs’ XOLAIR® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of ADL-018 before the expiration of the ’265 patent.

161. On information and belief, following FDA approval of their ADL-018, Defendants will induce and/or contribute to infringement of one or more claims of the ’265 patent under 35 U.S.C. §§ 271(b-c) by actively instructing, encouraging, recommending, and/or promoting healthcare providers and patients to take actions with respect to ADL-018 that will directly infringe claims of the ’265 patent. Defendants have knowledge of and are aware of the ’265 patent at least due to Genentech’s September 4, 2026 statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and the filing of this Complaint.

162. Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the ’265 patent at least because Kashiv filed a BLA that includes a proposed label having directions that instruct medical practitioners to administer and/or patients to use ADL-018 in a manner that infringes one or more claims of the ’265 patent.

163. On information and belief, Defendants know and/or are willfully blind to the fact that medical practitioners will administer and/or patients will use ADL-018 according to the proposed label, which administration and/or use will directly infringe one or more claims of the ’265 patent.

164. On information and belief, Defendants know or are willfully blind to the fact that they will aid and abet another's direct infringement of at least one of the claims of the '265 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in such proposed label.

165. In view of Kashiv's submission of Defendants' BLA, an actual controversy has arisen and now exists between the parties concerning whether Defendants have infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '265 patent.

166. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed and/or would infringe claims of the '265 patent by actively inducing and/or contributing to the infringement of one or more claims of the '265 patent, before the expiration of the '265 patent.

167. Plaintiffs would be irreparably harmed if Defendants are not enjoined from infringing claims of the '265 patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, and/or selling within the United States ADL-018, or actively inducing and/or contributing to the infringement of one or more claims of the '265 patent, before the expiration of the '265 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Defendants have infringed the Asserted Patents;

(b) Permanent equitable relief, pursuant to 35 U.S.C. § 271(e)(4)(B), including but not limited to a permanent injunction that enjoins Defendants, their officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns

from infringing the Asserted Patents, or contributing to the same, or actively inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, or distribution of any current or future versions of a product that infringes, or the use or manufacturing of which infringes, the Asserted Patents;

(c) Preliminary equitable relief, pursuant to 35 U.S.C. § 271(e)(4)(B), including but not limited to a preliminary injunction that enjoins Defendants, their officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns from infringing the Asserted Patents, or contributing to the same, or actively inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, or distribution of any current or future versions of a product that infringes, or the use or manufacturing of which infringes, the Asserted Patents;

(d) Damages pursuant to 35 U.S.C. § 271(e)(4)(C), if applicable, in the form of lost profits but in no event less than a reasonable royalty;

(e) A judgment that the infringement has been willful and an enhancement of damages;

(f) An award for an accounting of damages from Defendants' infringement;

(g) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285 and 35 U.S.C. § 271(e)(4);

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

(i) Such further relief as this court may deem just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury as to any issue so triable.

Dated: October 16, 2026

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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