IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Allergan, Inc. and Allergan Pharmaceuticals Ireland, Plaintiffs, v. Revance Therapeutics, Inc. and Ajinomoto Althea, Inc. d/b/a Ajinomoto Bio-Pharma Services, Defendants.	Civil Action No. 21 - _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Allergan, Inc. and Allergan Pharmaceuticals Ireland (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Revance Therapeutics, Inc. ("Revance") and Ajinomoto Althea, Inc. d/b/a Ajinomoto Bio-Pharma Services ("ABPS") (collectively, "Defendants"), and hereby allege as follows:

NATURE OF THE CASE

1. This is an action for infringement of U.S. Patent No. 11,033,625 ("the '625 patent"), U.S. Patent No. 7,354,740 ("the '740 patent"), U.S. Patent No. 8,409,828 ("the '828 patent"), U.S. Patent No. 11,124,786 ("the '786 patent"), and U.S. Patent No. 7,332,567 ("the '567 patent") (collectively, "the Asserted Patents") arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and for a declaratory judgment of infringement of the Asserted Patents arising under 28 U.S.C. §§ 2201-2202 and 35 U.S.C. § 271.

2. This action arises from a substantial controversy between the parties concerning Defendants' expressed intent to immediately manufacture, market, and sell Revance's DaxibotulinumtoxinA for Injection product following imminent approval by the U.S. Food and

Drug Administration ("FDA"). As described herein, an immediate, real, and justiciable controversy exists between Plaintiffs and Defendants as to whether Defendants' actions relating to DaxibotulinumtoxinA for Injection have infringed, presently infringe, and/or will infringe the Asserted Patents.

THE PARTIES

3. Plaintiff Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. Allergan, Inc. is a wholly owned, indirect subsidiary of AbbVie Inc.

4. Plaintiff Allergan Pharmaceuticals Ireland is a corporation organized and existing under the laws of the Republic of Ireland with a principal place of business at Castlebar Road, Westport, County Mayo, Ireland. Allergan Pharmaceuticals Ireland is a wholly owned, indirect subsidiary of AbbVie Inc.

5. On information and belief, Defendant Revance is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1222 Demonbreun Street, Suite 2000, Nashville, Tennessee 37203.

6. On information and belief, Defendant Ajinomoto Althea, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 11040 Roselle Street, San Diego, California 92121.

7. On information and belief, Ajinomoto Althea, Inc. is also doing business as "Ajinomoto Bio-Pharma Services." (*See, e.g.*, Ex. 6, Revance Therapeutics, Inc., Form 10-Q at 16-17 (Aug. 5, 2021).)

JURISDICTION AND VENUE

8. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

9. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

10. Revance is subject to personal jurisdiction in this District because, *inter alia*, it is a Delaware corporation and thus resides in Delaware.

11. Venue is proper in this Court as to Revance pursuant to 28 U.S.C. § 1400(b) because Revance is a Delaware corporation and thus resides in Delaware.

12. ABPS is subject to personal jurisdiction in this District because, *inter alia*, it is a Delaware corporation and thus resides in Delaware.

13. Venue is proper in this Court as to ABPS pursuant to 28 U.S.C. § 1400(b) because ABPS is a Delaware corporation and thus resides in Delaware.

BACKGROUND

I. Plaintiffs' BOTOX® and BOTOX® Cosmetic (OnabotulinumtoxinA) Products

14. The bacterium *Clostridium botulinum* produces extremely poisonous toxins, including various types of botulinum neurotoxins. To date, seven immunologically distinct botulinum neurotoxins (serotypes A-G) have been identified. One of them, botulinum neurotoxin type A ("BoNT/A"), is considered among the most lethal natural biological agents. Exposure to BoNT/A can lead to the development of botulism, a rare and serious condition characterized by muscle paralysis and difficulty breathing, which can potentially result in death.

15. BoNT/A acts in the human body by binding to certain receptors on nerves that release the neurotransmitter acetylcholine, which regulates important nerve impulses throughout the central and peripheral nervous systems. After binding to these receptors, BoNT/A enters the

nerves themselves and inhibits acetylcholine release, which stops nerve signaling entirely. BoNT/A achieves this inhibition by, for example, cleaving SNAP-25, a protein that is necessary for the release of acetylcholine. As a result, the nerves can no longer signal the muscles to expand and contract, which can have fatal consequences (*e.g.*, preventing expansion of the diaphragm, thus impairing breathing).

16. Plaintiffs and their predecessor pioneered the harnessing of botulinum toxins for use as safe and effective FDA-approved therapies, and Plaintiffs' innovations have led them to become the market leader in this field. Plaintiffs market these therapies under the well-known, commercially successful, and trusted BOTOX® and BOTOX® Cosmetic brands.

17. Since first gaining FDA approval for BOTOX® in 1989 (called "Oculinum" at that time) for treating two rare eye muscle disorders, Plaintiffs have invested significant scientific and financial resources in researching botulinum toxins for therapeutic and aesthetic uses as part of their ongoing commitment to helping improve the lives of patients. Extensive scientific research and large-scale clinical trials have resulted in the FDA granting approval to Plaintiffs for numerous medical and cosmetic indications for BOTOX® and BOTOX® Cosmetic.

18. Today, BOTOX® is FDA-approved for multiple therapeutic indications:

- treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication;
- treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury, multiple sclerosis] in adults who have an inadequate response to or are intolerant of an anticholinergic medication;
- treatment of neurogenic detrusor overactivity in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication;
- prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer);

- treatment of spasticity in patients 2 years of age and older;
- treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain;
- treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients;
- treatment of blepharospasm associated with dystonia in patients 12 years of age and older; and
- treatment of strabismus in patients 12 years of age and older.

(*See* Ex. 7, BOTOX® FDA Label (revised July 2021).)

19. In addition, BOTOX® Cosmetic is FDA-approved for numerous aesthetic indications in adult patients for the temporary improvement in the appearance of:

- moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity;
- moderate to severe lateral canthal lines associated with orbicularis oculi activity; and
- moderate to severe forehead lines associated with frontalis muscle activity.

(*See* Ex. 8, BOTOX® Cosmetic FDA Label (revised July 2020).)

20. Plaintiffs' innovations in the botulinum toxin field have been essential to using BOTOX® and BOTOX® Cosmetic to effectively treat these conditions, while also abiding by the strictest quality and safety standards. With more than 100 sponsored studies backing the more than 100 million vials of BOTOX® and BOTOX® Cosmetic manufactured worldwide since product launch, physicians, healthcare providers, and patients continue to trust Plaintiffs' products as reliable and effective treatment options for various therapeutic and aesthetics uses.

21. Plaintiffs' innovations in the field of botulinum toxin therapies have continued to the present day and include advancements in animal protein free BoNT/A products. These and other innovations resulted in the issuance of numerous patents covering Plaintiffs' inventive

formulations, manufacturing processes, and potency assays, which reflect Plaintiffs' ongoing, pioneering commitment to transforming botulinum toxins for safe and effective use in humans.

II. The Asserted Patents

A. U.S. Patent No. 11,033,625

22. The '625 patent, titled "Method for Stabilizing a Toxin," was duly and legally issued by the U.S. Patent and Trademark Office ("USPTO") on June 15, 2021. A true and accurate copy of the '625 patent is attached as Exhibit 1.

23. The named inventor listed on the '625 patent is Terrence J. Hunt.

24. Allergan, Inc. is the assignee of the '625 patent, and Allergan Pharmaceuticals Ireland is the exclusive licensee with respect to the '625 patent.

25. The '625 patent includes 19 claims. By way of example, claim 1 of the '625 patent recites the following pharmaceutical composition:

> **1.** A powder pharmaceutical composition, comprising:
> a botulinum toxin, wherein the botulinum toxin is a type A serotype;
> a surfactant;
> at least one disaccharide selected from the group consisting of sucrose and trehalose; and
> a buffer sufficient to maintain a pH of from about 5 to about 7.3 upon reconstitution with sterile normal saline or water;
> wherein the composition is suitable for intramuscular or subcutaneous injection following reconstitution with sterile normal saline or water,
> wherein the composition is animal protein free, and
> wherein the composition retains at least about 75% of the theoretical maximum potency of the botulinum toxin following storage as a powder for three months at below freezing temperature.

('625 patent at col. 73:38-54.)

B. U.S. Patent No. 7,354,740

26. The '740 patent, titled "Animal Product Free System and Process for Purifying a Botulinum Toxin," was duly and legally issued by the USPTO on April 8, 2008. A true and accurate copy of the '740 patent is attached as Exhibit 2.

27. The named inventors listed on the '740 patent are Hui Xiang, Mingjiang Luo, Ping Wang, and Stephen Donovan.

28. Allergan, Inc. is the assignee of the '740 patent, and Allergan Pharmaceuticals Ireland is the exclusive licensee with respect to the '740 patent.

29. The '740 patent includes eight claims. By way of example, claim 1 of the '740 patent recites an animal protein free process for purifying a biologically active botulinum toxin:

> **1.** An animal protein free ("APF") process for purifying a biologically active botulinum toxin, the process comprising the steps of:
> (a) obtaining a sample of a botulinum toxin fermentation culture, wherein the botulinum toxin fermentation culture results from a substantially APF process,
> (b) contacting a hydrophobic interaction chromatography column resin with the culture sample so as to permit capture of a botulinum toxin by the hydrophobic interaction chromatography column;
> (c) washing impurities off the hydrophobic interaction chromatography column;
> (d) eluting the botulinum toxin from the hydrophobic interaction column;
> (e) loading an ion exchange column chromatography column resin with the eluent from the hydrophobic interaction chromatography column;
> (f) washing impurities off the ion exchange chromatography column, and;
> (g) eluting the botulinum toxin from the ion exchange column, thereby obtaining a purified biologically active botulinum toxin through a process for purifying a botulinum toxin which is a substantially APF purification process.

('740 patent at col. 47:28-51.)

C. U.S. Patent No. 8,409,828

30. The '828 patent, titled "Animal Product Free System and Process for Purifying a Botulinum Toxin," was duly and legally issued by the USPTO on April 2, 2013. A true and accurate copy of the '828 patent is attached as Exhibit 3.

31. The named inventors listed on the '828 patent are Hui Xiang, Mingjiang Luo, Ping Wang, and Stephen Donovan.

32. Allergan, Inc. is the assignee of the '828 patent, and Allergan Pharmaceuticals Ireland is the exclusive licensee with respect to the '828 patent.

33. The '828 patent includes nine claims. By way of example, claim 1 of the '828 patent recites an animal product free process for purifying a biologically active botulinum toxin:

> **1.** An animal product free process for purifying a biologically active botulinum toxin, the process comprising the steps of:
> (a) preparing a botulinum toxin fermentation culture for passage over chromatography columns, wherein the fermentation culture is animal product free;
> (b) contacting a first chromatography column resin with prepared botulinum toxin fermentation culture, so as to permit capture of a botulinum toxin by the first column, wherein the first chromatography column resin utilizes a first separation mechanism selected from the group consisting of ion exchange, hydrophobic interaction, gel filtration and mixed mode mechanisms;
> (c) eluting the botulinum toxin from the first column;
> (d) loading a second column with eluent from the first column, wherein the second column interacts with eluent from the first column utilizing a second separation mechanism different from the first separation mechanism from the first column wherein the second separation mechanism is selected from the group consisting of ion exchange, hydrophobic interaction, gel filtration and mixed mode mechanisms; and
> (e) eluting the botulinum toxin from the second column, thereby obtaining a purified biologically active toxin.

('828 patent at col. 46:42-65.)

D. U.S. Patent No. 11,124,786

34. The '786 patent, titled "Process and System for Obtaining Botulinum Neurotoxin," was duly and legally issued by the USPTO on September 21, 2021. A true and accurate copy of the '786 patent is attached as Exhibit 4.

35. The named inventors listed on the '786 patent are Jennifer L. Ton, Hemant A. Patel, Ronald C. Bates, and Wajdie M. Ahmad.

36. Allergan, Inc. is the assignee of the '786 patent, and Allergan Pharmaceuticals Ireland is the exclusive licensee with respect to the '786 patent.

37. The '786 patent includes 14 claims. By way of example, claim 1 of the '786 patent recites a substantially animal product free process utilizing chromatography for purifying dissociated, approximately 150 kDa BoNT/A:

> **1.** A substantially animal product free (APF) process utilizing chromatography for purifying *Clostridium botulinum* toxin serotype A (BoNT/A) in a sample comprising dissociated, approximately 150 kDa BoNT/A and at least one impurity protein comprising:
> (a) contacting the sample with an anion exchange chromatography (AEX) media under conditions whereby the approximately 150 kDa BoNT/A is bound to the AEX media;
> (b) washing and eluting the bound approximately 150 kDa BoNT/A to provide a first eluent;
> (c) contacting the first eluent with a sodium phosphate buffer;
> (d) further contacting the first eluent with a cation exchange chromatography (CEX) media under conditions whereby the approximately 150 kDa BoNT/A is bound to the CEX media;
> (e) washing and eluting the bound approximately 150 kDa BoNT/A, including contacting the bound approximately 150 kDa BoNT/A with a salt comprising sodium chloride, to provide a second eluent; and
> (f) recovering purified dissociated, approximately 150 kDa BoNT/A.

('786 patent at col. 47:32-48:4.)

E. U.S. Patent No. 7,332,567

38. The '567 patent, titled "FRET Protease Assays for Clostridial Toxins," was duly and legally issued by the USPTO on February 19, 2008. A true and accurate copy of the '567 patent is attached as Exhibit 5.

39. The named inventors listed on the '567 patent are Lance E. Steward, Ester Fernandez-Salas, and Kei Roger Aoki.

40. Allergan, Inc. is the assignee of the '567 patent.

41. The '567 patent includes 131 claims. By way of example, claim 1 of the '567 patent recites a BoNT/A substrate for use in a potency assay:

> **1.** A botulinum toxin serotype A (BoNT/A) substrate, comprising:
> (a) a donor fluorophore;
> (b) an acceptor fluorophore having an absorbance spectrum overlapping the emission spectrum of said donor fluorophore; and
> (c) a BoNT/A recognition sequence comprising a cleavage site, wherein said cleavage site intervenes between said donor fluorophore and said acceptor fluorophore;
> wherein, under the appropriate conditions, resonance energy transfer is exhibited between said donor fluorophore and said acceptor fluorophore.

('567 patent at col. 107:41-54.)

III. Revance's DaxibotulinumtoxinA for Injection Product

A. Revance's Formulation for DaxibotulinumtoxinA for Injection

42. Revance has developed a botulinum toxin product called DaxibotulinumtoxinA for Injection (also sometimes referred to as "DAXI"), with the goal of obtaining FDA approval for both aesthetic and therapeutic uses that are in direct competition with Plaintiffs' BOTOX® and BOTOX® Cosmetic product lines. (*See, e.g.*, Ex. 9, Revance Therapeutics, Inc., Presentation at Slides 11, 13, 16-19, and 27-29 (Jan. 2021).)

43. Revance completed Phase III clinical studies regarding the use of DaxibotulinumtoxinA for Injection for the treatment of glabellar lines in human patients in late 2019. (*See, e.g.*, Ex. 9, Revance Therapeutics, Inc. Presentation at Slides 16-18 (Jan. 2021); *see also* Ex. 10, Carruthers *et al.*, *DaxibotulinumtoxinA for Injection for the Treatment of Glabellar Lines: Results from Each of Two Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Studies (SAKURA 1 and SAKURA 2)*, Plastic and Recon. Surg. 145(1):45-58, at 46 (Jan. 2020) ("Carruthers 2020").) These Phase III studies involved a series of treatments consisting of five intramuscular 0.1 mL injections. (*See, e.g.*, Ex. 10, Carruthers 2020 at 46-47.)

44. The formulation of DaxibotulinumtoxinA for Injection includes 150 kDa BoNT/A ("RTT150"), a peptide ("RTP004"), a sugar, a surfactant (*i.e.*, polysorbate-20), and buffers. (*See, e.g.*, Ex. 11, Revance Therapeutics, Inc., Form 10-K at 12 (Feb. 25, 2021); Ex. 10, Carruthers 2020 at 46.)

45. DaxibotulinumtoxinA for Injection "does not contain human or animal-based components." (*See* Ex. 11, Revance Therapeutics, Inc., Form 10-K at 1 (Feb. 25, 2021); Ex. 9, Revance Therapeutics, Inc., Presentation at Slide 19 (Jan. 2021).)

46. DaxibotulinumtoxinA for Injection will be supplied as a lyophilized powder, which will require reconstitution with saline before intramuscular injection. (*See, e.g.*, Ex. 11, Revance Therapeutics, Inc., Form 10-K at 12 (Feb. 25, 2021).)

47. On information and belief, the formulation of DaxibotulinumtoxinA for Injection retains at least about 75% of the theoretical maximum potency of the botulinum toxin following storage as a powder for three months.

B. Revance's Manufacturing Process for DaxibotulinumtoxinA for Injection

48. Revance has used, and will continue to use following FDA approval, a manufacturing process for DaxibotulinumtoxinA for Injection that is "entirely free of animal and human-derived materials and depends on standard raw materials available commercially." (*See* Ex. 11, Revance Therapeutics, Inc., Form 10-K at 13 (Feb. 25, 2021); *see also* Ex. 12, Revance Therapeutics, Inc., Presentation at Slide 19 (April 19, 2018) (stating "No Animal-Derived Material Used in Processing").)

49. On information and belief, U.S. Patent No. 9,469,849 ("the '849 patent"), which is assigned to Revance, recites the process used by Revance to manufacture DaxibotulinumtoxinA for Injection. (*See* Ex. 13, '849 patent at col. 18:5-19:62.)

50. Example 1 in the '849 patent, captioned "Comparison of Inventive Process with a Modified Schantz Process," describes, *inter alia*, a downstream chromatography strategy to purify non-complexed BoNT/A involving a hydrophobic interaction column followed by an anion exchange column. (*See* Ex. 13, '849 patent at col. 18:5-19:62.) The example describes the eluent from the anion exchange column being contacted with a sodium phosphate buffer and then loaded onto a cation exchange column, whereby the bound, non-complexed BoNT/A is contacted with sodium chloride. (*Id.*) The '849 patent further states that the process described in Example 1 "can find use in large-scale efficient purification of a non-complexed botulinum toxin suitable for use, *e.g.*, as an active ingredient in pharmaceutical compositions." (*Id.* at col. 19:63-20:2.)

51. Revance has entered into a Technology Transfer, Validation and Commercial Fill/Finish Services Agreement with at least ABPS ("the ABPS Service Agreement") to provide Revance "with expanded capacity and a second source for drug product manufacturing to support a global launch of [DaxibotulinumtoxinA for Injection]." (*See* Ex. 14, Revance Therapeutics, Inc.,

Form 10-K at 10 (Feb. 26, 2020); *see also* Ex. 15, Revance Therapeutics, Inc., Form 10-Q at 35, 38 (May 9, 2017) ("We plan to utilize our internal and external Althea facility to support commercial production of [DaxibotulinumtoxinA for Injection]."); Ex. 16, Revance Therapeutics, Inc., Form 10-Q Exhibit 10.4 (May 9, 2017).)

52. Revance directs and controls ABPS's manufacturing efforts with respect to DaxibotulinumtoxinA for Injection.

C. Revance's Potency Assay for DaxibotulinumtoxinA for Injection

53. Revance has used, and will continue to use following FDA approval, a BoNT/A substrate in connection with a cell-based potency assay designed to measure the relative potency of DaxibotulinumtoxinA for Injection for release and stability testing of both their drug substance and drug product.

54. Revance presented a public poster at the TOXINS 2019 conference in Denmark with the following statements:

> To measure relative potency of sample material to reference, a reporter cell line is used to evaluate the response of sample material relative to a reference with known potency previously defined by mouse LD_{50} testing. Briefly, the cells are engineered to stably express recombinant SNAP-25 protein with 2 distinct fluorescent proteins on SNAP-25's N- and C-termini. In the presence of [DaxibotulinumtoxinA for Injection], the recombinant SNAP-25 is cleaved releasing the C-terminal fluorophore into the cytosol where it is degraded. The second N-terminal fluorophore remains intact and can be used for signal normalization between wells. The extent of SNAP-25 cleavage is measured by assessing the emission ratio of the 2 fluorophores as a function of [DaxibotulinumtoxinA for Injection] concentration.

(*See* Ex. 17, Revance Therapeutics, Inc., Poster (Jan. 17-18, 2019); *see also* Ex. 18, Revance Therapeutics, Inc., Press Release (Jan. 15, 2019); Ex. 19, Smyth *et al.*, *Development of a Cell-Based Potency Assay for Release and Stability Testing of Drug Substance and Drug Product*, Abstracts / Toxicon, S2-S120, at S105 (2018).)

55. Revance has also in-licensed cell-based potency assay technology from BioSentinel, Inc. ("BioSentinel") for research, development, and manufacturing purposes. (*See, e.g.*, Ex. 20, Revance Therapeutics, Inc., Form 10-Q at 27 (Nov. 9, 2020).) This technology includes, for example, BioSentinel's BoCell™ A cell-based potency assay, which utilizes a full-length SNAP-25 protein as a reporter that is capable, under appropriate conditions, of exhibiting resonance energy transfer. (*See, e.g.*, Ex. 21, BioSentinel, Inc., *Nomination to ICCVAM: BoCell™ A Cell-based Assay for Botulinum Neurotoxin A Detection*.)

56. The ABPS Service Agreement includes certain quality control and inspection provisions for Revance to ensure the satisfactory quality of DaxibotulinumtoxinA for Injection. (*See, e.g.*, Ex. 11, Revance Therapeutics, Inc., Form 10-K at 14 (Feb. 25, 2021).)

57. On information and belief, Defendants' manufacturing efforts, including those related to quality control and inspection of DaxibotulinumtoxinA for Injection, involve certain cell-based potency assays that utilize the BoNT/A substrate technology described above for release and stability testing of Defendants' DaxibotulinumtoxinA for Injection drug substance and drug product.

IV. Imminent FDA Approval of DaxibotulinumtoxinA for Injection, and Revance's Related Preparations to Launch

58. Revance filed a biologics license application ("BLA") for DaxibotulinumtoxinA for Injection for the treatment of glabellar lines in November 2019.

59. Revance's BLA was accepted by the FDA on February 5, 2020, with a Prescription Drug User Fee Act ("PDUFA") "target action date" initially set for November 25, 2020. (*See, e.g.*, Ex. 11, Revance Therapeutics, Inc., Form 10-K at 7 (Feb. 25, 2021).) The PDUFA "target action date" is the date when the applicant can expect the FDA to render its decision regarding

approval of a BLA. In general, the FDA will typically render a decision on a BLA no later than 10 months after its submission. *See* 21 U.S.C. § 379 *et seq.*

60. On November 24, 2020, the FDA deferred its decision on Revance's BLA for DaxibotulinumtoxinA for Injection and, at the same time, postponed the original PDUFA target action date of November 25, 2020. (*See, e.g.*, Ex. 6, Revance Therapeutics, Inc., Form 10-Q at 44 (Aug. 5, 2021).)

61. The FDA's deferral decision with respect to Revance's BLA for DaxibotulinumtoxinA for Injection was due to travel restrictions related to the ongoing COVID-19 pandemic, which impacted the ability of the FDA to conduct an inspection of Revance's manufacturing facility for DaxibotulinumtoxinA for Injection. (*See, e.g.*, Ex. 9, Revance Therapeutics, Inc., Investor Presentation at Slide 13 (Jan. 21, 2021).)

62. An on-site inspection of Revance's manufacturing facility for DaxibotulinumtoxinA for Injection by the FDA was one of the final steps that needed to occur before Revance obtains FDA approval of its BLA. (*See* Ex. 22, Revance Therapeutics, Inc., Form 10-Q at 40 (May 10, 2021 ("Though our BLA is still under review, the FDA did not indicate there were any other review issues at the time beyond the on-site inspection.").)

63. On May 26, 2021, Revance announced that the FDA planned to initiate pre-approval inspection of Revance's manufacturing facility for DaxibotulinumtoxinA for Injection by the end of June 2021. (*See, e.g.*, Ex. 23, Revance Therapeutics, Inc., Form 8-K (May 26, 2021)).

64. In its most recent quarterly earning filing with the U.S. Securities and Exchange Commission from August 5, 2021, Revance confirmed that the FDA had initiated the pre-approval

inspection of Revance's manufacturing facility for DaxibotulinumtoxinA for Injection in June 2021. (*See, e.g.*, Ex. 6, Revance Therapeutics, Inc., Form 10-Q at 9 (Aug. 5, 2021).)

65. FDA approval of Revance's DaxibotulinumtoxinA for Injection product is now imminent, and Revance anticipates launching its DaxibotulinumtoxinA for Injection product shortly after FDA approval. (*See, e.g.*, Ex. 24, Revance Therapeutics, Inc., Investor Conference at 5-6 (Sept. 9, 2021) (Revance CEO Mark Foley stating, "We've got our launch strategy and everything in place. And so we're ready to flip the switch as soon as we receive notice from the agency."); *see also* Ex. 25, Revance Therapeutics, Inc., Earnings Call at 7-8 (Aug. 5, 2021); Ex. 9, Revance Therapeutics, Inc., Presentation at Slide 9 (Jan. 2021).)

66. Defendants have undertaken significant, concrete, and meaningful preparations to launch DaxibotulinumtoxinA for Injection upon FDA approval, which is now imminent. For example, Revance has announced the manufacturing process for DaxibotulinumtoxinA for Injection "is already scaled up to support expected future commercial demands" upon FDA approval. (*See, e.g.*, Ex. 11, Revance Therapeutics, Inc., Form 10-K at 13 (Feb. 25, 2021).)

67. Defendants are presently stockpiling commercial batches of DaxibotulinumtoxinA for Injection for immediate release upon the FDA's imminent approval. For example, Revance's CEO Mark Foley stated on August 5, 2021, that Revance "is actively building inventory and solidifying [Revance's] commercial launch plans" for DaxibotulinumtoxinA for Injection. (Ex. 25, Revance Therapeutics, Inc., Earnings Call at 4 (Aug. 5, 2021).) Moreover, Revance's Chief Commercial Officer of Aesthetics & Therapeutics, Dustin Sjuts, has stated that, "in preparation for the anticipated FDA approval for our next-generation neuromodulator, DaxibotulinumtoxinA for Injection in glabellar lines, we continue to build out and test the

infrastructure, operations, and back-office support to ensure a smooth launch upon approval." (Ex. 26, Revance Therapeutics, Inc., Earnings Call at 8 (Feb. 22, 2021).)

68. Defendants have coordinated with respect to the manufacture of DaxibotulinumtoxinA for Injection, and will continue to do so, in substantial and meaningful preparation for immediate launch of DaxibotulinumtoxinA for Injection upon FDA approval, which is now imminent.

69. A real, substantial, and immediate controversy currently exists between Plaintiffs and Defendants concerning Defendants' activities with respect to DaxibotulinumtoxinA for Injection.

COUNT I: DECLARATORY JUDGMENT
OF INFRINGEMENT OF THE '625 PATENT

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

71. Revance and its agents intend to, and have expressed that they will immediately upon the imminent FDA approval of the BLA, manufacture, use, offer to sell, or sell within the United States, or import into the United States, DaxibotulinumtoxinA for Injection.

72. Revance and its agents' manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of DaxibotulinumtoxinA for Injection before the expiration of the '625 patent has directly infringed or will directly infringe one or more claims of that patent, including claim 1, literally or under the doctrine of equivalents.

73. ABPS's manufacture, either on its own accord or under Revance's direction and control, within the United States, or importation into the United States, of DaxibotulinumtoxinA for Injection before the expiration of the '625 patent has directly infringed or will directly infringe one or more claims of that patent, including claim 1, literally or under the doctrine of equivalents.

74. An actual case or controversy has arisen and now exists between the parties concerning whether DaxibotulinumtoxinA for Injection has infringed or will infringe one or more claims of the '625 patent.

75. Plaintiffs are entitled to a judgment that Defendants have infringed or will infringe one or more claims of the '625 patent by making, using, offering to sell, or selling within the United States, or by importing into the United States DaxibotulinumtoxinA for Injection, before the expiration of that patent.

76. Defendants' manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of DaxibotulinumtoxinA for Injection before the expiration of the '625 patent will cause Plaintiffs injury, entitling Plaintiffs to damages under 35 U.S.C. § 284.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '740 PATENT

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

78. Revance and its agents intend to, and have expressed that they will immediately upon the imminent FDA approval of the BLA, manufacture, use, offer to sell, or sell within the United States, or import into the United States, DaxibotulinumtoxinA for Injection.

79. Revance and its agents' manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of DaxibotulinumtoxinA for Injection made according to the claimed manufacturing process of the '740 patent before the expiration of that patent has directly infringed or will directly infringe one or more claims of that patent, including claim 1, literally or under the doctrine of equivalents.

80. ABPS's manufacture, either on its own accord or under Revance's direction and control, within the United States, or importation into the United States, of DaxibotulinumtoxinA for Injection made according to the claimed manufacturing process of the '740 patent before the

expiration of that patent has directly infringed or will directly infringe one or more claims of that patent, including claim 1, literally or under the doctrine of equivalents.

81. An actual case or controversy has arisen and now exists between the parties concerning whether Defendants' manufacture of DaxibotulinumtoxinA for Injection has infringed or will infringe one or more claims of the '740 patent.

82. Plaintiffs are entitled to a judgment that Defendants have infringed or will infringe one or more claims of the '740 patent by making DaxibotulinumtoxinA for Injection according to the claimed process of that patent within the United States, or by importing into the United States DaxibotulinumtoxinA for Injection manufactured by the claimed process of that patent, before the expiration of that patent.

83. Defendants' manufacture of DaxibotulinumtoxinA for Injection according to the claimed process of the '740 patent before the expiration of that patent will cause Plaintiffs injury, entitling Plaintiffs to damages under 35 U.S.C. § 284.

COUNT III: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '828 PATENT

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

85. Revance and its agents intend to, and have expressed that they will immediately upon the imminent FDA approval of the BLA, manufacture, use, offer to sell, or sell within the United States, or import into the United States, DaxibotulinumtoxinA for Injection.

86. Revance and its agents' manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of DaxibotulinumtoxinA for Injection made according to the claimed manufacturing process of the '828 patent before the expiration of that patent has directly infringed or will directly infringe one or more claims of that patent, including claim 1, literally or under the doctrine of equivalents.

87. ABPS's manufacture, either on its own accord or under Revance's direction and control, within the United States, or importation into the United States, of DaxibotulinumtoxinA for Injection made according to the claimed manufacturing process of the '828 patent before the expiration of that patent has directly infringed or will directly infringe one or more claims of that patent, including claim 1, literally or under the doctrine of equivalents.

88. An actual case or controversy has arisen and now exists between the parties concerning whether Defendants' manufacture of DaxibotulinumtoxinA for Injection has infringed or will infringe one or more claims of the '828 patent.

89. Plaintiffs are entitled to a judgment that Defendants have infringed or will infringe one or more claims of the '828 patent by making DaxibotulinumtoxinA for Injection according to the claimed process of that patent within the United States, or by importing into the United States DaxibotulinumtoxinA for Injection manufactured by the claimed process of that patent, before the expiration of that patent.

90. Defendants' manufacture of DaxibotulinumtoxinA for Injection according to the claimed process of the '828 patent before the expiration of that patent will cause Plaintiffs injury, entitling Plaintiffs to damages under 35 U.S.C. § 284.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '786 PATENT

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

92. Revance and its agents intend to, and have expressed that they will immediately upon the imminent FDA approval of the BLA, manufacture, use, offer to sell, or sell within the United States, or import into the United States, DaxibotulinumtoxinA for Injection.

93. Revance and its agents' manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of DaxibotulinumtoxinA for Injection made

according to the claimed manufacturing process of the '786 patent before the expiration of that patent has directly infringed or will directly infringe one or more claims of that patent, including claim 1, literally or under the doctrine of equivalents.

94. ABPS's manufacture, either on its own accord or under Revance's direction and control, within the United States, or importation into the United States, of DaxibotulinumtoxinA for Injection made according to the claimed manufacturing process of the '786 patent before the expiration of that patent has directly infringed or will directly infringe one or more claims of that patent, including claim 1, literally or under the doctrine of equivalents.

95. An actual case or controversy has arisen and now exists between the parties concerning whether Defendants' manufacture of DaxibotulinumtoxinA for Injection has infringed or will infringe one or more claims of the '786 patent.

96. Plaintiffs are entitled to a judgment that Defendants have infringed or will infringe one or more claims of the '786 patent by making DaxibotulinumtoxinA for Injection according to the claimed process of that patent within the United States, or by importing into the United States DaxibotulinumtoxinA for Injection manufactured by the claimed process of that patent, before the expiration of that patent.

97. Defendants' manufacture of DaxibotulinumtoxinA for Injection according to the claimed process of the '786 patent before the expiration of that patent will cause Plaintiffs injury, entitling Plaintiffs to damages under 35 U.S.C. § 284.

COUNT V: DECLARATORY JUDGMENT
OF INFRINGEMENT OF THE '567 PATENT

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

99. Revance and its agents intend to, and have expressed that they will immediately upon the imminent FDA approval of the BLA, manufacture, use, offer to sell, or sell within the United States, or import into the United States, DaxibotulinumtoxinA for Injection.

100. Revance and its agents' manufacture or use within the United States, or importation into the United States, of BoNT/A substrates in connection with DaxibotulinumtoxinA for Injection before the expiration of the '567 patent has directly infringed or will directly infringe one or more claims of that patent, including claim 1, literally or under the doctrine of equivalents.

101. ABPS's manufacture or use, either on its own accord or under Revance's direction and control, within the United States, or importation into the United States, of BoNT/A substrates, including in connection with cell-based potency assays for release and stability testing of DaxibotulinumtoxinA for Injection, before the expiration of the '567 patent has directly infringed or will directly infringe one or more claims of that patent, including claim 1, literally or under the doctrine of equivalents.

102. An actual case or controversy has arisen and now exists between the parties concerning whether any BoNT/A substrates used by Defendants in cell-based potency assays for release and stability testing of DaxibotulinumtoxinA for Injection have infringed or will infringe one or more claims of the '567 patent.

103. Plaintiffs are entitled to a judgment that Defendants have infringed or will infringe one or more claims of the '567 patent by making or using within the United States, or by importing into the United States, any infringing BoNT/A substrates, including in connection with cell-based

potency assays for release and stability testing of DaxibotulinumtoxinA for Injection, before the expiration of that patent.

104. Defendants' manufacture and/or use of any infringing BoNT/A substrates, including in connection with cell-based potency assays for release and stability testing of DaxibotulinumtoxinA for Injection, before the expiration of the '567 patent, and manufacture, use, offer to sell, and/or sale of any DaxibotulinumtoxinA for Injection product released or tested in accordance with any cell-based potency assay utilizing infringing BoNT/A substrates before the expiry of that patent, will cause Plaintiffs injury, entitling Plaintiffs to damages under 35 U.S.C. § 284.

JURY DEMAND

105. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

A. A judgment that the '625 patent has been or will be directly infringed by Defendants' manufacture, use, offers to sell, and sales within the United States, or importation into the United States, of DaxibotulinumtoxinA for Injection before the expiration of that patent.

B. A judgment that the '740 patent has been or will be directly infringed by Defendants' making DaxibotulinumtoxinA for Injection according to the claimed process of that patent within the United States, or by importing into the United States DaxibotulinumtoxinA for Injection manufactured by the claimed process of that patent, before the expiration of that patent.

C. A judgment that the '828 patent has been or will be directly infringed by Defendants' making DaxibotulinumtoxinA for Injection according to the claimed process of that

patent within the United States, or by importing into the United States DaxibotulinumtoxinA for Injection manufactured by the claimed process of that patent, before the expiration of that patent.

D. A judgment that the '786 patent has been or will be directly infringed by Defendants' making DaxibotulinumtoxinA for Injection according to the claimed process of that patent within the United States, or by importing into the United States DaxibotulinumtoxinA for Injection manufactured by the claimed process of that patent, before the expiration of that patent.

E. A judgment that the '567 patent has been or will be directly infringed by Defendants' manufacture or use within the United States, or importation into the United States, of BoNT/A substrates in connection with DaxibotulinumtoxinA for Injection before the expiration of that patent.

F. A declaration that Revance's commercial manufacture, use, offer for sale, or sale of DaxibotulinumtoxinA for Injection within the United States, of importation of DaxibotulinumtoxinA for Injection into the United States, before the expiration of the '625 patent, the '740 patent, the '828 patent, the '786 patent, and/or the '567 patent, would constitute an act of infringement of the Asserted Patents.

G. An order granting any equitable relief that the Court deems appropriate.

H. Actual damages adequate to compensate Plaintiffs for Defendants' past, present, and future infringement of the Asserted Patents, and that are no less than a reasonable royalty and lost profits together with any prejudgment and post-judgment interest as allowed by law, costs, and other damages permitted by 35 U.S.C. § 284.

I. A declaration that this is an exceptional case and an award of Plaintiffs' attorney fees pursuant to 35 U.S.C. § 285.

J. Such further and additional relief as this Court deems just and proper.

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