IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RESHAPE LIFESCIENCES INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ALLURION TECHNOLOGIES, INC.	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff ReShape Lifesciences Inc. ("ReShape" or "Plaintiff") brings this action for patent infringement against Allurion Technologies, Inc. ("Allurion" or "Defendant").

NATURE OF THE ACTION

1. This is a civil action for patent infringement. This action concerns Allurion's infringement of at least Claims 1 and 18 of ReShape's U.S. Patent No. 10,463,520 ("the '520 Patent" or "Patent-in-Suit") by making the Allurion Gastric Balloon system (also previously called the "Elipse," and collectively referred to here as "the Allurion system") in the United States for exportation and/or sales from the United States and/or for potential sales in the United States relating to Allurion's application to FDA for approval to sell the Allurion system in the United States.

2. This action arises under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. §271, and the Declaratory Judgment Act, Title 28, United States Code, including §§ 2201, 2202.

THE PARTIES

3. ReShape is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1001 Calle Amanecer, San Clemente, CA 92673.

4. On information and belief, Allurion is a corporation organized and existing under the laws of Delaware, having a principal place of business at 11 Huron Drive, Natick, MA 01760.

5. On information and belief, Alllurion may be served through its registered agent, The Corporation Trust Company, located at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

JURISDICTION AND VENUE

6. This civil action for patent infringement arises under the patent laws of the United States, 35 U.S.C § 1 et seq., including in particular under 35 U.S.C. § 271. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a) and the Declaratory Judgment Act, Title 28, United States Code, including §§ 2201, 2202.

7. This Court has personal jurisdiction over Allurion, and venue is proper in this district pursuant to 28 U.S.C. § 1400(b), because Allurion is a Delaware corporation and thus resides in this district.

THE PATENT-IN-SUIT

8. The ’520 Patent, entitled “Intragastric Device,” was duly and legally issued on November 5, 2019 by the U.S. Patent and Trademark Office (“USPTO”). A copy of the ’520 Patent is attached as Exhibit A.

9. Obalon Therapeutics, Inc. (“Obalon”) filed U.S. patent application number 15/690,095 on August 29, 2017, which resulted in the ’520 Patent.

10. As listed on its face, the ’520 Patent has a priority date of January 21, 2011, through the following series of continuation patent applications: Continuation of application No. 14/860,538, filed on Sep. 21, 2015, now Pat. No. 9,827,128, which is a continuation of application No. 14/227,195, filed on Mar. 27, 2014, now Pat. No. 9,351,862, which is a continuation of

application No. 13/510,921, filed as application No. PCT/US2011/022165 on Jan. 21, 2011, now Pat. No. 8,740,927.

11. ReShape is the assignee and owner of all rights, title, and interest in the '520 Patent as a result of its merger with Obalon in June 2021. The name change was recorded at the USPTO on October 6, 2021 at reel 057726, frame 0716.

FACTUAL BACKGROUND ON RESHAPE

12. ReShape is America's premier weight-loss solutions company, offering an integrated portfolio of proven products and services that manage and treat obesity and metabolic disease, including the FDA-approved Lap-Band®.

13. In June 2021, ReShape merged with Obalon, and began trading as ReShape Lifesciences Inc. with the trading symbol "RSLS" on the NASDAQ.

14. Before the merger, Obalon was a company focused on developing and commercializing novel balloon technologies for weight loss.

15. The merger between Obalon and ReShape brought together their innovative weight-loss solutions, including Obalon's own extensive patent portfolio, combining their substantial investments in their innovative solutions.

16. As a result of the merger, ReShape became the assignee and owner of all rights, title, and interest in a portfolio of Obalon patents, which includes the '520 Patent.

FACTUAL BACKGROUND ON ALLURION

17. Dr. Shantanu Gaur, Allurion Co-Founder and CEO, co-founded Allurion in 2009 while at Harvard Medical School.

18. Allurion achieved CE approval for the Allurion system in Europe in 2015.

19. On information and belief, Allurion has manufactured its Allurion system in the United States since 2015 and continues to do so.

20. Allurion has a current FDA registration for manufacturing the Allurion system in the United States for export only (FEI Number 3011299930).

21. The FDA lists Allurion's address as 11 Huron Dr., Natick, MA 01760. Allurion also has issued press releases from its Natick, MA location.

22. On April 7, 2020, Allurion announced its submission to the FDA of a Premarket Approval (PMA) Application for the Allurion system in the United States.

23. Allurion has known of ReShape's patents at least by July 7, 2017, when it cited ReShape's U.S. Patent No. 9,662,239 ("the '239 Patent") in an Information Disclosure Statement ("IDS") filed in the USPTO in connection with Allurion's U.S. patent application number 15/174,864.

24. Allurion cited ReShape's '239 Patent again in an IDS as late as April 29, 2020 in Allurion's U.S. patent application number 16/505,468.

25. The '239 Patent and the '520 Patent claim priority to the same patent application filed on January 21, 2011. Therefore, Allurion has been aware of ReShape's patent rights since 2017.

26. On October 5, 2022, ReShape wrote to Dr. Gaur explaining the basis for Allurion's infringement of Claims 1 and 18 of the '520 Patent. ReShape's October 5, 2022 letter to Allurion stated that Allurion's manufacturing of the Allurion system in the United States infringes the '520 patent claims, and that the Allurion system is infringing the inventions in the '520 patent, including for example, claims 1 and 18 of the '520 patent. ReShape's October 5, 2022 letter defined the Allurion Gastric Balloon system (also previously called the "Elipse") as "the Allurion system".

27. Among other things, ReShape's October 5, 2022 letter to Allurion also requested that Dr. Gaur fulfill his duty to read the '520 Patent and carefully consider Allurion's infringement of ReShape's patent rights and respond to the letter accordingly.

28. ReShape's October 5, 2022 letter also stated that Allurion can resolve its infringement of the '520 Patent by taking a patent license and paying a reasonable royalty.

29. On February 9, 2023, Allurion issued a press release from its Natick, MA location about its plans to become a public company ("Allurion's February 9 press release"). A copy of Allurion's February 9 press release is attached as Exhibit B (https://www.allurion.com/en/newsroom/allurion-to-become-publicly-listed).

30. Allurion's February 9 press release announced, among other things: "Allurion Technologies, Inc. ("Allurion"), a company dedicated to ending obesity, and Compute Health Acquisition Corp, a special purpose acquisition company ("Compute Health") (NYSE: CPUH), today announced that they have entered into a definitive business combination agreement that will result in Allurion becoming a publicly listed company. Upon closing, the combined company (the "Company") will be named Allurion Technologies, Inc. and its common stock (the "Common Stock") is expected to be traded on the New York Stock Exchange under the symbol "ALUR"."

31. Allurion's February 9 press release also stated: "Allurion's revenue growth has been fueled by increasing utilization of The Allurion Program by existing providers and rapid geographical expansion. Allurion's revenues in 2020, 2021, and 2022 were $20 million, $38 million, and $64 million, respectively."

32. Allurion's February 9 press release also stated as a "Key Transaction Term": "The proposed transaction also includes a minimum cash condition of $70 million (net of certain expenses) and is expected to provide a minimum of $87 million of gross cash proceeds."

33. Allurion's February 9 press release also stated as a "Key Transaction Term": "The proposed transaction is expected to close in the first half of 2023."

34. In an investor presentation dated February 2023 ("Allurion's Investor Presentation"), Allurion projects its revenue will be $100 million in 2023 and $140 million in 2024. A copy of Allurion's Investor Presentation is attached as Exhibit C.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 10,463,520

35. ReShape incorporates and realleges the foregoing paragraphs above as if fully set forth herein.

36. The '520 Patent, which is attached as Exhibit A and is entitled "Intragastric Device," was duly and legally issued on November 5, 2019 by the USPTO.

37. ReShape is the owner by assignment of all title, right, and interest in and to the '520 Patent.

38. Allurion's manufacturing of the Allurion system in the United States for exportation and/or sales from the United States infringes the '520 Patent. To the extent Allurion is manufacturing and stockpiling the Allurion system in the United States for sale in the United States in anticipation of FDA approval, such activities also infringe the '520 Patent. Individually and collectively, these infringing acts will be referred to as "Allurion's infringing activities".

39. Allurion's infringing activities directly infringe at least Claims 1 and 18 of the '520 Patent, literally or under any equivalents, under 35 U.S.C. §§ 271(a).

40. Claim 1 of the '520 Patent recites:

1. An intragastric volume-occupying device system, comprising:

a) a capsule configured to be swallowable by normal peristalsis and to degrade in a gastric environment;

b) a volume-occupying component compacted and contained within the capsule, the volume-occupying component comprising:
i) a composite wall defining an outer surface and an interior cavity with an inner surface,
ii) a self-sealing valve system including a septum, and
iii) a deflation component including an erodible portion, a moisture absorbing expandable portion and an inlet port in fluid communication with the interior cavity;

c) a catheter coupled to the valve system, the catheter comprising:
i) a lumen in fluid communication with the interior cavity of the volume-occupying component, wherein the lumen is configured for filling the volume-occupying component interior cavity with an inflation fluid.

41. Claim 18 of the ’520 Patent recites: “18. The intragastric volume-occupying device system of claim 1, wherein the inflation fluid is a liquid inflation fluid selected from the group consisting of a saline solution and pure water.”

42. Claim 1 of the ’520 Patent recites “An intragastric volume-occupying device system, comprising” elements a), b), and c), each of which is further addressed below. The Allurion system comprises such an intragastric volume-occupying device system, as is further discussed below.

43. The components of the Allurion system include, but are not limited to, a capsule, a balloon, and a catheter.

44. Allurion describes the capsule, the balloon, and the catheter of the Allurion system: Exhibit D (Figure 1: Elipse™ Device and Figure 2: Elipse™ Balloon, INSTRUCTIONS FOR USE, Elipse™, Gastric Balloon System), as depicted below.

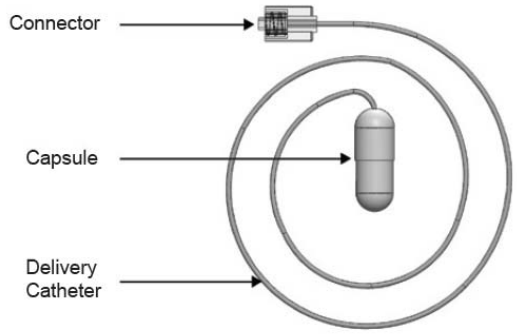

Figure 1: Elipse™ Device

Figure 2: Elipse™ Balloon

45. Claim 1 of the ’520 Patent recites “a) a capsule configured to be swallowable by normal peristalsis and to degrade in a gastric environment.” The Allurion system includes a capsule configured to be swallowable by normal peristalsis and to degrade in a gastric environment, as further discussed below.

46. As stated by Allurion or others using the Allurion system: “Previously known as the ‘Elipse Balloon’, the Allurion Balloon is a pill balloon capsule, which is swallowed under the guidance of our Healthcare Professionals without anaesthesia or endoscopy”) (Exhibit E (https://www.allurion.com/en/allurion-gastric-balloon)); “After ~16 weeks the pill balloon degrades and leaves the body naturally” (Id.); “The pill balloon is placed in your stomach in a quick 15 minute treatment[:] Swallow a small capsule which contains the deflated gastric balloon” (Id.); and “The Elipse Device is a gastric balloon (also known as an intragastric balloon or IGB) that is enclosed in a Capsule and is swallowed by the patient to introduce the Device into the stomach” and the “Capsule [is] composed of a vegetarian, non-animal derived, degradable material that encloses the Balloon.”) (Exhibit D (Figure 1 and Figure 2)).

47. Claim 1 of the ’520 Patent recites “b) a volume-occupying component compacted and contained within the capsule, the volume-occupying component comprising: i) a composite

wall defining an outer surface and an interior cavity with an inner surface, ii) a self-sealing valve system including a septum, and iii) a deflation component including an erodible portion, a moisture absorbing expandable portion and an inlet port in fluid communication with the interior cavity." The Allurion system includes such a volume-occupying component compacted and contained within the capsule, as further discussed below.

48. As stated by Allurion or others using the Allurion system: "The Elipse Device is a gastric balloon (also known as an intragastric balloon or IGB) that is enclosed in a Capsule" (Exhibit D (Figure 1)); "Once the Device position has been confirmed to be in the stomach, the Balloon can be filled with the provided Filler Kit"; and that "The Elipse Filler Kit (Figure 3) is comprised of the following items: … Filling Fluid, consisting of 560 ml of distilled water containing the food preservative potassium sorbate and citric acid" (Exhibit D (Figure 1 and Figure 2 (both depicted previously), and Figure 3 (depicted below))); "The Allurion Balloon is designed to hold 550ml in volume" (Exhibit F (https://www.allurion.com/en-us/allurion-balloon/how-it-works)).

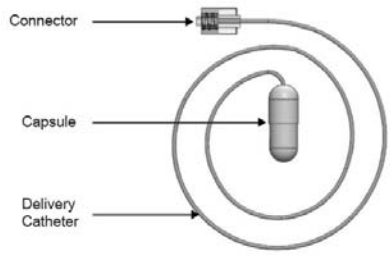

Figure 1: Elipse™ Device

Figure 2: Elipse™ Balloon

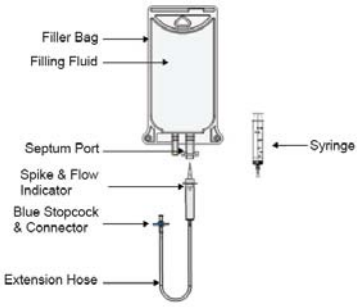

Figure 3: Elipse™ Filler Kit

49. With regard to the "i) a composite wall defining an outer surface and an interior cavity with an inner surface" recited in element b) of claim 1 of the '520 Patent, the Allurion

system includes such a composite wall defining an outer surface and an interior cavity with an inner surface, as further discussed below.

50. As stated by Allurion or others using the Allurion system: the Allurion "Balloon (Figure 2) [is] constructed from polymers forming a thin film" (Exhibit D (Figure 1, Figure 2 (depicted below), and Figure 3)); "The Balloon is thin, smooth and flexible which allows it to safely pass through the digestive system – meaning it does not require endoscopic removal" (Exhibit F); The Allurion system includes a "Release Valve" (Exhibit D (Figure 2)); "The single knot release valve degrades and opens at approximately 16 weeks" (Exhibit F). The Allurion system includes a "gastric balloon made from polyurethane" (Exhibit G ("Ultrasound-guided insertion of the Elipse® gastric balloon: technical details, learning curve, and perioperative outcome in 36 cases", Andrea Salmi et al., Journal of Ultrasound (2020) 23:593–597 https://doi.org/10.1007/s40477-020-00499-y)). The Allurion system includes a "Balloon Film … Made from thin film with a hole, closed shut by a degradable filament" (Exhibit H (Figure 2, "The Procedureless Elipse Gastric Balloon Program: Multicenter Experience in 1770 Consecutive Patients", R. Ienca et al., Obesity Surgery (2020) 30:3354–3362, https://doi.org/10.1007/s11695-020-04539-8 (11 April 2020)). The Allurion system includes an "Opening in the balloon closed by a degradable filament exposed only to the interior of balloon" (Exhibit H (Figure 3)); "During gastric residence, a resorbable material inside the balloon degrades. The resorbable material must completely degrade before a release valve opens and allows the balloon to empty spontaneously" (Exhibit I (Page 2, "Elipse™, a Procedureless Gastric Balloon for Weight Loss: a Proof-of-Concept Pilot Study", E. Machytka et al., Obesity Surgery, DOI: 10.1007/s11695-015-1783-7 Source: PubMed (August 2015)). A registered provider for the Allurion system states that: "The balloon is made from a material called polyurethane, which is 85% lighter than other silicone

gastric balloons … A special filament bounds the Allurion Balloon together, which is exposed only to the internal contents of the gastric balloon" (Exhibit J (https://allureweightloss.com/the-allurion-balloon/)).

Figure 2: Elipse™ Balloon

51. With regard to the "ii) a self-sealing valve system including a septum" recited in element b) of claim 1 of the '520 Patent, the Allurion system includes such a self-sealing valve system including a septum, as further discussed below.

52. As stated by Allurion or others using the Allurion system: "You will swallow a small capsule which contains the deflated Balloon. It is attached to a very thin tube that the doctor will use to inflate the Balloon with water once placed in your stomach. X-rays are used to ensure the Balloon is in the right position and filled correctly before the tube is gently removed" (Exhibit K (https://www.allurion.com/en/faqs/what-to-expect)). The Allurion system includes a "Fill Valve" and "The Catheter distal end will separate from Balloon Fill Valve" (Exhibit D (Figure 2 and Section "5. Elipse Balloon Detachment")); The Allurion system includes a "Fill Valve" (Exhibit H (Figure 2)) "attached to a thin catheter via a self-sealing valve" (Exhibit I (Page 2)) that "Seals shut after Delivery Catheter is pulled out" (Exhibit H (Figure 2)).

53. With regard to the "iii) a deflation component including an erodible portion, a moisture absorbing expandable portion and an inlet port in fluid communication with the interior cavity" recited in element b) of claim 1 of the '520 Patent, the Allurion system includes such a

deflation component including an erodible portion, a moisture absorbing expandable portion and an inlet port in fluid communication with the interior cavity, as further discussed below.

54. As stated by Allurion or others using the Allurion system: "The single knot release valve degrades and opens at approximately 16 weeks. The liquid empties and the empty balloon passes naturally" (Exhibit F). "At the end of the treatment period, the Device is designed to automatically open and drain. At this point, the empty Device is designed to transit the gastrointestinal tract and be excreted without further intervention" (Exhibit D (page 1)). The Allurion system includes the following functions and structures: "During gastric residence, a resorbable material inside the balloon degrades. The resorbable material must completely degrade before a release valve opens and allows the balloon to empty spontaneously. The deflated balloon is designed to pass through the gastrointestinal tract and be excreted" (Exhibit I (Page 2)). The Allurion system includes a "Release Valve[:] Made from thin film with a hole, closed shut by a degradable filament … Exposed only to the constant environment inside the device … Filament weakens over time, then breaks and opens the hole …" (Exhibit H (Figure 2)). The Allurion system includes an "Opening in the balloon closed by a degradable filament exposed only to the interior of the balloon … The degradable filament weakens over time and breaks at 4 months" (Exhibit H (Figure 3)). The Allurion system includes the following functions and structures: "After 4 months, a self-releasing valve opens and the fluid is gradually expelled into the stomach" (Exhibit L (Page 1, "A prospective pilot study of the efficacy and safety of Elipse intragastric balloon: A single-center, single-surgeon experience", Saud Al-Subaie et al., International Journal of Surgery 48) (2017) 16-22)).

55. Claim 1 of the '520 Patent recites "a catheter coupled to the valve system, the catheter comprising: i) a lumen in fluid communication with the interior cavity of the volume

occupying component, wherein the lumen is configured for filling the volume-occupying component interior cavity with an inflation fluid." The Allurion system includes a catheter coupled to the valve system, the catheter comprising: i) a lumen in fluid communication with the interior cavity of the volume-occupying component, wherein the lumen is configured for filling the volume-occupying component interior cavity with an inflation fluid, as further discussed below.

56. As stated by Allurion or others using the Allurion system: "The pill balloon is placed in your stomach in a quick 15 minute treatment[:] Swallow a small capsule which contains the deflated gastric balloon. It is attached to a very thin catheter that the doctor will use to inflate the Balloon with water once placed in your stomach" (Exhibit E); "You will swallow a small capsule which contains the deflated Balloon. It is attached to a very thin tube that the doctor will use to inflate the Balloon with water once placed in your stomach" (Exhibit K). "During swallowing, the Device Delivery Catheter remains outside of the patient's mouth to permit filling" (Exhibit D (Figure 1)). "The Allurion Balloon is designed to hold 550ml in volume" (Exhibit F). "Once the Device position has been confirmed to be in the stomach, the Balloon can be filled with the provided Filler Kit"; and "The Elipse Filler Kit (Figure 3) is comprised of the following items: … Filling Fluid, consisting of 560 ml of distilled water containing the food preservative potassium sorbate and citric acid" (Exhibit D (Figure 1, Figure 2, and Figure 3)). The Allurion system includes a "thin catheter (Fig. 1), through which the balloon is filled with 550 mL of liquid after it reaches the stomach" (Exhibit H (Page 2, Figure 1)).

57. The Allurion system thus meets each and every limitation of claim 1 of the '520 Patent, literally (including any literal equivalents, if applicable) or under the doctrine of equivalents.

58. Claim 18 of the ’520 Patent recites “The intragastric volume-occupying device system of claim 1, wherein the inflation fluid is a liquid inflation fluid selected from the group consisting of a saline solution and pure water.” The Allurion system comprises such an inflation fluid which is a liquid inflation fluid selected from the group consisting of a saline solution and pure water, as further discussed below.

59. As explained in the foregoing paragraphs, the Allurion system meets all the elements of Claim 1. The Allurion system also meets the additional limitation of dependent claim 18.

60. As Allurion explains: The Allurion system uses a “Filling Fluid, consisting of 560 ml of distilled water containing the food preservative potassium sorbate and citric acid” (Exhibit D (Figure 3)).

61. The Allurion system thus meets each and every limitation of claim 18 of the ’520 Patent, literally (including any literal equivalents, if applicable) or under the doctrine of equivalents. Allurion has thus infringed at least Claims 1 and 18 of the ’520 Patent under 35 U.S.C. § 271(a).

62. ReShape is further entitled to declaratory judgment that to the extent that Allurion is manufacturing and stockpiling the Allurion system in the United States for sales in the United States in anticipation of FDA approval, Allurion has infringed or will infringe the ’520 Patent under 35 U.S.C. § 271.

63. On information and belief, Allurion has known of the ’520 Patent at least as of its receipt of the notice letter sent by ReShape to Allurion on October 5, 2022 (“ReShape Notice Letter”).

64. On information and belief, Allurion knew of ReShape's patent rights before receiving the ReShape Notice Letter because Allurion cited the related '239 Patent in an IDS in 2017 and 2020, and the '239 Patent and the '520 Patent claim priority to the same patent application filed on January 21, 2011.

65. Through Allurion's knowledge of the '520 Patent and Allurion's infringing activities, Allurion has willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

66. As a direct and proximate result of Allurion's infringement of the '520 Patent, ReShape has been, is being, and will be irreparably and monetarily damaged. ReShape is entitled to an award of damages for Allurion's infringement of the '520 Patent, in an amount to be determined at trial, but in no event less than a reasonable royalty.

67. ReShape will be substantially and irreparably harmed by Allurion's infringing activities described above unless those activities are enjoined by this Court. ReShape has no adequate remedy at law.

JURY DEMAND

ReShape hereby demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully request that this Court grant the following relief:

a) Judgment that Defendant has infringed and will infringe the '520 Patent under 35 U.S.C. § 271(a);

b) An award of damages to Plaintiff for Defendant's infringement of the '520 Patent, in an amount to be determined at trial, but in no event less than a reasonable royalty pursuant to 35 U.S.C. § 284;

c) An award of treble damages to Plaintiff for Defendant's willful infringement of the '520 Patent pursuant to 35 U.S.C. § 284;

d) A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, expenses, and disbursements of this action to Plaintiff; and

e) An award of Plaintiffs' reasonable costs and expenses in this action;

f) An order enjoining and restraining Defendant and its officers, agents, employees, and those acting in privity with them, from further infringement of the '520 Patent; and

g) Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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