IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HALOZYME, INC., Plaintiff, v. MERCK SHARP & DOHME CORP., Defendant.	CASE NO.: [[]]

COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

Plaintiff Halozyme, Inc., ("Halozyme" or "Plaintiff"), by its attorneys, alleges as follows for its Complaint for Patent Infringement and for a Declaratory Judgment of Patent Infringement against Merck Sharp & Dohme Corp. ("Merck" or "Defendant"):

NATURE OF THE ACTION

1. This is an action for patent infringement and for a declaration of patent infringement of United States Patent Nos. 10,865,400, 11,041,149, 11,066,656, 11,952,600, 12,018,298, 12,037,618, 12,049,652, 12,054,758, 12,077,791, 12,091,692, 12,104,185, 12,110,520, 12,152,262, 12,195,773, and 12,264,345 (collectively, the "asserted patents" or the "patents-in-suit") against Merck. All asserted patents belong to a single patent family.

2. The asserted patents arise out of Halozyme's extensive research into over 6000 modifications to a human hyaluronidase, known as PH20. Among its uses, PH20 allows for rapid subcutaneous administration of therapeutic drugs. In the course of Halozyme's study of PH20, Halozyme's inventors identified several modifications to PH20's amino acid sequence, including

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specific amino acid substitutions, that resulted in novel modified PH20 structures with varying activity and stability profiles. This body of work culminated in Halozyme's patented MDASE™ technology (the "MDASE technology"). The asserted patents embody this technology and cover certain of these modifications and their use in drug products.

3. This action arises out of Merck's current and/or imminent manufacture, use, sale, offer to sell within the United States and/or importation into the United States, of Merck's new drug product—SC KEYTRUDA, allowing for rapid subcutaneous (SC) administration of KEYTRUDA® (pembrolizumab).

4. SC KEYTRUDA infringes one or more claims of each of the asserted patents. Merck's SC KEYTRUDA includes berahyaluronidase alfa ("BHA"), a modified PH20 that makes rapid subcutaneous administration of KEYTRUDA possible. BHA includes the amino acid modifications first identified by Halozyme's inventors and covered by the asserted patents.

5. Notably, Merck previously conducted a Phase 3 clinical trial of subcutaneous Keytruda without use of a PH20. It is believed that trial failed, since Merck declined to publish the results. When questioned regarding the results and failure to publish, Merck publicly indicated it was now focused on a formulation of SC KEYTRUDA that included berahyaluronidase alfa. Ex. A (06/26/2024 Barron's: Merck Didn't Publicize the Results of a Key Cancer Trial).

6. Merck is aware of Halozyme's patents covering SC KEYTRUDA and has filed post-grant reviews ("PGR") against Halozyme's U.S. Patent Nos. 11,952,600, 12,018,298, 12,152,262, 12,123,035, 12,110,520, 12,060,590, 12,054,758, 12,049,652, 12,104,185, and 12,037,618 (PGR2025-0003, -0004, -0006, -0009, -0017, -0024, -0030, -0033, -0039, and -0042, respectively), demonstrating that awareness. Yet Merck is intentionally proceeding to launch its

infringing product without the right to practice Halozyme's MDASE technology.

7. On information and belief, Merck chose to infringe Halozyme's asserted patents covering a modified PH20 because of the importance to its business of subcutaneous administration of KEYTRUDA. Merck has made numerous public statements confirming that importance.

8. For instance, Merck's Chairman and CEO, Robert M. Davis highlighted the value of subcutaneous administration of SC KEYTRUDA, noting that "the quality-of-life benefits this brings does demonstrate and afford [Merck] the ability to get a premium price." Ex. B (02/01/2024 Q4 2023 Merck & Co Inc Earnings Call Transcript), 14. Similarly, Dean Li, President of Merck Research Labs, has explained that subcutaneous administration of KEYTRUDA "is going to be demanded and is being demanded by the field." *Id*., 14; *see also* Ex. C (06/03/2024 Merck & Co Inc Investor Event at ASCO Transcript), 15-16 (Dean Li, President of Merck Research Labs, explaining that "potentially not having to go to an infusion center all the time is quite important" because patients "don't want to be going to an infusion center at a major medical infusion center every 3 weeks or every 6 weeks.").

9. In remarks at the 2025 JP Morgan Healthcare Conference, Merck's Chairman and CEO, Robert M. Davis explained as to SC KEYTRUDA that "it was crucial to get approval and launch as soon as possible" in order to "launch well ahead of the LOE [loss of patent exclusivity for Keytruda], so a meaningful portion of patients are already transitioned to the subcutaneous version. From there, you can manage brand loyalty post-LOE, especially if you're strategic with pricing."

10. Without the use of the MDASE technology covered by the asserted patents, Merck apparently has no way to bring SC KEYTRUDA to market before its own patent(s) covering

KEYTRUDA expire.

11. Merck's infringement is and has been knowing, reckless, and willful, and has resulted in and will continue to result in significant damage to Halozyme.

12. Halozyme brings this action to hold Merck accountable for its willful disregard of Halozyme's patent rights.

THE PARTIES

13. Plaintiff Halozyme is a corporation organized and existing under the laws of the State of California with its principal place of business located at 12390 El Camino Real, San Diego, California 92130.

14. Halozyme is a biopharmaceutical company advancing innovative and disruptive solutions to improve patient experiences and outcomes for emerging and established therapies. Since inception, Halozyme's employees have been dedicated to discovering, developing, and commercializing drug delivery technologies to improve outcomes in patients undergoing treatment for debilitating and life-threatening conditions.

15. Halozyme has over 25 years of experience innovating and conducting pioneering research in the field of hyaluronidases for use in conjunction with subcutaneous injectables. The industry saw the benefit of this technology as evidenced by the 11 collaborations and licensing agreements that include 10 commercial partner products with ENHANZE® for the subcutaneous delivery of important medications using its technology. Over a million patients have benefited from Halozyme's ENHANZE product.

16. Defendant Merck is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 126 East Lincoln Avenue, Rahway, New Jersey 07065.

17. Merck is one of the largest pharmaceutical companies in the world and ranked in the top-five global pharmaceutical companies by revenue in 2024.

JURISDICTION AND VENUE

18. This civil action for patent infringement arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*. and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* and 2202.

19. This Court has personal jurisdiction over Merck because Merck, *inter alia*, incorporates in and maintains its principal place of business in the State of New Jersey. Upon information and belief, Merck has availed itself of this forum by filing suit in the United States District Court for the District of New Jersey, including, for example, *Merck Sharp & Dohme LLC v. Hetero USA Inc. et al.*, 2-23-cv-02364 (DNJ), *Merck Sharp & Dohme LLC v. Lupin Limited et al.*, 2-23-cv-00094 (DNJ), *Merck Sharp & Dohme LLC v. Hetero USA, Inc. et al*., 2-22-cv-06820 (DNJ), *Merck Sharp & Dohme LLC v. Gland Pharma Limited*, 2-22-cv-05461 (DNJ) *BioMarin Pharmaceutical Inc. et al v. Aurobindo Pharmaceuticals Limited et al.,* 3-22-cv-02345 (DNJ). Upon information and belief, Merck intends to market and sell SC KEYTRUDA throughout the United States, including in this judicial district, and has applied for approval to do so with the FDA for launch in 2025.

20. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) because Merck resides in this District and because Merck is subject to personal jurisdiction in this District.

THE ASSERTED PATENTS

21. On December 15, 2020, United States Patent No. 10,865,400 ("the '400 Patent") entitled "PH20 polypeptide variants, formulations and uses thereof" issued to Halozyme as

assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the ’400 Patent is attached as Exhibit D.

22. On June 22, 2021, United States Patent No. 11,041,149 (“the ’149 patent”) entitled “PH20 polypeptide variants, formulations and uses thereof” issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the ’149 Patent is attached as Exhibit E.

23. On July 20, 2021, United States Patent No. 11,066,656 (“the ’656 patent”) entitled “PH20 polypeptide variants, formulations and uses thereof” issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the ’656 Patent is attached as Exhibit F.

24. On April 9, 2024, United States Patent No. 11,952,600 (“the ’600 patent”) entitled “PH20 polypeptide variants, formulations and uses thereof” issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the ’600 Patent is attached as Exhibit G.

25. On June 25, 2024, United States Patent No. 12,018,298 (“the ’298 patent”) entitled “PH20 polypeptide variants, formulations and uses thereof” issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the ’298 Patent is attached as Exhibit H.

26. On July 16, 2024, United States Patent No. 12,037,618 (“the ’618 patent”) entitled “PH20 polypeptide variants, formulations and uses thereof” issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the ’618 Patent is attached as Exhibit I.

27. On July 30, 2024, United States Patent No. 12,049,652 (“the ’652 patent”) entitled

"PH20 polypeptide variants, formulations and uses thereof" issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the '652 Patent is attached as Exhibit J.

28. On August 6, 2024, United States Patent No. 12,054,758 ("'758 patent") entitled "PH20 polypeptide variants, formulations and uses thereof" issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the '758 patent is attached as Exhibit K.

29. On September 3, 2024, United States Patent No. 12,077,791 ("the '791 patent") entitled "PH20 polypeptide variants, formulations and uses thereof" issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the '791 Patent is attached as Exhibit L.

30. On September 17, 2024, United States Patent No. 12,091,692 ("the '692 patent") entitled "PH20 polypeptide variants, formulations and uses thereof" issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the '692 Patent is attached as Exhibit M.

31. On October 1, 2024, United States Patent No. 12,104,185 ("the '185 patent") entitled "PH20 polypeptide variants, formulations and uses thereof" issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the '185 Patent is attached as Exhibit N.

32. On October 8, 2024, United States Patent No. 12,110,520 ("'520 patent") entitled "PH20 polypeptide variants, formulations and uses thereof" issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the '520 patent is attached as Exhibit O.

33. On November 26, 2024, United States Patent No. 12,152,262 ("'262 patent") entitled "PH20 polypeptide variants, formulations and uses thereof" issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the '262 patent is attached as Exhibit P.

34. On January 14, 2025, United States Patent No. 12,195,773 ("'773 patent") entitled "PH20 polypeptide variants, formulations and uses thereof" issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the '773 patent is attached as Exhibit Q.

35. On April 1, 2025, United States Patent No. 12,264,345 ("'345 patent") entitled "PH20 polypeptide variants, formulations and uses thereof" issued to Halozyme as assignee of the named inventors Ge Wei, H. Michael Shepard, Qiping Zhao, and Robert James Connor. A copy of the '345 patent is attached as Exhibit R.

BACKGROUND

36. The extracellular matrix ("ECM") is a vital component of all the tissues in the human body, providing structure and support to cells and tissues. Hyaluronan ("HA") is a naturally occurring carbohydrate that is a major component of the ECM, particularly the portion of the ECM into which subcutaneous injections can be made.

37. HA in the ECM can prevent subcutaneous injections by constricting the injected substance from reaching the blood stream or lymphatic system, causing significant localized swelling and discomfort. The delay in reaching the blood stream or lymphatic system can also make drugs less effective and cause adverse reactions for patients, including painful swelling.

38. While injections can be given directly into the blood stream intravenously, known as infusions, this can take a long time and usually requires the patient to go to an infusion site

where they are monitored for adverse reactions and other complications by medical professionals.

39. Starting in the 1920s, certain "spreading factors," later termed "hyaluronidase" for their ability to break down HA, were identified. These hyaluronidases were used to aid subcutaneous injections. But early hyaluronidases were derived from animals, not humans, and could create adverse immune reactions when given to humans, including severe immune responses.

40. By at least the 1960s, an enzyme called PH20 was identified in human sperm and understood to function as a hyaluronidase. PH20 had unrecognized potential as a human-derived hyaluronidase that could be used to aid subcutaneous injections without the risks associated with animal-derived hyaluronidases. But human PH20 was not soluble and could not be used to aid subcutaneous injections.

41. Halozyme was founded in 1998 with the intention of developing a recombinant human hyaluronidase for therapeutic uses. Through extensive research, Halozyme scientists discovered how to make PH20 soluble, while still retaining hyaluronidase activity within the human body's pH range.

42. Halozyme's soluble PH20 technology allows rapid subcutaneous administration of large molecule therapeutics that previously could only be administered intravenously over a matter of hours. Through its ENHANZE platform, Halozyme has partnered with several pharmaceutical companies to make subcutaneous versions of important medications using this technology. Halozyme's products and associated research, in conjunction with those of its partners, have revolutionized drug delivery and have benefited patients all over the world.

DEVELOPMENT OF HALOZYME'S PATENTED MODIFIED PH20 MDASE TECHNOLOGY

43. Through Halozyme's continued study of the human PH20 enzyme, Halozyme

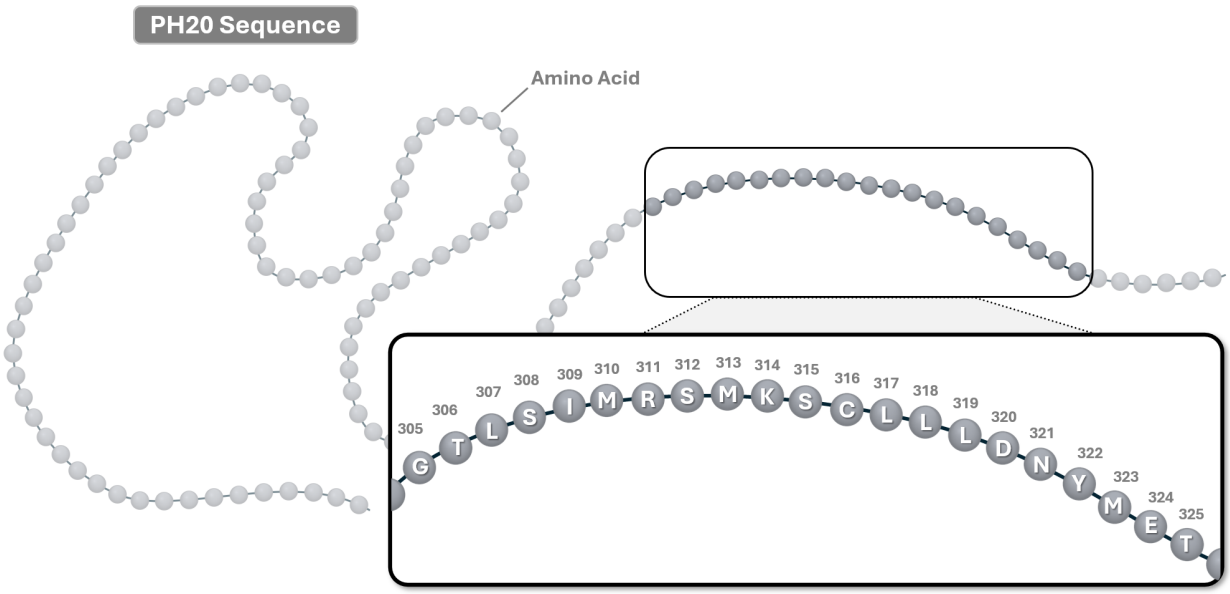
inventors also went on to create a library of 6,753 additional PH20s with modified amino acid chains. The Halozyme inventors conducted extensive experimentation on each of these modified PH20s, determining the effect on activity and stability of various amino acid substitutions. This demonstrated how to modify the PH20 enzyme to yield PH20 structures with improved function by teaching the specific ways that various amino acid substitutions at each amino acid position in the PH20 enzyme affect activity and stability, an understanding that was previously missing from the art.

44. These experiments included specially designed assays in which the Halozyme inventors determined the ability of the modified PH20 to degrade a hyaluronan substrate, leading to the discovery of modifications to PH20 that made it a more effective and stable enzyme. By measuring the "hyaluronidase activity," for example, the inventors demonstrated, *inter alia*, the modified PH20's ability to facilitate rapid subcutaneous delivery of therapeutic agents normally hindered by the hyaluronan barrier. Halozyme's patented MDASE technology embodies this work and covers modified PH20s that include certain of these modifications.

45. In particular, among the 6,753 modified PH20 peptides, the Halozyme inventors discovered specific modifications at five amino acid residues, specifically positions 309, 313, 317, 320, and 324[1], that showed increases (+115% to +642%) in hyaluronidase activity when compared to native ("wild type") PH20. *See* Patent Tables 3, 9.

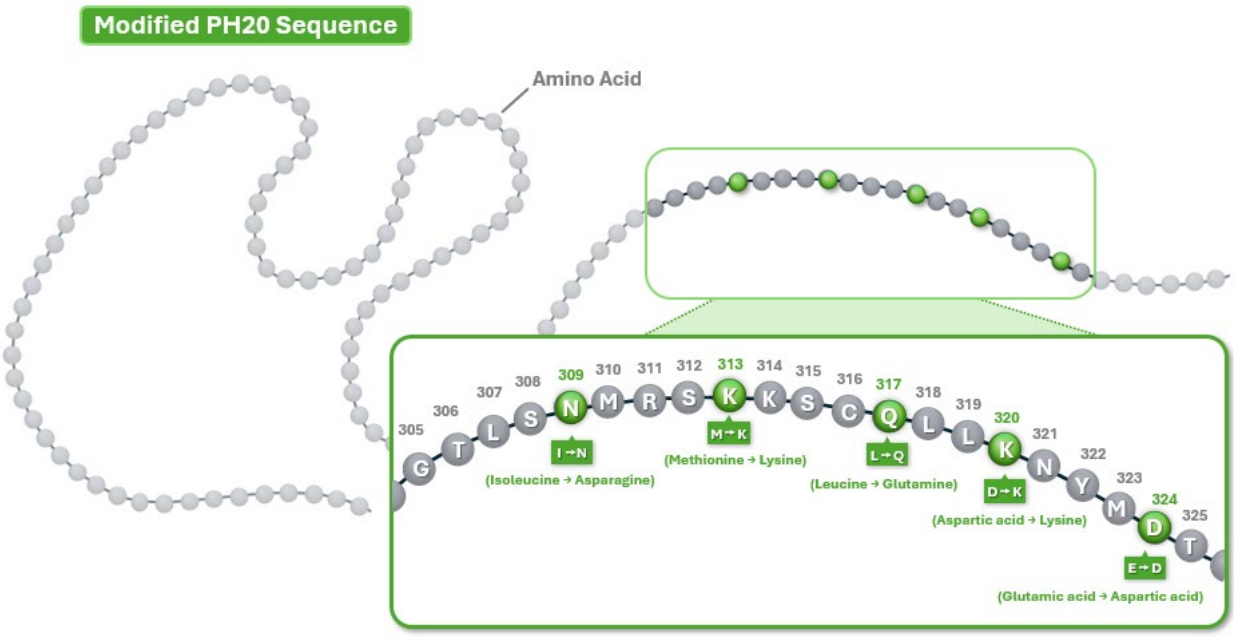
46. This is illustrated in the diagrams below. The first diagram depicts a simplified version of the wild type PH20 sequence, including an area of detail showing the section of the PH20 sequence encompassing positions 309, 313, 317, 320, and 324:

[1] The amino acid residue numbers correspond to the amino acid position in the amino acid chain for recombinant PH20 protein as represented by amino acid Sequence ID NO: 3 in the patents-in-suit.



Unmodified PH20 Sequence

47. The second diagram shows the modifications at positions 309, 313, 317, 320, and 324 that were first identified by the Halozyme inventors and which showed increases in hyaluronidase activity when compared to native PH20:



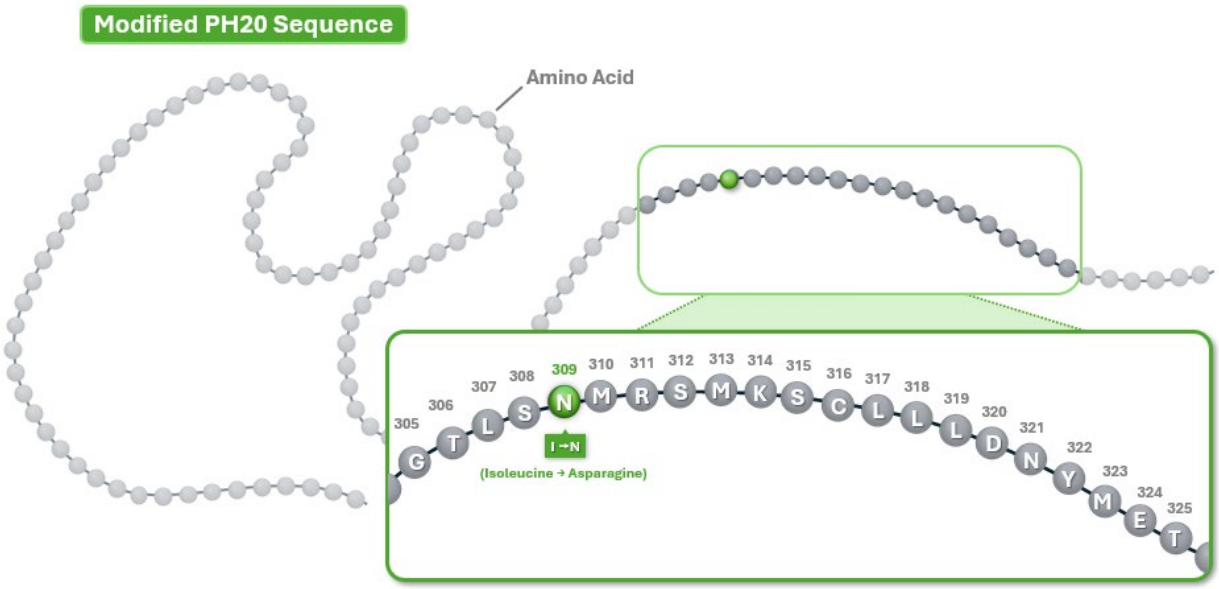
48. Halozyme's research also showed the modifications that made the enzymes less

effective and less stable, in addition to modifications that could be made without affecting activity and/or stability.

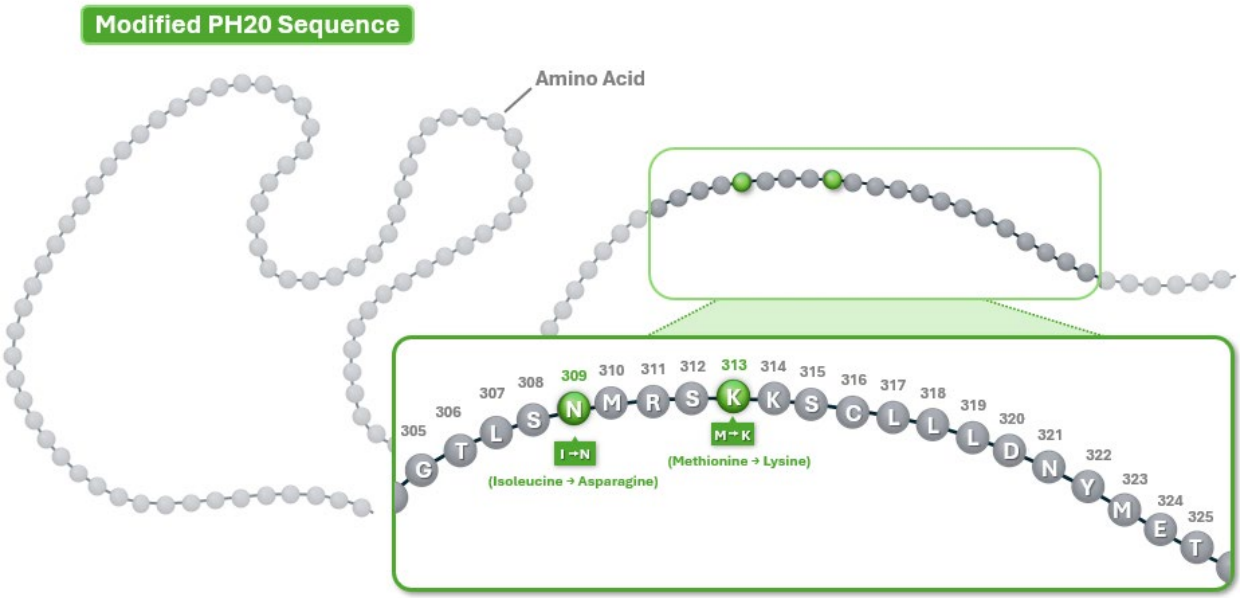
49. Beginning in 2011, Halozyme filed patent applications disclosing its inventors' extensive work on the MDASE technology covering modified PH20s in exchange for patent rights to their discovery. These applications disclose the 6,753 modified PH20 peptides and their activity and stability under various conditions. The data in the published patent applications provided a detailed specification describing how amino acid modifications change the activity and stability of the PH20.

50. After receiving the public disclosure of the Halozyme inventors' extensive work, and in acknowledgement of their novel discoveries, starting in 2016, the U.S. Patent Office ("USPTO") began issuing patents to Halozyme for the MDASE technology claimed in these applications. The claims in the asserted patents that issued from these applications cover modified PH20s, including modifications at numbers 309, 313, 317, 320, and 324.

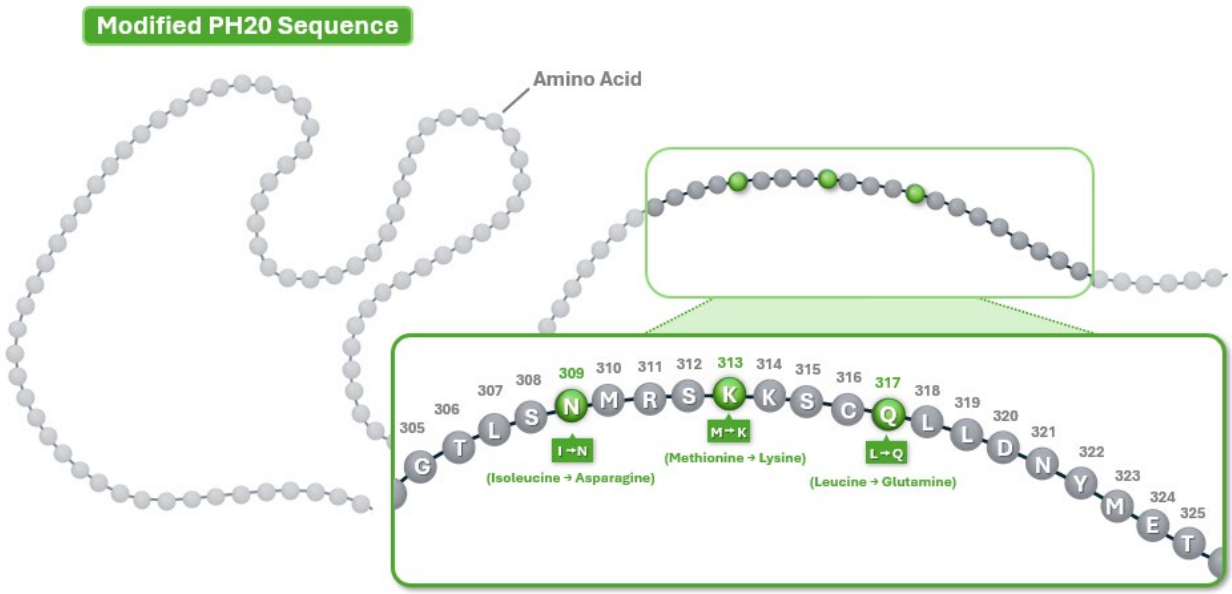
51. For instance, the '400 patent, the '656 patent, the '618 patent, and the '791 patent have claims directed to modified PH20s with modifications to residue 309. The asserted patents disclose fifteen modified amino acids at amino acid residue number 309, including asparagine (N). *See* Patent Table 8. Fourteen of the modifications at residue 309 resulted in PH20 enzymes retaining 20% or more of the hyaluronidase activity of the wild-type PH20 enzyme, with ten exhibiting increased activity exceeding 100% of the wild-type. But the asserted patents specifically identify a substitution using asparagine as providing the greatest improvement in activity—311% compared to wild-type—among the fifteen amino acid modifications made by the inventors. This modification is illustrated in the simplified diagram below:



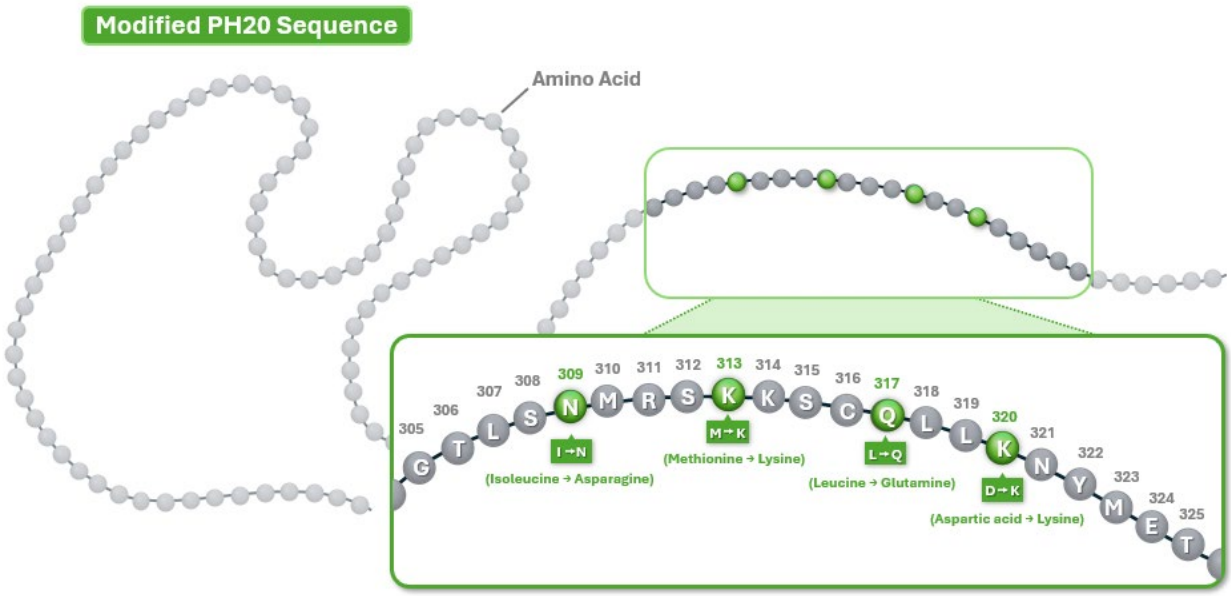
52. In addition, the ’400 patent, the ’149 patent, the ’298 patent, the ’345 patent, and the ’692 patent have claims directed to modified PH20s with modifications to residue 313. The asserted patents disclose fifteen modified amino acids at amino acid residue number 313, including lysine (K). *See* Patent Table 8. Twelve of the modifications at residue 313 led to a PH20 enzyme with 20% or more hyaluronidase activity compared to wild-type PH20 enzyme, and seven of the modifications increased activity exceeding 100% of the wild-type. *See* Patent Table 3; Table 9. But the asserted patents specifically identify a substitution using lysine as providing the greatest improvement in activity—285% compared to wild-type—among the fifteen amino acid modifications made by the inventors. This modification has been added to the simplified diagram below:



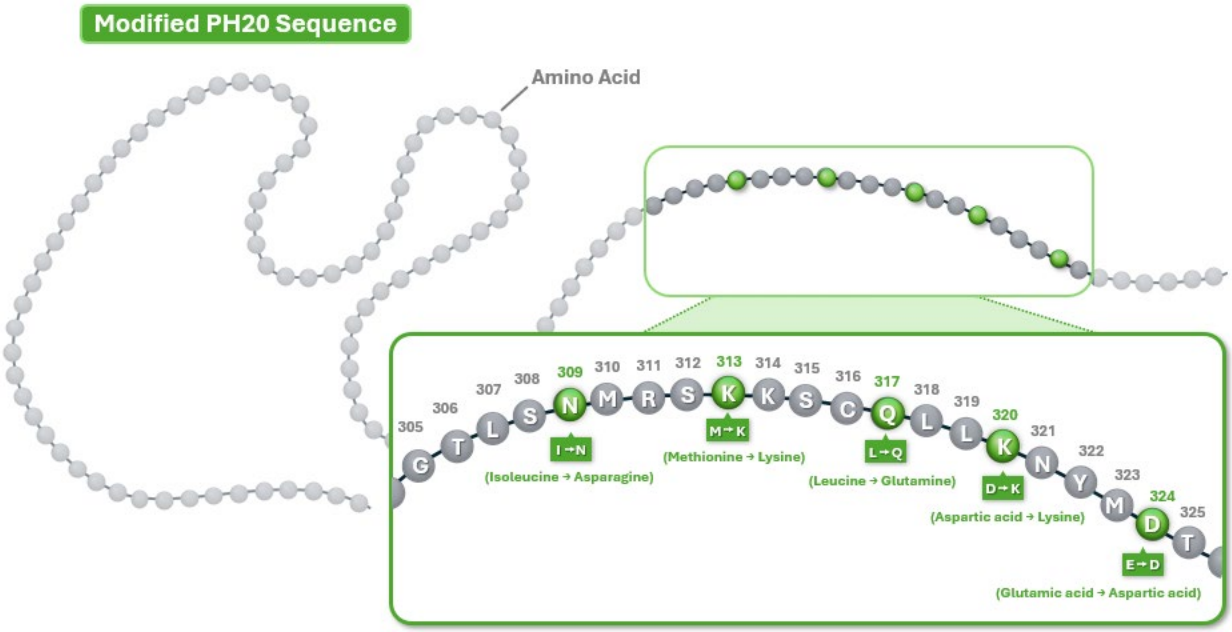
53. Similarly, the ’758 patent and ’262 patent have claims directed to modified PH20s with modifications to residue 317. The asserted patents disclose fifteen modified amino acids at amino acid residue number 317, including glutamine (Q). *See* Patent Table 8. Twelve of the modifications at residue 317 led to a PH20 enzyme with 20% or more hyaluronidase activity compared to wild-type PH20 enzyme, and eight of the modifications increased activity exceeding 100% of the wild-type. *See* Patent Table 3; Table 9. Among the eight modifications conferring increased activity, the asserted patents specifically identify a substitution using glutamine as providing 167% activity compared to wild-type. This modification has been added to the simplified diagram below:



54. Moreover, the ’400 patent, the ’652 patent, the ’185 patent, the ’600 patent and the ’773 patent have claims directed to modified PH20s with modifications to residue 320. The asserted patents disclose sixteen modified amino acids at amino acid residue number 320, including lysine (K). *See* Patent Table 8. Thirteen of the modifications at residue 320 led to a PH20 enzyme with 20% or more hyaluronidase activity compared to wild-type PH20 enzyme, and four of the modifications increased activity exceeding 100% of the wild-type. *See* Patent Table 3; Table 9. But the asserted patents specifically identify a substitution using lysine as providing the greatest improvement in activity—642% compared to wild-type—among the sixteen amino acid modifications made by the inventors. This modification has been added to the simplified diagram below:



55. Finally, the ’520 patent has claims directed to modified PH20s with modifications to residue 324. The asserted patent discloses fifteen modified amino acids at amino acid residue number 324, including aspartic acid (D). *See* Patent Table 8. Seven of the modifications at residue 324 led to a PH20 enzyme with 20% or more hyaluronidase activity compared to wild-type PH20 enzyme, and three of the modifications increased activity exceeding 100% of the wild-type. *See* Patent Table 3; Table 9. Among the three modifications conferring increased activity, the asserted patents specifically identify a substitution using aspartic acid as providing 115% activity compared to wild type. This modification has been added to the simplified diagram below:

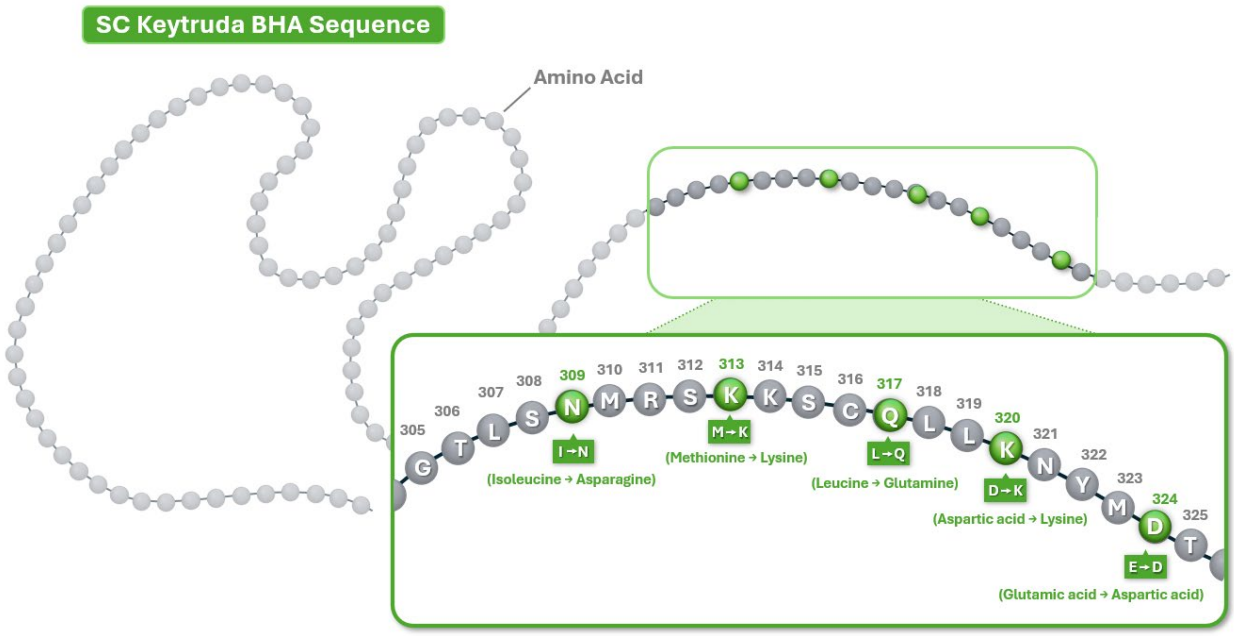


56. Thus, in sum, the USPTO has issued several patents with claims covering the MDASE technology, including the five specific modifications at the above-described positions that showed 115% to 642% increase in hyaluronidase activity compared with wild type PH20.

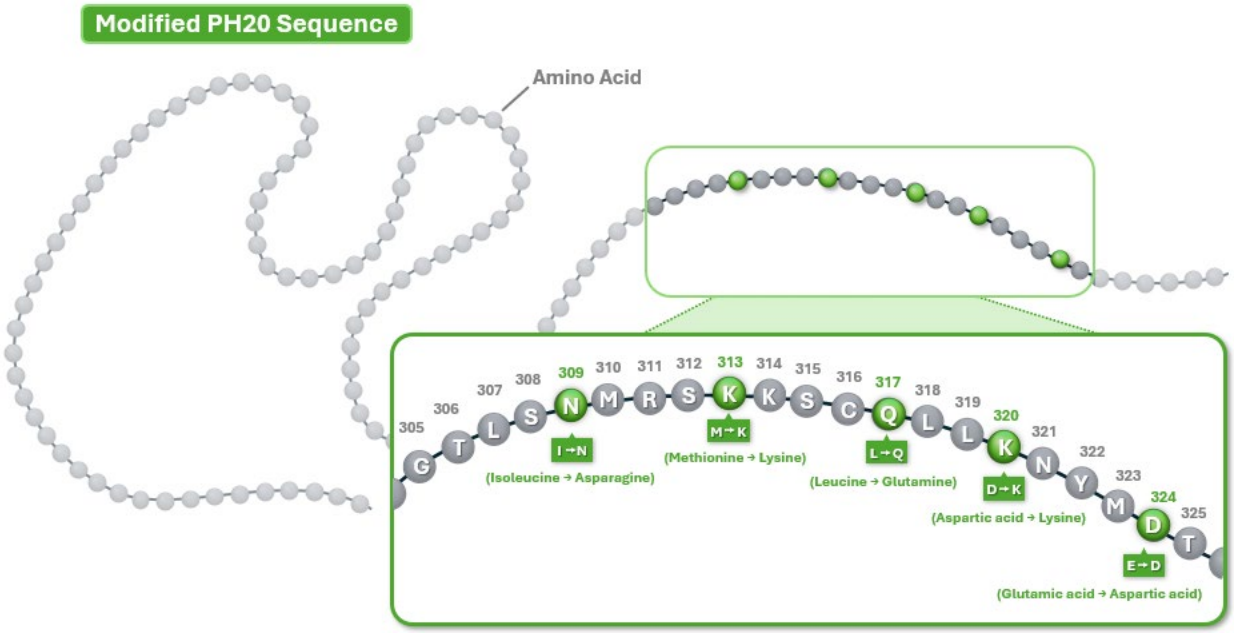
SC KEYTRUDA USES HALOZYME'S PATENTED MODIFIED PH20 MDASE TECHNOLOGY

57. To make rapid subcutaneous administration possible, SC KEYTRUDA includes a modified PH20, BHA, in its formulation. The amino acid sequence of BHA is known and was published in September, 2024, in the Global Substance Registration System ("GSRS") maintained by the National Institute of Health ("NIH"). *See* Ex. S. The BHA amino acid sequence and related information confirm SC KEYTRUDA's infringement of the claims of asserted patents covering Halozyme's MDASE technology, and in particular SC KEYTRUDA's use of the key modifications identified and claimed in the asserted patents.

58. The modifications at each of positions 309, 313, 317, 320, and 324 included in Merck's SC KEYTRUDA are illustrated below:



59. Those substitutions are the same as those covered by the claims of the asserted patents as illustrated in the simplified diagram below, showing the modifications at positions 309, 313, 317, 320, and 324:



60. More specifically, the BHA sequence has an amino acid modification at residue 309 when compared to wild-type PH20, SEQ ID NO:3. That modification is a substitution taught

and claimed in the patents-in-suit as detailed above: an asparagine instead of an isoleucine at amino acid residue 309.

61. Similarly, the BHA sequence also has an amino acid modification at residue 313 when compared to wild-type PH20, SEQ ID NO:3. That modification is a substitution taught and claimed in the patents-in-suit as detailed above: a lysine instead of a methionine at amino acid residue 313.

62. In addition, the BHA sequence also has an amino acid modification at residue 317 when compared to wild-type PH20, SEQ ID NO:3. That modification is a substitution taught and claimed in the patents-in-suit as detailed above: a glutamine instead of a leucine at amino acid residue 317.

63. Moreover, the BHA sequence further has an amino acid modification at residue 320 when compared to wild-type PH20, SEQ ID NO:3. That modification is a substitution taught and claimed in the patents-in-suit as detailed above: a lysine instead of an aspartic acid at amino acid residue 320.

64. Finally, the BHA sequence further has an amino acid modification at residue 324 when compared to wild-type PH20, SEQ ID NO:3. That modification is a substitution taught and claimed in the patents-in-suit as detailed above: an aspartic acid instead of a glutamic acid at amino acid residue 324.

65. Moreover, publication of the BHA sequence confirms that it is greater than 95% identical to at least SEQ ID NOs: 32-37 disclosed in the patents-in-suit. *See, e.g.,* Ex. T (BLAST Sequence Alignments), 1-4. Upon information and belief, the BHA sequence is greater than 91% identical to SEQ ID NOs: 3, 32-58 and 591-598 in the patents-in-suit. *Id.*, 1-18.

66. Upon information and belief, SC KEYTRUDA'S BHA, developed using

Halozyme's MDASE technology, has increased hyaluronidase activity compared to wild-type PH20, SEQ ID NO: 3. Specifically, upon information and belief, SC KEYTRUDA'S BHA has greater than 120% hyaluronidase activity compared to wild-type PH20, SEQ ID NO: 3, allowing for the rapid subcutaneous administration of SC KEYTRUDA without swelling, discomfort, or risk of degradation of the drug substance.

MERCK'S KNOWLEDGE OF HALOZYME'S PATENTED MODIFIED PH20 MDASE TECHNOLOGY AND DEVELOPMENT OF THE ACCUSED PRODUCT, SC KEYTRUDA

67. On information and belief, Merck has known of the asserted patents and has deliberately chosen to infringe because its blockbuster product, KEYTRUDA, is set to lose its patent protection in 2028. On information and belief, Merck desires to convert sales of KEYTRUDA to SC KEYTRUDA before that date to protect its market share. On information and belief, Merck has been unable to develop SC KEYTRUDA without infringing Halozyme's patented MDASE technology. On information and belief, despite knowing that Halozyme's MDASE technology was necessary for the development of its successor product, Merck has been unwilling to resolve the issue of use of these patented inventions with Halozyme, necessitating this suit.

68. In particular, Merck's sales of KEYTRUDA have grown dramatically over the years. In 2014, when KEYTRUDA was first approved, Merck's sales were $55 million. Ex. U (Merck Q4 2014 Financial Results), 8, 26-28. By 2017, KEYTRUDA's sales had grown to $3.7 billion. Ex. V (Merck Q4 2017 Financial Results), 32. In 2020, KEYTRUDA's sales grew to more than $14 billion. Ex. W (Merck Q4 2020 Financial Results), 1. And by 2023, KEYTRUDA's sales had grown to $25 billion, and KEYTRUDA was one of the best selling drugs worldwide, in addition to being Merck's best-selling drug accounting for 40% of Merck's pharmaceutical sales. Ex. X (Merck Q4 2023 Financial Results), 1. Merck projects KEYTRUDA sales to increase to

$30 billion by 2026. Ex. Y (Merck Seeks More Deals to Prepare for KEYTRUDA's Revenue Decline), 4.

69. Merck, however, has announced that the patent protection for KEYTRUDA is set to expire in 2028. Ex. Z (04/25/2024 Q1 2024 Merck Earnings Call Transcript), 18.

70. Merck has acknowledged that expiration of patent protection of KEYTRUDA has motivated it to develop a subcutaneous version of KEYTRUDA—SC KEYTRUDA, the accused product here. Ex. AA, (02/02/2023 Q4 2022 Merck Earnings Call Transcript), 8-12. For instance, Merck's CEO has explained of SC KEYTRUDA that "it was so important …[to get] the approval and … launch as soon as possible" in order to "get well ahead of the LOE [loss of exclusivity], so that … a meaningful portion of patients [are] already adopted into the subcu, [and] then … manage[d] through the brand loyalty post the LOE." Ex. BB (01/14/2025 JP Morgan Healthcare Conference Transcript).

71. Despite having knowledge of Halozyme's patents, and having no authorization to use the inventions claimed therein, Merck has pursued development of and prepared to launch SC KEYTRUDA by using Halozyme's patented MDASE technology without Halozyme's permission.

72. Merck has been aware of Halozyme's work on PH20s since at least 2009, when the two first had collaboration discussions.

73. As part of those ongoing discussions, in 2015, Halozyme shared data and described the ability of subcutaneous delivery to improve KEYTRUDA's dosing and frequency profiles using Halozyme's technology.

74. Upon information and belief, during the course of these negotiations, Merck became aware of Halozyme's asserted patents and patent applications covering modified PH20s.

75. Merck is aware of its infringement of Halozyme's asserted patents based at least on these discussions, yet intends to launch SC KEYTRUDA.

76. Despite Merck's knowledge of the asserted patents, Merck has proceeded with its plans to launch SC KEYTRUDA by co-formulating KEYTRUDA with BHA, in full knowledge of its infringement and without having the rights to practice the patents.

77. Specifically, Merck has and is testing this co-formulation in multiple clinical trials, including MK-3475A-C18, -E39, -F11, -D77, and -F65.

78. Upon information and belief, Merck has pursued the clinical development of SC KEYTRUDA with the goal of launching it for sale in the United States and worldwide marketplace. For example, during Merck's Q4 2022 earnings call, Merck specified "we're very eager to push our subcu pembrolizumab with hyaluronidase into Phase 3 this year." Ex. AA (02/02/2023 Q4 2022 Merck & Co Inc Earnings Call Transcript), 8. Then again, at its Q4 2023 earnings call, Merck discussed strategies of "bringing this to the market," referring to SC KEYTRUDA. Ex. B (02/01/2024 Q4 2023 Merck & Co Inc Earnings Call Transcript), 14. During its Q1 2024 earnings call, Merck stated that by 2028 the "addressable market" for SC KEYTRUDA accounts for "50% of the patient population." Ex. Z (04/25/2024 Q1 2024 Merck & Co Inc Earnings Call Transcript), 13.

79. Moreover, on information and belief, Merck's Phase III clinical trial for SC KEYTRUDA, which is necessary to submit its Biologics License Application ("BLA")[2] to the FDA, reached its primary completion date on September 2024. Ex. CC (MK-3475A-D77 Clinical Trial Entry). Merck stated in its Q1 2024 earnings call that clinical readouts for the primary

[2] A BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce. *See* 21 CFR § 601.2.

completion milestone will be shared with the public by early 2025. Ex. Z (04/25/2024 Q1 2024 Merck & Co Inc Earnings Call Transcript), 13.

80. In November 2024, Merck announced that its Phase 3 trial of SC KEYTRUDA co-formulated with berahyaluronidase alfa (ALT-B4) has achieved primary endpoints. The trial, involving approximately 378 patients with metastatic non-small cell lung cancer demonstrated the noninferiority of SC KEYTRUDA to intravenous Keytruda, with secondary endpoints of efficacy and safety showing consistency between the two formulations.

81. On information and belief, Merck has submitted its BLA for SC KEYTRUDA to the FDA. Ex. DD (03/03/2025 TD Cowen Healthcare Conference Transcript). Based on Merck's public statements, Merck expects to have FDA approval and launch SC KEYTRUDA on October 1, 2025, with at least 30-40% conversion of the KEYTRUDA market to occur within the first two years. Ex. BB (01/14/2025 JP Morgan Healthcare Conference Transcript); Ex. EE (Reuters March 28, 2025 Article).

82. Merck has also been conducting patient preference trials of intravenous to subcutaneous administration of Keytruda to effectuate the conversion of intravenous to subcutaneous administration. Upon information and belief, Merck anticipates that 50% of its patients using intravenous Keytruda will convert to subcutaneous Keytruda by 2028.

83. Further, upon information and belief, a launch of SC KEYTRUDA in the United States is imminent, and Merck has been and is making meaningful preparations to market and sell SC KEYTRUDA in the United States. Upon receipt of regulatory approval to market and sell SC KEYTRUDA, Merck's manufacture, importation, use, sale, and/or offer to sell SC KEYTRUDA will infringe, either literally or under the doctrine of equivalents, one or more claims of each of the asserted patents.

84. Despite these extensive preparations, Merck has refused to find a resolution to its infringement with Halozyme, such that a definite and concrete controversy now exists between Halozyme and Merck regarding Merck's continued and impending infringement of one or more claims of each of the asserted patents. Accordingly, Halozyme was forced to bring this suit to seek a judicial determination and declaration that Merck is currently infringing or will, upon FDA approval, infringe one or more claims of each of the asserted patents.

MERCK'S INFRINGEMENT IS WILLFUL

85. As set out above, Merck is attempting to unfairly compete against Halozyme by knowingly infringing Halozyme's patented MDASE technology to market and sell SC KEYTRUDA. Merck has knowledge of and is aware of the asserted patent at least due to Halozyme's disclosure of the patents covering the MDASE technology and the PGRs Merck has filed against Halozyme's patents (PGR2025-0003, -0004, -0006, -0009, -0017, -0024, -0030, -0033, -0039, and -0042) that require knowledge of the asserted patents within the family.

86. Merck knew about Halozyme's proprietary MDASE technology directed to modified PH20, including the Halozyme inventors' identification of the five specific modifications included in SC KEYTRUDA. Upon information and belief, despite knowing of the asserted patents, Merck developed the infringing co-formulation – SC KEYTRUDA. Upon information and belief, Merck is knowingly infringing Halozyme's patents and flouting Halozyme's right to exclude others from using its inventions during the patent terms of the patents-in-suit.

<u>CLAIMS FOR RELIEF</u>

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 10,865,400

87. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

88. The '400 patent was duly and legally issued on December 15, 2020, and has not yet

expired.

89. Halozyme is the owner of all right, title, and interest in the ’400 patent.

90. Upon information and belief, Defendant has infringed the ’400 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’400 patent.

91. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’400 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

92. Merck has knowledge of and is aware of the ’400 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme’s patents that require knowledge of this patent and its family, and the filing of this Complaint.

93. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the ’400 patent, at least prior to the filing of its PGRs.

94. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’400 patent.

95. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the ’400 patent, before the expiration of the ’400 patent.

96. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 11,041,149

97. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

98. The ’149 patent was duly and legally issued on June 22, 2021, and has not yet expired.

99. Halozyme is the owner of all right, title, and interest in the ’149 patent.

100. Upon information and belief, Defendant has infringed the ’149 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’149 patent.

101. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’149 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

102. Merck has knowledge of and is aware of the ’149 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme’s patents that require knowledge of this patent and its family, and the filing of this Complaint.

103. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the ’149 patent, at least prior to the filing of its PGRs.

104. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’149 patent.

105. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the

infringement of one or more claims of the ’149 patent, before the expiration of the ’149 patent.

106. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 11,066,656

107. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

108. The ’656 patent was duly and legally issued on July 20, 2021, and has not yet expired.

109. Halozyme is the owner of all right, title, and interest in the ’656 patent.

110. Upon information and belief, Defendant has infringed the ’656 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’656 patent.

111. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’656 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

112. Merck has knowledge of and is aware of the ’656 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme’s patents that require knowledge of this patent and its family, and the filing of this Complaint.

113. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the ’656 patent, at least prior to the filing of its PGRs.

114. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’656 patent.

115. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the ’656 patent, before the expiration of the ’656 patent.

116. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 4: INFRINGEMENT OF U.S. PATENT NO. 11,952,600

117. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

118. The ’600 patent was duly and legally issued on April 9, 2024, and has not yet expired.

119. Halozyme is the owner of all right, title, and interest in the ’600 patent.

120. Upon information and belief, Defendant has infringed the ’600 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’600 patent.

121. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’600 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

122. Merck has knowledge of and is aware of the ’600 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme’s patents that require knowledge of this patent and its family, and the filing of this Complaint.

123. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the ’600 patent, at least prior to the filing of its

PGRs.

124. On information and belief, Merck will induce infringement of one or more claims of the ’600 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States SC KEYTRUDA manufactured by the method patented in one or more claims of the ’600 patent.

125. On information and belief, Merck will induce one or more of its subsidiaries, affiliates, or agents to manufacture, directly or indirectly, SC KEYTRUDA by using a method patented in one or more claims of the ’600 patent knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’600 patent.

126. On information and belief, Merck has an affirmative intent to actively induce infringement by others of one or more claims of the ’600 patent at least because it will encourage subsidiaries, affiliates, and/or agents to manufacture, import, offer to sell, and/or sell SC KEYTRUDA in a manner that directly infringes one or more claims of the ’600 patent.

127. On information and belief, Merck knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’600 patent at least by encouraging others to manufacture, import, offer to sell, and/or sell SC KEYTRUDA.

128. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’600 patent.

129. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the

infringement of one or more claims of the ’600 patent, before the expiration of the ’600 patent.

130. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 12,018,298

131. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

132. The ’298 patent was duly and legally issued on June 25, 2024, and has not yet expired.

133. Halozyme is the owner of all right, title, and interest in the ’298 patent.

134. Upon information and belief, Defendant has infringed the ’298 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’298 patent.

135. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’298 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

136. Merck has knowledge of and is aware of the ’298 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme’s patents that require knowledge of this patent and its family, and the filing of this Complaint.

137. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the ’298 patent, at least prior to the filing of its PGRs.

138. On information and belief, Merck will induce infringement of one or more claims of the ’298 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries,

affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States SC KEYTRUDA manufactured by the method patented in one or more claims of the ’298 patent.

139. On information and belief, Merck will induce one or more of its subsidiaries, affiliates, or agents to manufacture, directly or indirectly, SC KEYTRUDA by using a method patented in one or more claims of the ’298 patent knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’298 patent.

140. On information and belief, Merck has an affirmative intent to actively induce infringement by others of one or more claims of the ’298 patent at least because it will encourage subsidiaries, affiliates, and/or agents to manufacture, import, offer to sell, and/or sell SC KEYTRUDA in a manner that directly infringes one or more claims of the ’298 patent.

141. On information and belief, Merck knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’298 patent at least by encouraging others to manufacture, import, offer to sell, and/or sell SC KEYTRUDA.

142. The ’298 patent further claims methods of treatment and/or administration using modified PH20.

143. On information and belief, the sale of SC KEYTRUDA would be accompanied by a label that would effectively instruct the user to practice the claimed method of the ’298 patent.

144. Therefore, the sale of SC KEYTRUDA pursuant to that label will contribute to and induce infringement of at least one claim of the ’298 patent.

145. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’298 patent.

146. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the ’298 patent, before the expiration of the ’298 patent.

147. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 6: INFRINGEMENT OF U.S. PATENT NO. 12,037,618

148. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

149. The ’618 patent was duly and legally issued on July 16, 2024, and has not yet expired.

150. Halozyme is the owner of all right, title, and interest in the ’618 patent.

151. Upon information and belief, Defendant has infringed the ’618 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’618 patent.

152. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’618 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

153. Merck has knowledge of and is aware of the ’618 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme’s patents that require knowledge of this patent and its family, and the filing of this Complaint.

154. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the ’618 patent, at least prior to the filing of its

PGRs.

155. The ’618 patent further claims methods of treatment and/or administration using modified PH20.

156. On information and belief, the sale of SC KEYTRUDA would be accompanied by a label that would effectively instruct the user to practice the claimed method.

157. Therefore, the sale of SC KEYTRUDA pursuant to that label will contribute to and induce infringement of at least one claim of the ’618 patent.

158. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’618 patent.

159. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the ’618 patent, before the expiration of the ’618 patent.

160. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 7: INFRINGEMENT OF U.S. PATENT NO. 12,049,652

161. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

162. The ’652 patent was duly and legally issued on July 30, 2024, and has not yet expired.

163. Halozyme is the owner of all right, title, and interest in the ’652 patent.

164. Upon information and belief, Defendant has infringed the ’652 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’652 patent.

165. Defendant's commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the '652 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

166. Merck has knowledge of and is aware of the '652 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme's patents that require knowledge of this patent and its family, and the filing of this Complaint.

167. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the '652 patent, at least prior to the filing of its PGRs.

168. The '652 patent further claims methods of treatment and/or administration using modified PH20.

169. On information and belief, the sale of SC KEYTRUDA would be accompanied by a label that would effectively instruct the user to practice the claimed method.

170. Therefore, the sale of SC KEYTRUDA pursuant to that label will contribute to and induce infringement of at least one claim of the '652 patent.

171. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the '652 patent.

172. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the '652 patent, before the expiration of the '652 patent.

173. This case is exceptional, and Halozyme is entitled to an award of attorneys' fees

under 35 U.S.C. § 285.

COUNT 8: INFRINGEMENT OF U.S. PATENT NO. 12,054,758

174. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

175. The ’758 patent was duly and legally issued on August 6, 2024 and has not yet expired.

176. Halozyme is the owner of all right, title, and interest in the ’758 patent.

177. Upon information and belief, Defendant has infringed the ’758 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’758 patent.

178. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’758 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

179. Merck has knowledge of and is aware of the ’758 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme’s patents that require knowledge of this patent and its family, and the filing of this Complaint.

180. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the ’758 patent, at least prior to the filing of its PGRs.

181. The ’758 patent further claims methods of treatment and/or administration using modified PH20.

182. On information and belief, the sale of SC KEYTRUDA would be accompanied by a label that would effectively instruct the user to practice the claimed method.

183. Therefore, the sale of SC KEYTRUDA pursuant to that label will contribute to and induce infringement of at least one claim of the ’758 patent.

184. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’758 patent.

185. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the ’758 patent, before the expiration of the ’758 patent.

186. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 9: INFRINGEMENT OF U.S. PATENT NO. 12,077,791

187. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

188. The ’791 patent was duly and legally issued on September 3, 2024, and has not yet expired.

189. Halozyme is the owner of all right, title, and interest in the ’791 patent.

190. Upon information and belief, Defendant has infringed the ’791 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’791 patent.

191. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’791 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

192. Merck has knowledge of and is aware of the ’791 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against

Halozyme's patents that require knowledge of this patent and its family, and the filing of this Complaint.

193. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the '791 patent, at least prior to the filing of its PGRs.

194. On information and belief, Merck will induce infringement of one or more claims of the '791 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States SC KEYTRUDA manufactured by the method patented in one or more claims of the '791 patent.

195. On information and belief, Merck will induce one or more of its subsidiaries, affiliates, or agents to manufacture, directly or indirectly, SC KEYTRUDA by using a method patented in one or more claims of the '791 patent knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '791 patent.

196. On information and belief, Merck has an affirmative intent to actively induce infringement by others of one or more claims of the '791 patent at least because it will encourage subsidiaries, affiliates, and/or agents to manufacture, import, offer to sell, and/or sell SC KEYTRUDA in a manner that directly infringes one or more claims of the '791 patent.

197. On information and belief, Merck knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '791 patent at least by encouraging others to manufacture, import, offer to sell, and/or sell SC KEYTRUDA.

198. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined

from infringing the ’791 patent.

199. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the ’791 patent, before the expiration of the ’791 patent.

200. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 10: INFRINGEMENT OF U.S. PATENT NO. 12,091,692

201. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

202. The ’692 patent was duly and legally issued on September 17, 2024, and has not yet expired.

203. Halozyme is the owner of all right, title, and interest in the ’692 patent.

204. Upon information and belief, Defendant has infringed the ’692 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’692 patent.

205. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’692 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

206. Merck has knowledge of and is aware of the ’692 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme’s patents that require knowledge of this patent and its family, and the filing of this Complaint.

207. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a

formulation patented in one or more claims of the ’692 patent, at least prior to the filing of its PGRs.

208. The ’692 patent further claims methods of treatment and/or administration using modified PH20.

209. On information and belief, the sale of SC KEYTRUDA would be accompanied by a label that would effectively instruct the user to practice the claimed method.

210. Therefore, the sale of SC KEYTRUDA pursuant to that label will contribute to and induce infringement of at least one claim of the ’692 patent.

211. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’692 patent.

212. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the ’692 patent, before the expiration of the ’692 patent.

213. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 11: INFRINGEMENT OF U.S. PATENT NO. 12,104,185

214. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

215. The ’185 patent was duly and legally issued on October 1, 2024, and has not yet expired.

216. Halozyme is the owner of all right, title, and interest in the ’185 patent.

217. Upon information and belief, Defendant has infringed the ’185 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale,

or importation of SC KEYTRUDA prior to the expiration of the ’185 patent.

218. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’185 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

219. Merck has knowledge of and is aware of the ’185 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme’s patents that require knowledge of this patent and its family, and the filing of this Complaint.

220. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the ’185 patent, at least prior to the filing of its PGRs.

221. The ’185 patent further claims methods of treatment and/or administration using modified PH20.

222. On information and belief, the sale of SC KEYTRUDA would be accompanied by a label that would effectively instruct the user to practice the claimed method.

223. Therefore, the sale of SC KEYTRUDA pursuant to that label will contribute to and induce infringement of at least one claim of the ’185 patent.

224. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’185 patent.

225. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the ’185 patent, before the expiration of the ’185 patent.

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

COUNT 12: INFRINGEMENT OF U.S. PATENT NO. 12,110,520

227. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

228. The '520 patent was duly and legally issued on October 8, 2024 and has not yet expired.

229. Halozyme is the owner of all right, title, and interest in the '520 patent.

230. Upon information and belief, Defendant has infringed the '520 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the '520 patent.

231. Defendant's commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the '520 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

232. Merck has knowledge of and is aware of the '520 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme's patents that require knowledge of this patent and its family, and the filing of this Complaint.

233. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the '520 patent, at least prior to the filing of its PGRs.

234. The '520 patent further claims methods of treatment and/or administration using modified PH20.

235. On information and belief, the sale of SC KEYTRUDA would be accompanied by

a label that would effectively instruct the user to practice the claimed method.

236. Therefore, the sale of SC KEYTRUDA pursuant to that label will contribute to and induce infringement of at least one claim of the ’520 patent.

237. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’520 patent.

238. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the ’520 patent, before the expiration of the ’520 patent.

239. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 13: INFRINGEMENT OF U.S. PATENT NO. 12,152,262

240. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

241. The ’262 patent was duly and legally issued on November 26, 2024 and has not yet expired.

242. Halozyme is the owner of all right, title, and interest in the ’262 patent.

243. Upon information and belief, Defendant has infringed the ’262 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’262 patent.

244. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’262 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

245. Merck has knowledge of and is aware of the ’262 patent at least due to Halozyme's

disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme's patents that require knowledge of this patent and its family, and the filing of this Complaint.

246. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the '262 patent, at least prior to the filing of its PGRs.

247. The '262 patent further claims methods of treatment and/or administration using modified PH20.

248. On information and belief, the sale of SC KEYTRUDA would be accompanied by a label that would effectively instruct the user to practice the claimed method.

249. Therefore, the sale of SC KEYTRUDA pursuant to that label will contribute to and induce infringement of at least one claim of the '262 patent.

250. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the '262 patent.

251. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the '262 patent, before the expiration of the '262 patent.

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

COUNT 14: INFRINGEMENT OF U.S. PATENT NO. 12,195,773

253. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

254. The '773 patent was duly and legally issued on January 14, 2025 and has not yet

expired.

255. Halozyme is the owner of all right, title, and interest in the ’773 patent.

256. Upon information and belief, Defendant has infringed the ’773 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’773 patent.

257. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’773 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

258. Merck has knowledge of and is aware of the ’773 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme’s patents that require knowledge of this patent and its family, and the filing of this Complaint.

259. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the ’773 patent, at least prior to the filing of its PGRs.

260. The ’773 patent further claims methods of treatment and/or administration using modified PH20.

261. On information and belief, the sale of SC KEYTRUDA would be accompanied by a label that would effectively instruct the user to practice the claimed method.

262. Therefore, the sale of SC KEYTRUDA pursuant to that label will contribute to and induce infringement of at least one claim of the ’773 patent.

263. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’773 patent.

264. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the ’773 patent, before the expiration of the ’773 patent.

265. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 15: INFRINGEMENT OF U.S. PATENT NO. 12,264,345

266. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

267. The ’345 patent was duly and legally issued on April 1, 2025, and has not yet expired.

268. Halozyme is the owner of all right, title, and interest in the ’345 patent.

269. Upon information and belief, Defendant has infringed the ’345 patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA prior to the expiration of the ’345 patent.

270. Defendant’s commercial manufacture, use, offer for sale, sale, or importation of SC KEYTRUDA before the expiration of the ’345 patent will cause Halozyme injury, entitling Halozyme to damages and/or other monetary relief.

271. Merck has knowledge of and is aware of the ’345 patent at least due to Halozyme's disclosure of this patent and the underlying MDASE technology, the PGRs Merck has filed against Halozyme’s patents that require knowledge of this patent and its family, and the filing of this Complaint.

272. Merck knew and/or is willfully blind to the fact that SC KEYTRUDA comprises a formulation patented in one or more claims of the ’345 patent, at least prior to the filing of its

PGRs.

273. Halozyme will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’345 patent.

274. Halozyme has no adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the ’345 patent, before the expiration of the ’345 patent.

275. This case is exceptional, and Halozyme is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 16: DECLARATORY JUDGMENT OF INFRINGEMENT

276. Halozyme incorporates by reference all of the allegations set forth above as if fully set forth below.

277. Upon information and belief, Defendant’s contemplated imminent submission of a BLA to FDA seeking approval to market SC KEYTRUDA in the United States, coupled with Defendants preparations to actually launch SC KEYTRUDA for marketing and sale to the domestic marketplace upon receiving that approval, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Defendant has directly or indirectly infringed or will directly or indirectly infringe at least one claim of each of the asserted patents by engaging in the commercial manufacture, use, offer to sell, sale, or importation of SC KEYTRUDA, or by actively inducing or contributing to the infringement of at least one claim of each of the asserted patents prior to the expiration of the asserted patents.

278. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

279. Halozyme would be substantially and irreparably harmed if Merck is not enjoined

from infringing claims of the asserted patents.

280. Halozyme does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Merck from making, using, offering to sell, and/or selling within the United States, or importing into the United States, SC KEYTRUDA, or actively inducing or contributing to the infringement of one or more claims of the asserted patents, before the expiration of the asserted patents.

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

PRAYER FOR RELIEF

WHEREFORE, Halozyme prays for judgment against Defendant and respectfully requests the following relief:

1. A judgment that Merck has infringed and will infringe the patents-in-suit;

2. A judgment that Merk has contributed and/or will contribute to the infringement of the patents-in-suit or has actively induced and/or will actively induce anyone to do the same by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacturing of which infringes, the patents-in-suit.

3. A judgment for an injunction against Merck and its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling SC KEYTRUDA within the United States, or importing SC KEYTRUDA into the United States, prior to the expiration of the asserted patents pursuant to 35 U.S.C. § 283;

4. A judgment awarding Halozyme monetary relief together with interest;

5. A judgment that the infringement has been willful and an enhancement of damages;

6. A judgment that this is an exceptional case and that Halozyme be awarded its attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

7. Costs and expenses in this action; and

8. Such other and further relief as the Court deems just and appropriate.

JURY DEMAND

Halozyme hereby demands a jury trial on all issues appropriately triable by a jury.

Dated: April 24, 2025

/s/ Liza M. Walsh
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Attorneys for Plaintiff Halozyme, Inc.

LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, other than PGR2025-0003, -0004, -0006, -0009, -0017, -0024, -0030, -0033, -0039, and -0042 against the U.S. Patent Nos. 11,952,600, 12,018,298, 12,152,262, 12,123,035, 12,110,520, 12,060,590, 12,054,758, 12,049,652, 12,104,185, and 12,037,618 respectively, the matter in controversy is not the subject of any other pending litigation in any court, administrative proceeding, or arbitration proceeding, nor are there any non-parties known to Plaintiff that should be joined to this action.

/s/Liza M. Walsh
Liza M. Walsh

LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, inter alia, injunctive relief.

/s/*Liza M. Walsh*
Liza M. Walsh