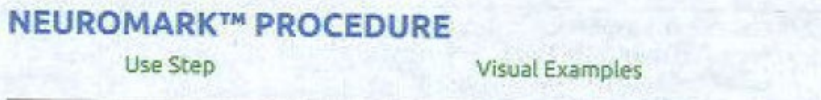
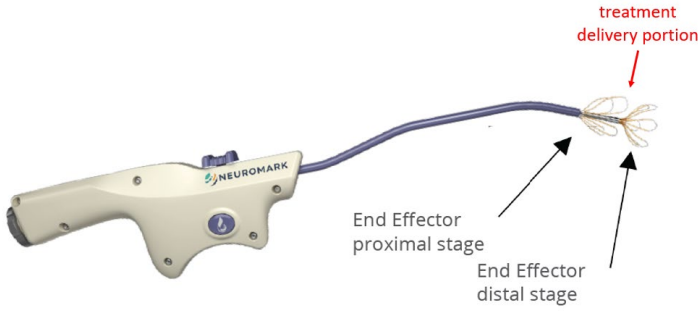


EXHIBIT U—U.S. Patent No. 9,415,194**I. Claim 1**

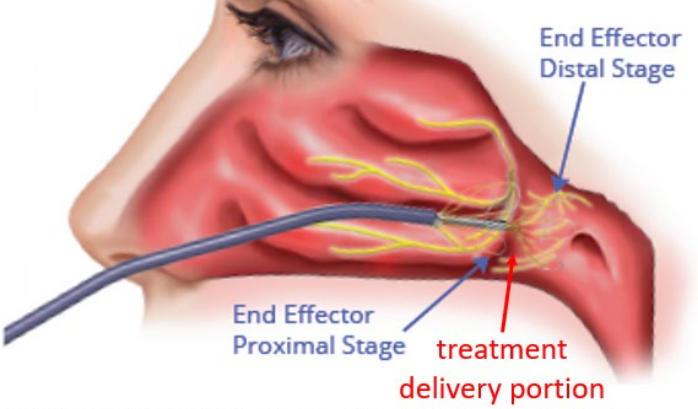
Claim 1 of the '194 Patent	Neuromark System and Method Using Neuromark System
[1.pre] A method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough, the method comprising:	Neurent's Neuromark system is used in a method for reducing mucus secretion in an upper airway of a patient to treat at least one of post nasal drip or chronic cough. Neurent instructs users to perform such a method. Neurent's Neuromark system is indicated for use in "patients with chronic rhinitis." Ex. H (Letter from FDA dated Oct. 22, 2021, regarding 510(k)) at 3. Neurent's marketing literature for the Neuromark system describes how chronic rhinitis can "create[] a near-constant runny, stuffy nose and/or post-nasal drip" and that "[p]ersistent post-nasal drip that leads to . . . coughing" are "[c]ommon [s]ymptoms" of chronic rhinitis. Ex. R (Neurent Brochure, NEUROMARK, Rhinitis Neurolysis Therapy, Posterior Nerves Matter) at 4. The Instructions for Use of the Neuromark system describes a "Neuromark procedure" that instructs users to perform several "[u]se [s]tep[s]." Ex. K (Instructions for Use, NEUROMARK® System) at 3-4.  Neurent's technical and marketing literature for the Neuromark system states that using the Neuromark system pursuant to the procedure "disrupts posterior nasal nerves, resulting in disruption of the neural signals, and so addresses the inflammatory process of the nasal mucosa" and "reduce[s] the symptoms of rhinitis." Ex. Q (NEUROMARK® System Mechanism of Action) at 3-4. It further states that using the Neuromark system pursuant to the procedure "may provide beneficial outcomes in patients with chronic rhinitis." Ex. Q at 4. Clinical studies funded by Neurent indicate that using the Neuromark system pursuant to the procedure led to "significant improvement" of "[r]hinorrhea, nasal congestion, nasal itching, sneezing,

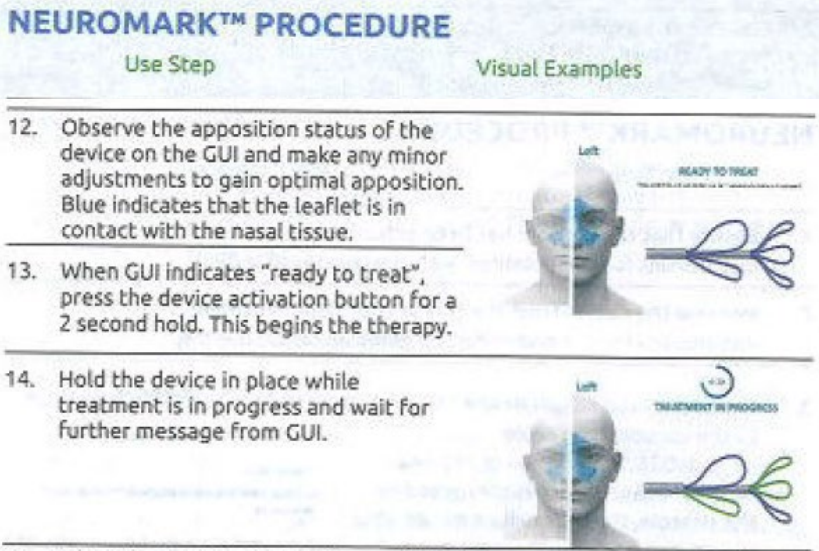
Claim 1 of the '194 Patent	Neuromark System and Method Using Neuromark System
	and postnasal drip” and that “[w]hile all symptoms improved, the greatest changes were seen in rhinorrhea, nasal congestion, and postnasal drip.” Ex. S (“Clinical evaluation of a novel multipoint radiofrequency ablation device to treat chronic rhinitis,” Douglas D. Reh, MD et al., <i>Laryngoscope Investigative Otolaryngology</i>, 8:367-372 (2023)) at 369. <i>See also</i> Ex. H at 8 (stating that clinical studies indicate an “improvement in symptoms” of chronic rhinitis using the Neurent Neuromark system).
[1.a] advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient;	Neurent’s Neuromark system is used in a method that includes advancing a treatment delivery portion of an energy-based treatment device into a nostril of the patient. Neurent instructs users to perform such a step. Neurent’s Neuromark system includes “a handheld bipolar radiofrequency device which is designed for use in [ENT] procedures.” Ex. H at 4. The Neuromark Device has a “treatment tip, which is referred to as the End Effector, [and which] consists of an array of bipolar micro electrodes,” which “deliver bipolar RF energy.” Ex. H at 4-5; <i>see also</i> Ex. K at 1 (“The treatment tip, which is referred to as the end effector, consists of an array of bipolar electrodes that deliver bipolar RF energy.”); Ex. Q at 3 (“The device is a hand-held, single-use, low-power, bipolar radiofrequency device with an electrode array (end effector) at the device tip.”).  Figure 2: NEUROMARK Device energy-based treatment device Ex. Q at 3 (red annotations added).

Claim 1 of the '194 Patent	Neuromark System and Method Using Neuromark System
	The Neuromark “Device [is] inserted via the nostrils.” Ex. H at 6. The Instructions for Use of the Neuromark system describes a “Neuromark procedure” that instructs users to perform several “[u]se [s]tep[s],” including “[i]nset[ing] the device into the selected nares under endoscopic guidance.” Ex. K at 3. Neurent’s technical and marketing literature for the Neuromark system shows that the end effector is advanced into a patient’s nostril. Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves. Ex. Q at 3 (red annotations added).

Claim 1 of the '194 Patent	Neuromark System and Method Using Neuromark System						
[1.b] contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue; and	Neurent's Neuromark system is used in a method that includes contacting mucosal tissue of the upper airway with the treatment delivery portion, without piercing the mucosal tissue. Neurent instructs users to perform such a step. Neurent's Neuromark system has a "target location" of "the nasal cavity in the area of the posterior nasal nerves." Ex. H at 6. Neurent's technical and marketing literature for the Neuromark system states the Neuromark Device is "advanced to the posterior recesses of the inferior/middle/superior meatus. The distal stage of the end effector is placed in the nasal choanae (posterior to the lateral attachment of the middle turbinate), while the proximal stage is placed in the middle meatus region." Ex. Q at 3. The Instructions for Use of the Neuromark system describes a "Neuromark procedure" that instructs users to perform several "[u]se [s]tep[s]," including "[a]dvanc[ing] the device to the posterior recesses of the inferior/middle/superior meatus under endoscopic guidance," "deploy[ing] the end effector fully," "[e]nsur[ing] that the proximal end of the end effector wraps around the middle turbinate anterior to the attachment of the turbinate to the lateral wall," and "[o]bserv[ing] the apposition status of the device on the GUI . . . to gain optimal apposition" (with blue "indicat[ing] that the leaflet is in contact with the nasal tissue"). Ex. K at 3-4. NEUROMARK™ PROCEDURE <table border="1"> <thead> <tr> <th>Use Step</th> <th>Visual Examples</th> </tr> </thead> <tbody> <tr> <td> 6. Advance the device to the posterior recesses of the inferior/middle/superior meatus under endoscopic guidance (OPTIONAL – If required, carefully manipulate the shaft configuration to reduce / exaggerate the shaft curvature to enhance delivery – see figure 3) </td> <td>  </td> </tr> <tr> <td> 9. Move the slider backwards to deploy the end effector fully CAUTION: Ensure that the slider is fully pulled back to allow for full deployment of the end effector </td> <td></td> </tr> </tbody> </table>	Use Step	Visual Examples	6. Advance the device to the posterior recesses of the inferior/middle/superior meatus under endoscopic guidance (OPTIONAL – If required, carefully manipulate the shaft configuration to reduce / exaggerate the shaft curvature to enhance delivery – see figure 3)		9. Move the slider backwards to deploy the end effector fully CAUTION: Ensure that the slider is fully pulled back to allow for full deployment of the end effector	
Use Step	Visual Examples						
6. Advance the device to the posterior recesses of the inferior/middle/superior meatus under endoscopic guidance (OPTIONAL – If required, carefully manipulate the shaft configuration to reduce / exaggerate the shaft curvature to enhance delivery – see figure 3)							
9. Move the slider backwards to deploy the end effector fully CAUTION: Ensure that the slider is fully pulled back to allow for full deployment of the end effector							

Claim 1 of the '194 Patent	Neuromark System and Method Using Neuromark System
	10. Make any necessary minor adjustments to ensure that the device is positioned in the correct anatomical position. Verify the correct position endoscopically. CAUTION: Ensure that the proximal end of the end effector wraps around the middle turbinate anterior to the attachment of the turbinate to the lateral wall. NOTE: The end effector consists of a distal and proximal stage. The leaflets are super elastic and spring out to enforce mucosal apposition on the lateral wall. The multi-stage elastic leaflet set-up accommodates the area of the posterior nasal nerves.  12. Observe the apposition status of the device on the GUI and make any minor adjustments to gain optimal apposition. Blue indicates that the leaflet is in contact with the nasal tissue.  The user of Neurent's Neuromark system then "initiates a bio-impedance check" "to assess[] and confirm contact between the end effector and the treatment area" before "appl[ying] RF energy to mucosal tissue." Ex. H at 5; <i>see also</i> Ex. I (Letter from FDA dated Oct. 26, 2022, regarding 510(k)) at 4 ("[T]he user initiates a bio-impedance check to assess and confirm contact between the End Effector and the treatment area. Once the System confirms contact has been achieved, a subsequent press of the activation button initiates the RF energy delivery cycle."); Ex. K at 1 ("[T]he user initiates a bio-impedance check to assess and confirm contact between the end effector and the treatment area."). The Graphical User Interface ("GUI") of the Neuromark console "indicates when the device is in contact with tissue." Ex. I at 5; <i>see also</i> Ex. K at 1 (the GUI "indicates when the device is in contact with tissue.")

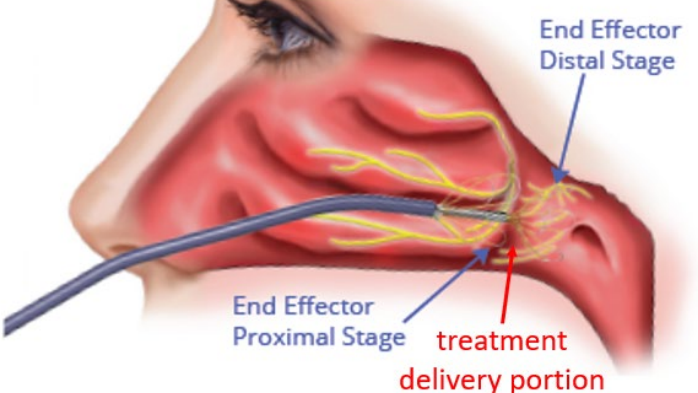
Claim 1 of the '194 Patent	Neuromark System and Method Using Neuromark System
	Neurent's technical and marketing literature for the Neuromark system shows the end effector contacting mucosal tissue of the upper airway without piercing the mucosal tissue.  Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves. Ex. Q at 3 (red annotations added). Neurent's literature also describes using the Neuromark system in a "minimally invasive" procedure. Ex. Q at 4. Neurent's literature does not describe piercing the mucosal tissue. And none of the "[u]se [s]tep[s]" described in the Instructions for Use include piercing the mucosal tissue. Ex. K at 3-4.
[1.c] delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or	Neurent's Neuromark system is used in a method that includes delivering a treatment from the treatment delivery portion to at least one tissue selected from the group of the mucosal tissue and another tissue underlying the mucosal tissue to modify a property of the at least one tissue and thus treat at least one of post nasal drip or chronic cough in the patient. Neurent instructs users to perform such a step. Neurent's Neuromark system "appl[ies] RF energy to mucosal tissue." Ex. H at 5; <i>see also</i> Neuromark 510(k) (2022) ("application of [RF] energy to create lesions in mucosal tissue"); Ex. L (NEURENT Medical, NEUROMARK Generator, Instructions for Use) at 2 (the Neuromark Generator "will deliver RF energy to soft mucosal tissue in [ENT] procedures").

Claim 1 of the '194 Patent	Neuromark System and Method Using Neuromark System
chronic cough in the patient.	The Instructions for Use of the Neuromark Generator state that “[t]he operator initiates RF energy delivery by pressing a button on the Neuromark device.” Ex. L at 3. Specifically, “[o]nce the system confirms contact has been achieved, a subsequent press of the button [by the user] initiates the RF delivery cycle.” Ex. H at 5; <i>see also</i> Ex. K at 1 (“Once the System confirms contact has been achieved, a subsequent press of the activation button initiates the RF energy delivery cycle.”) The Instructions for Use of the Neuromark system describes a “Neuromark procedure” that instructs users to perform several “[u]se [s]tep[s],” including “press[ing] the device activation button for a 2 second hold,” which “begins the therapy” and “hold[ing] the device in place while treatment is in progress.” Ex. K at 3-4.  The Instructions for Use of the Neuromark system also states that it “is intended for the application of [RF] energy to create lesions in the mucosal tissue in [ENT] procedures in patients with chronic rhinitis.” Ex. K at 1; <i>see also</i> Ex. H at 5 (describing the Neuromark system “for creation of [RF] lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.”); Ex. L at 2 (same).

Claim 1 of the '194 Patent	Neuromark System and Method Using Neuromark System
	Neurent's technical and marketing literature states that using its Neuromark system pursuant to the procedure "disrupts posterior nasal nerves, resulting in disruption of the neural signals, and so addresses the inflammatory process of the nasal mucosa." Ex. Q at 3. It further states that "[i]nterruption of the posterior nasal nerves has been shown to reduce the symptoms of rhinitis." Ex. Q at 4. Clinical studies funded by Neurent indicate that using the Neuromark system pursuant to the procedure led to "significant improvement" of "[r]hinorrhea, nasal congestion, nasal itching, sneezing, and postnasal drip" and that "[w]hile all symptoms improved, the greatest changes were seen in rhinorrhea, nasal congestion, and postnasal drip." Ex. S at 369. <i>See also</i> Ex. H at 8 (stating that clinical studies indicate an "improvement in symptoms" of chronic rhinitis using the Neurent Neuromark system).

II. Claim 2

Claim 2 of the '194 Patent	Neuromark System and Method Using Neuromark System
[2.pre] The method of claim 1,	<i>See</i> Claim 1.
[2.a] wherein the treatment is delivered without forming an incision in the mucosal tissue and without delivering an implant.	Neurent's Neuromark system is used in a method wherein the treatment is delivered without forming an incision in the mucosal tissue and without delivering an implant. Neurent instructs users to perform such a step. As discussed in [1.c], the Neuromark system delivers a treatment by applying radiofrequency energy. <i>See</i> [1.c]. Neurent's technical and marketing literature for the Neuromark system shows that the treatment is delivered without forming an incision in the mucosal tissue and without delivering an implant.

Claim 2 of the '194 Patent	Neuromark System and Method Using Neuromark System
	 Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves. Ex. Q at 3 (red annotations added). Neurent's literature describes using the Neuromark system in a "minimally invasive" procedure. Ex. Q at 4. Neurent's literature does not describe forming an incision in the mucosal tissue or delivering an implant. And none of the "[u]se [s]tep[s]" described in the Instructions for Use include forming an incision in the mucosal tissue or delivering an implant. Ex. K at 3-4.

III. Claim 3

Claim 3 of the '194 Patent	Neuromark System and Method Using Neuromark System
[3.pre] The method of claim 1,	See Claim 1.
[3.a] wherein delivering the treatment comprises delivering energy from the delivery treatment portion in a form selected from the	Neurent's Neuromark system is used in a method wherein delivering the treatment comprises delivering energy from the delivery treatment portion in a form selected from the group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy. Neurent instructs users to perform such a step.

Claim 3 of the '194 Patent	Neuromark System and Method Using Neuromark System
group consisting of ultrasound, microwave, heat, radiofrequency, electrical, light and laser energy.	As discussed in [1.c], the end effector (treatment delivery portion) of the Neuromark system delivers a treatment by applying radiofrequency energy. <i>See</i> [1.c].

IV. Claim 6

Claim 6 of the '194 Patent	Neuromark System and Method Using Neuromark System
[6.pre] The method of claim 3,	<i>See</i> Claims 1 and 3.
[6.a] wherein the at least one tissue comprises nerve tissue underlying the mucosal tissue, and wherein delivering the energy comprises ablating the nerve tissue.	Neurent's Neuromark system is used in a method wherein the at least one tissue comprises nerve tissue underlying the mucosal tissue, and wherein delivering the energy comprises ablating the nerve tissue. Neurent instructs users to perform such a step. As discussed in [1.c], Neurent's Neuromark system applies RF energy to mucosal tissue. <i>See</i> [1.c]; <i>see also</i> Ex. H at 5; Neuromark 510(k) (2022); Ex. L at 2. This "create[s] lesions in the mucosal tissue" and creates RF lesions that "disrupt posterior nasal nerves in patients." Ex. K at 1; Ex. H at 5; Ex. L at 2; <i>see also</i> Ex. Q at 3 (describing "disrupt[ing] posterior nasal nerves, resulting in disruption of the neural signals"). Neurent's technical and marketing literature for the Neuromark system describes the application of RF energy during the use of the Neuromark system as "creating multiple lesions (RF ablation sites)." Ex. Q at 2. It further explains that the Neuromark system "allow[s] RF ablation sites to be created in nerve-rich areas of the lateral wall." Ex. Q at 3.

V. Claim 12

Claim 12 of the '194 Patent	Neuromark System and Method Using Neuromark System
[12.pre] The method of claim 1,	<i>See</i> Claim 1.
[12.a] wherein delivering the treatment comprises injuring the at least one tissue.	Neurent's Neuromark system is used in a method wherein delivering the treatment comprises injuring the at least one tissue. Neurent instructs users to perform such a step. As discussed in [1.c], Neurent's Neuromark system applies RF energy to mucosal tissue, which "create[s] lesions in the mucosal tissue." <i>See</i> [1.c]; <i>see also</i> Ex. K at 1; <i>see also</i> Ex. H at 5 (describing "creation of [RF] lesions"); Ex. L at 2 (same). And as discussed in [6.a], Neurent's Neuromark system "create[es] multiple lesions (RF ablation sites)," including "in nerve-rich areas of the lateral wall." Ex. Q at 2-3.

VI. Claim 14

Claim 14 of the '194 Patent	Neuromark System and Method Using Neuromark System
[14.pre] The method of claim 12,	<i>See</i> Claims 1 and 12.
[14.a] wherein the at least one tissues is selected from the group consisting of cilia, goblet cells, nerves, submucosal tissue, muscle, ligaments, cartilage, tendon, and skin.	Neurent's Neuromark system is used in a method wherein the at least one tissues is selected from the group consisting of cilia, goblet cells, nerves, submucosal tissue, muscle, ligaments, cartilage, tendon, and skin. Neurent instructs users to perform such a step. As discussed in [1.c], Neurent's Neuromark system applies RF energy to mucosal tissue. <i>See</i> [1.c]; <i>see also</i> Ex. H at 5; Neuromark 510(k) (2022); Ex. L at 2. This "create[s] lesions in the mucosal tissue." The mucosal tissue includes at least goblet cells.

Claim 14 of the '194 Patent	Neuromark System and Method Using Neuromark System
	And as discussed in [6.a], Neurent's Neuromark system "create[es] . . . [RF] lesions to disrupt posterior nasal nerves." <i>See</i> [6.a]; Ex. H at 5; Ex. L at 2; <i>see also</i> Ex. Q at 3 (describing "disrupt[ing] posterior nasal nerves, resulting in disruption of the neural signals"). Neurent's technical and marketing literature describes how Neurent's Neuromark system "create[es] multiple lesions (RF ablation sites)," including "in nerve-rich areas of the lateral wall." Ex. Q at 2-3.

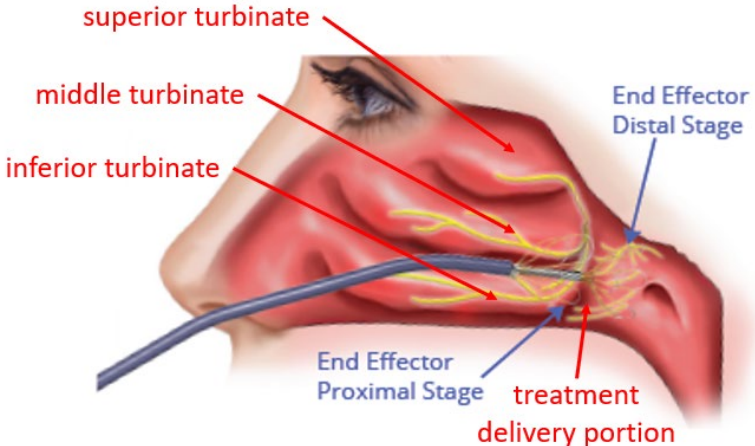
VII. Claim 16

Claim 16 of the '194 Patent	Neuromark System and Method Using Neuromark System
[16.pre] The method of claim 1,	<i>See</i> Claim 1.
[16.a] wherein delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue.	Neurent's Neuromark system is used in a method wherein delivering the treatment comprises modifying the at least one tissue in a manner that decreases a volumetric rate of mucus production of the mucosal tissue without changing a shape of the mucosal tissue. Neurent instructs users to perform such a step. As discussed in [1.c], Neurent's technical and marketing literature for the Neuromark system states that using its Neuromark system pursuant to the procedure "disrupts posterior nasal nerves, resulting in disruption of the neural signals, and so addresses the inflammatory process of the nasal mucosa." Ex. Q at 3. It further states that "[i]nterruption of the posterior nasal nerves has been shown to reduce the symptoms of rhinitis." Ex. Q at 4. Neuromark's literature shows that the treatment is delivered without changing the shape of the mucosal tissue.

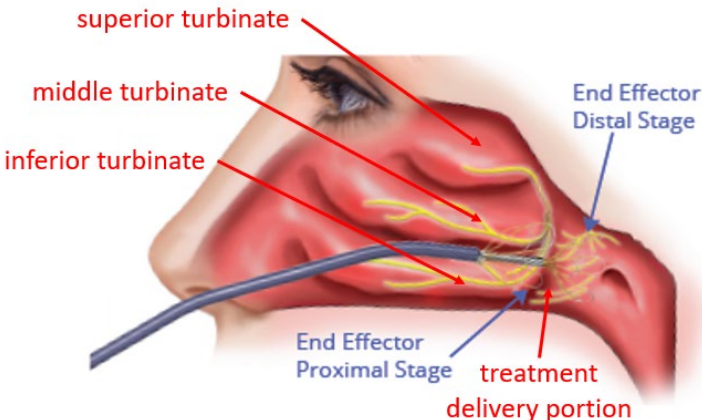
Claim 16 of the '194 Patent	Neuromark System and Method Using Neuromark System
	Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves. Ex. Q at 3 (red annotations added). Neuromark’s literature describes using the Neuromark system in a “minimally invasive” procedure. Ex. Q at 4. Neurent’s literature for the Neuromark system does not describe changing the shape of the mucosal tissue. And none of the “[u]se [s]tep[s]” described in the Instructions for Use include changing the shape of the mucosal tissue. Ex. K at 3-4.

VIII. Claim 18

Claim 18 of the '194 Patent	Neuromark System and Method Using Neurent’s Neuromark System
[18.pre] The method of claim 1,	<i>See</i> Claim 1.
[18.a] wherein delivering the treatment comprises delivering the treatment to at least one turbinate of the upper airway.	Neurent’s Neuromark system is used in a method wherein delivering the treatment comprises delivering the treatment to at least one turbinate of the upper airway. Neurent instructs users to perform such a step.

Claim 18 of the '194 Patent	Neuromark System and Method Using Neurent's Neuromark System
	As discussed in [1.b], Neurent's technical and marketing literature for the Neuromark system states that the Neuromark Device is "advanced to the posterior recesses of the inferior/middle/superior meatus. The distal stage of the end effector is placed in the nasal choanae (posterior to the lateral attachment of the middle turbinate), while the proximal stage is placed in the middle meatus region." Ex. Q at 3. <i>See</i> [1.b]. As also discussed in [1.b], the Instructions for Use of the Neuromark system describes a "Neuromark procedure" that instructs users to perform several "[u]se [s]tep[s]," including "[e]nsur[ing] that the proximal end of the end effector wraps around the middle turbinate anterior to the attachment of the turbinate to the lateral wall." Ex. K at 3. Neurent's literature for the Neuromark system shows that the treatment is delivered to at least the middle turbinate and inferior turbinate.  Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves. Ex. Q at 3 (red annotations added). And as discussed in [1.c], the operator of the Neuromark system delivers the treatment once the end effector is properly placed as described above. <i>See</i> [1.c].

IX. Claim 19

Claim 19 of the '194 Patent	Neuromark System and Method Using Neuromark System
[19.pre] The method of claim 18,	<i>See</i> Claims 1 and 18.
[19.a] wherein the at least one turbinate comprises an inferior turbinate, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate.	Neurent's Neuromark system is used in a method wherein the at least one turbinate comprises an inferior turbinate, and contacting the mucosal tissue comprises contacting a posterior aspect of the inferior turbinate. Neurent instructs users to perform such a step. As discussed in [1.b] and [18.a], Neurent's technical and marketing literature for the Neuromark system states the Neuromark Device is "advanced to the posterior recesses of the inferior/middle/superior meatus. The distal stage of the end effector is placed in the nasal choanae (posterior to the lateral attachment of the middle turbinate), while the proximal stage is placed in the middle meatus region." Ex. Q at 3. <i>See</i> [1.b]. Neurent's literature for the Neuromark system shows that at least the end effector distal stage contacts at least the posterior aspect of the inferior turbinate.  Figure 3: NEUROMARK Device with deployed end effector accommodating the area of the posterior nasal nerves. Ex. Q at 3 (red annotations added).