

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

INSPIRE MEDICAL SYSTEMS, INC.,

Plaintiff /
Counter-Defendant,

v.

NYXOAH, INC. and
NYXOAH SA,

Defendants /
Counter-Plaintiffs.

C.A. No. 25-cv-00667-RGA

JURY TRIAL DEMANDED

**DEFENDANTS NYXOAH, INC. AND NYXOAH, SA’S ANSWER, AFFIRMATIVE
DEFENSES AND COUNTERCLAIMS TO PLAINTIFF’S COMPLAINT FOR
PATENT INFRINGEMENT OR, IN THE ALTERNATIVE,
DECLARATORY JUDGMENT OF PATENT INFRINGEMENT**

Defendants Nyxoah, Inc. and Nyxoah, SA (collectively “Nyxoah” or “Defendants”) respond to the Complaint for Patent Infringement (“Complaint”) of Plaintiff, Inspire Medical Systems, Inc. (“Inspire” or “Plaintiff”). The following answer, affirmative defenses, and counterclaims are on behalf of Defendants. Pursuant to Fed. R. Civ. P. 8(b)(3), Defendants deny all allegations in Plaintiff’s Complaint except those specifically admitted below.

ANSWER

RESPONSE TO “INTRODUCTION”

1. Inspire brings this suit to prevent self-proclaimed “smart follower” Nyxoah from infringing at least three of Inspire’s U.S. patents protecting Inspire’s innovations in the field of neurostimulation therapy for obstructive sleep apnea (“OSA”). OSA is a severe, debilitating, and potentially life-threatening condition, affecting over one billion people worldwide.

RESPONSE: Nyxoah admits the allegations in the second sentence of paragraph 1. Nyxoah denies that it has infringed any patent rights belonging to Plaintiff. Nyxoah denies the remaining allegations of paragraph 1.

2. Unwilling to settle for the traditional standard of care for OSA patients-cumbersome and intrusive continuous positive airway pressure (“CPAP”) masks-Inspire set out to change the paradigm, adopting the motto: “If we put the patient first, we will never lose our way.” Since 2007, Inspire has devoted itself entirely to developing pioneering treatments for people struggling with OSA, and has been granted more than 60 U.S. patents for its innovations.

RESPONSE: Nyxoah denies that Inspire has developed “pioneering treatments” or innovations.” Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 2, and on that basis denies those allegations.

3. Inspire also brought to market the first FDA-approved OSA treatment of its kind. Through hard work and innovation, Inspire succeeded in developing a neurostimulation implant that could provide life-changing sleep for OSA patients without the need for a mask. Inspire received FDA approval in 2014 and, to date, Inspire’s groundbreaking device has been implanted in over 100,000 patients.

RESPONSE: Nyxoah admits upon information and belief that Inspire received FDA approval in 2014. Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 3, and on that basis denies those allegations.

4. Enter Nyxoah. Nyxoah saw an opportunity to piggyback on Inspire’s success with its follow-on “Genio” product, which also treats OSA through a neurostimulation implant. After selling Genio abroad for the past five years, Nyxoah is now preparing to launch Genio in the United States, following imminent FDA approval. But Genio infringes at least three Inspire U.S. patents.

RESPONSE: Nyxoah admits that it has developed a product called Genio for treatment of obstructive sleep apnea (“OSA”). Nyxoah further admits that it sells the Genio product outside the United States, and that it has recently received FDA approval for Genio and has launched Genio in the United States. Nyxoah denies that it has infringed or will infringe any patent rights belonging to Plaintiff. Nyxoah denies the remaining allegations in paragraph 4.

5. Nyxoah has plans to employ its infringing product to take U.S. market share from Inspire. Nyxoah has publicly stated its intent to target the very centers where Inspire is already being sold to capitalize on Inspire’s “heavy lifting.” Although Inspire welcomes fair competition, the law does not permit Nyxoah to use Inspire’s patented technology without authorization and improperly reap the benefits of Inspire’s investments and hard work.

RESPONSE: Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the allegation that “Inspire welcomes fair competition,” and on that basis denies that allegations. Nyxoah denies the remaining allegations in paragraph 5.

RESPONSE TO ALLEGATIONS REGARDING “NATURE OF THE ACTION”

6. This is an action seeking a judgment of patent infringement under the Patent Laws of the United States, Title 35, United States Code, or in the alternative, a declaratory judgment of patent infringement under the Declaratory Judgment Act and the Patent Laws of the United States, to enjoin and obtain damages resulting from Nyxoah’s current and/or imminent unauthorized manufacture, use, sale, and/or offer for sale in and/or importation into the United States of, or inducement of others to manufacture, use, sale, and/or offer for sale in and/or importation into the United States, products that infringe or will infringe at least one claim of each of the ’709 Patent, the ’526 Patent, and the ’424 Patent.

RESPONSE: Nyxoah admits that Plaintiff’s Complaint seeks a judgment of patent infringement under the Patent Laws of the United States, Title 35, United States Code, or in the

alternative, a declaratory judgment of patent infringement under the Declaratory Judgment Act and the Patent Laws of the United States. Nyxoah denies that it has infringed or will infringe any patent rights belonging to Plaintiff, and that Plaintiff is entitled to any of the relief it seeks. Nyxoah denies the remaining allegations in paragraph 6.

7. On information and belief, Nyxoah's current activity in the United States related to its Genio sleep apnea treatment product ("Genio") infringes (directly and/or by inducement) one or more claims of the Asserted Patents.

RESPONSE: Denied.

8. Furthermore, on information and belief, the Food and Drug Administration ("FDA") will imminently approve Nyxoah's application related to Genio. On information and belief, Nyxoah will commercialize Genio as soon as possible following such imminent FDA approval. As discussed below, upon Nyxoah's imminent commercialization thereof in the United States, Genio will infringe one or more claims of the Asserted Patents.

RESPONSE: Nyxoah admits that it has recently received FDA approval for Genio and has begun to commercialize Genio in the United States. Nyxoah denies that it has infringed or will infringe any patent rights belonging to Plaintiff. Nyxoah denies the remaining allegations in paragraph 8.

9. Inspire seeks monetary, declaratory, injunctive, and/or any other relief that this Court deems just and proper for Nyxoah's current and/or imminent infringement of the Asserted Patents.

RESPONSE: Nyxoah admits that Plaintiff's Complaint purports to seek monetary, declaratory, injunctive, and/or other relief from this Court. Nyxoah denies that it has infringed or

will infringe any patent rights belonging to Plaintiff, and that Plaintiff is entitled to any of the relief it seeks. Nyxoah denies the remaining allegations in paragraph 9.

RESPONSE TO ALLEGATIONS REGARDING “PARTIES”

10. Plaintiff Inspire is a company incorporated and existing under the laws of Delaware, with its corporate offices and principal place of business at 5500 Wayzata Blvd., Suite 1600, Golden Valley, Minnesota 55416.

RESPONSE: Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 10, and on that basis denies those allegations.

11. On information and belief, Defendant Nyxoah, Inc. is a company incorporated and existing under the laws of Delaware, with a registered agent at 251 Little Falls Drive, Wilmington, New Castle County, Delaware 19808. On information and belief, Defendant Nyxoah, Inc. has a main business address at 350 Springfield Ave, Suite 200, Summit, New Jersey 07901.

RESPONSE: Admitted.

12. On information and belief, Defendant Nyxoah SA is a Belgian company organized and existing under the laws of Belgium, with its principal place of business at Rue Edouard Belin 12 1435 Mont-Saint-Guibert, Belgium.

RESPONSE: Admitted.

RESPONSE TO ALLEGATIONS REGARDING “JURISDICTION AND VENUE”

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 2201 2202, 1331, and 1338(a) because this action arises under the laws of the United States, in particular the Patent Act of the United States, 35 U.S.C. §§ 100 et seq., and seeks relief under the Federal Declaratory Judgment Act.

RESPONSE: Nyxoah denies that this Court had subject matter jurisdiction over this action as of the date when Plaintiff filed its complaint.

14. This Court has personal jurisdiction over Nyxoah, Inc. because it is a company organized and existing under the laws of Delaware and thus resides in this District.

RESPONSE: Nyxoah, Inc. admits that it is subject to personal jurisdiction in this district.

15. In addition, this Court has personal jurisdiction over Nyxoah, Inc. because, on information and belief, Nyxoah will engage in a persistent course of conduct within Delaware by continuously and systematically placing goods, including products that infringe the Asserted Patents, into the stream of commerce for distribution throughout the United States, including in Delaware.

RESPONSE: Nyxoah, Inc. admits that it is subject to personal jurisdiction in this district. Nyxoah denies that it has infringed any patent rights belonging to Plaintiff. Nyxoah denies the remaining allegations in paragraph 15.

16. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) at least because Nyxoah, Inc. is incorporated in Delaware and therefore resides in this District. Venue is also proper in this Court under 28 U.S.C. § 1391(b)(3) because Nyxoah, Inc. is subject to personal jurisdiction in this District.

RESPONSE: Nyxoah, Inc. admits that venue is proper in this Court.

17. This Court has personal jurisdiction over Nyxoah SA under Fed. R. Civ. P. 4(k)(2).

RESPONSE: Nyxoah SA does not contest personal jurisdiction in this district for purposes of this action only.

18. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because Nyxoah SA is a foreign corporation. Venue is proper in this Court under 28 U.S.C. § 1391(b)(3) because Nyxoah SA is subject to personal jurisdiction in this District. Venue is also proper under

28 U.S.C. § 1391(c)(3) because Nyxoah SA is not a resident of the United States and therefore may be sued in any judicial district.

RESPONSE: Nyxoah SA does not contest venue in this district for purposes of this action only.

19. For at least the above reasons, it would not be unfair or unreasonable for Nyxoah to litigate this action in this District, and there is personal jurisdiction over Nyxoah for purposes of this action.

RESPONSE: Nyxoah, Inc. admits that it is subject to personal jurisdiction in this district. Nyxoah SA does not contest personal jurisdiction in this district for purposes of this action only. Otherwise denied.

RESPONSE TO ALLEGATIONS REGARDING “BACKGROUND”

RESPONSE TO ALLEGATIONS REGARDING “INSPIRE’S SLEEP APNEA TREATMENT INNOVATIONS”

20. OSA is a condition characterized by excessive relaxation of throat muscles, soft tissue, and the tongue during sleep. This relaxation causes a partial or complete closure of the upper airway, obstructing air flow during sleep. As a result, breathing pauses, or “apneas,” occur repeatedly throughout the night. These interruptions can last from a few seconds to over a minute, reducing oxygen levels in the blood and often causing the person to wake up intermittently throughout the night. Repeated sleep interruptions due to apneas cause sleep quality to decline, which in turn leads to harmful symptoms. For example, people may experience daytime sleepiness, mood irregularity, and cognitive impairments. OSA is also associated with elevated risks of cardiovascular issues, such as hypertension and heart disease, due to the strain on the heart from repeated drops in blood oxygen levels.

RESPONSE: Admitted.

21. Traditional OSA treatments typically involve CPAP therapy, which delivers steady stream of air through a mask worn over the nose or mouth during sleep. However, the combination of the CPAP machine and accompanying mask can be cumbersome, noisy, and uncomfortable, which can reduce effectiveness by hindering sleep quality and can lead to poor patient compliance.

RESPONSE: Admitted.

22. Plaintiff Inspire, based in Minneapolis, Minnesota, is a medical device company that pioneered minimally invasive solutions for patients with OSA. Leveraging a deep understanding of the complexities of OSA, Inspire concentrates on creating patient-focused solutions for OSA. Inspire is, and always has been, focused on treating OSA through electrical stimulation of upper airway nerves. Instead of using airway pressure, neurostimulation opens a user's airway by stimulating nerves to activate key airway muscles that cause the tongue to protrude forward.

RESPONSE: Nyxoah admits that neurostimulation may be used to stimulate nerves to activate airway muscles that cause the tongue to protrude forward. Nyxoah denies that Inspire "pioneered minimally invasive solutions for patients with OSA." Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 22, and on that basis denies those allegations.

23. Inspire Chief Executive Officer Tim Herbert began work on what is now Inspire while working at Medtronic. Following nearly two decades of development work, in 2007 Mr. Herbert spun out the Inspire technology and related intellectual property portfolio from Medtronic and started Inspire in his basement. Since then, Inspire has developed into one of the world's leading medical device companies focused on treating OSA.

RESPONSE: Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 23, and on that basis denies those allegations.

24. Since 2007, Inspire has spent hundreds of millions of dollars on research and development. As a result, Inspire has greatly advanced the field of neurostimulation OSA therapy.

RESPONSE: Nyxoah denies that “Inspire has greatly advanced the field of neurostimulation OSA therapy.” Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 24, and on that basis denies those allegations.

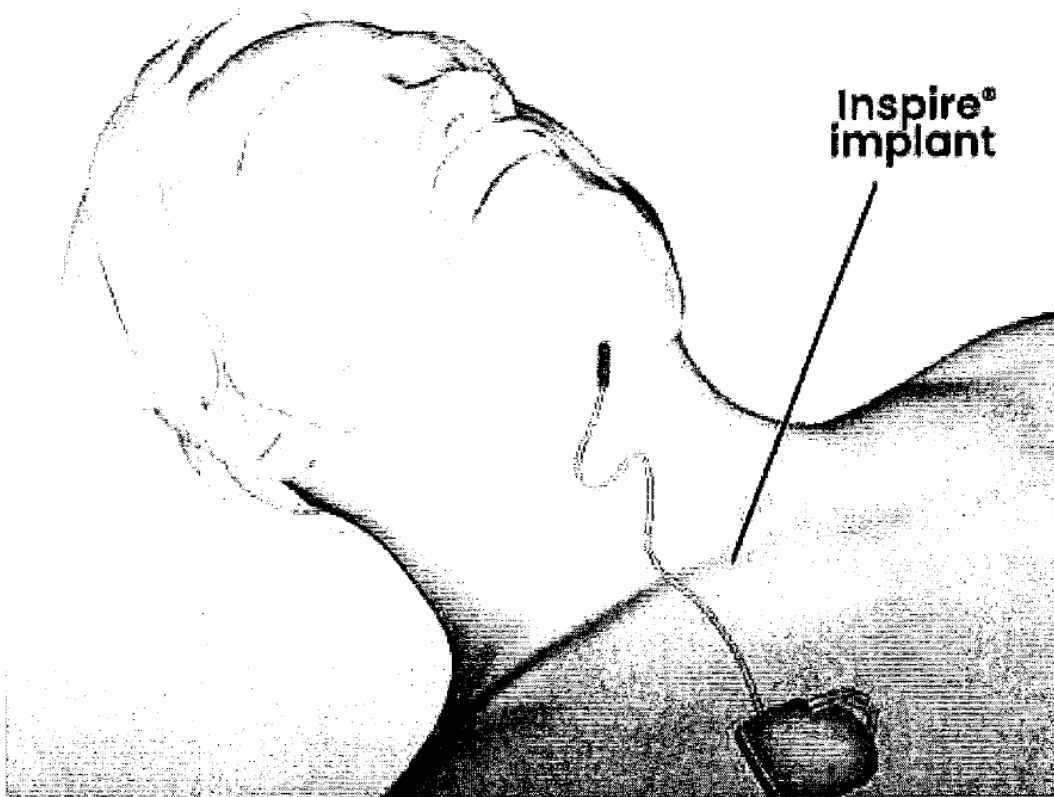
25. Inspire has been diligent about protecting the innovations it has worked so hard to develop. Inspire has been granted over 60 U.S. patents on its neurostimulation technologies, including the three Asserted Patents.

RESPONSE: Nyxoah denies that Inspire has developed “innovations.” Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 25, and on that basis denies those allegations.

26. Among the innovations developed and patented by Inspire are devices that treat OSA asynchronously (independent of the user’s breathing) and devices that treat OSA synchronously (coordinated with the user’s breathing).

RESPONSE: Denied.

27. Inspire transformed the OSA treatment market with its “Inspire” product, the first FDA-approved OSA treatment of its kind-using neurostimulation synchronized with a patient’s breathing to provide life-changing sleep for OSA patients without the need for a mask.



RESPONSE: Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 27, and on that basis denies those allegations.

28. The Inspire system includes a breathing sensor, a stimulation cuff electrode, a generator, a patient remote, and a proprietary algorithm. These components work together to monitor and adapt to the patient's natural breathing rhythm during application of therapy (*i.e.*, at night while sleeping). Patients use the remote control to activate the device before sleep and deactivate it upon waking. All components except the remote are implanted in the body: an electrode in the upper neck area for stimulating the hypoglossal nerve; the breathing sensor and generator adjacent to the ribcage; and electrical leads connecting all the components. To control the therapy timing and parameters, the patient uses the remote control to communicate wirelessly with the implanted generator. This stimulation prevents the tongue from relaxing and obstructing

the airway during sleep. *See, e.g.,* “What is Inspire Therapy,” YouTube, available at <https://www.youtube.com/watch?v=J-VUnReBF7g&t=18s>.

RESPONSE: Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 28, and on that basis denies those allegations.

29. Inspire began clinical trials of its device in 2010, involving testing and observation of 126 patients. After seeing resoundingly positive results, Inspire applied for FDA approval in 2013. In 2014, the FDA approved Inspire’s implant, making it the first FDA-approved OSA neurostimulation therapy of its kind. Inspire’s implant has been on sale in the U.S. ever since. In 2018, Inspire made an initial public offering, noting success across nearly a dozen clinical studies that evaluated approximately 775 patients, including more than 280 patients evaluated in independent clinical studies. At the time, the results of such studies had been highlighted in more than 40 peer-reviewed publications.

RESPONSE: Nyxoah admits upon information and belief that Inspire received FDA approval in 2014. Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 29, and on that basis denies those allegations.

30. To date, Inspire therapy has been implanted in over 100,000 patients.

RESPONSE: Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 30, and on that basis denies those allegations.

**RESPONSE TO ALLEGATIONS REGARDING “NYXOAH’S FOLLOW-ON
GENIO SLEEP APNEA TREATMENT PRODUCT”**

31. Nyxoah is a medical device company based in Belgium.

RESPONSE: Nyxoah admits that Nyxoah SA is a medical device company based in Belgium. Otherwise denied.

32. In July 2020, six years after Inspire introduced its revolutionary device, Nyxoah began selling its “Genio” device in Europe. Genio practices Inspire’s U.S. patented inventions, as illustrated in the attached infringement claim charts.

RESPONSE: Nyxoah admits that it began generating revenue from the sale of its Genio product in Europe in July 2020. Nyxoah denies that it has infringed any patent rights belonging to Plaintiff. Nyxoah denies the remaining allegations in paragraph 32, and denies the allegations made in the claim charts attached to the Complaint as Exhibits 4, 5 and 6.

33. Genio is an OSA treatment device that uses asynchronous hypoglossal neurostimulation. *See, e.g.*, Nyxoah 2024 Annual Report, at 16-17. A cross-sectional view of a patient with Genio deployed within the patient is shown below.



“Genio - How it works,” YouTube Video, at 1:02, available at <https://www.youtube.com/watch?v=I0Jh9emwOsA>.

RESPONSE: Nyxoah admits that the cited Annual Report and YouTube video speak for themselves.

34. Genio includes an implantable stimulator and an activation chip. The activation chip attaches to the chin of a wearer via an adhesive patch and supplies power and control signals to the implantable stimulator, which electrically stimulates the hypoglossal nerve.

1.4.2 Components of the Genio system

Implantable stimulator

The implantable stimulator consists of a saddle-like antenna with two legs, each containing two metal pads, called paddle electrodes. The paddle electrodes are placed in contact with both branches of the hypoglossal nerve and deliver bilateral stimulation to the hypoglossal nerve. Pulses from the stimulator trigger a slight forward movement of the posterior portion of the tongue in order to maintain an open airway throughout the night. The implantable stimulator is FDA and CE labeled as MR conditional for 1.5T and 3T full body MRI scans.

Activation chip

The activation chip is a detachable, external power source for the implantable stimulator and is composed of a chipset, which provides the patient's personalized therapy program, and a rechargeable battery. The chipset is programmable, which allows us to make future updates and upgrades, or to provide additional services to the Genio system without having to replace the implantable stimulator during an additional surgery. We advise that patients charge the activation chip with the charging unit after use.

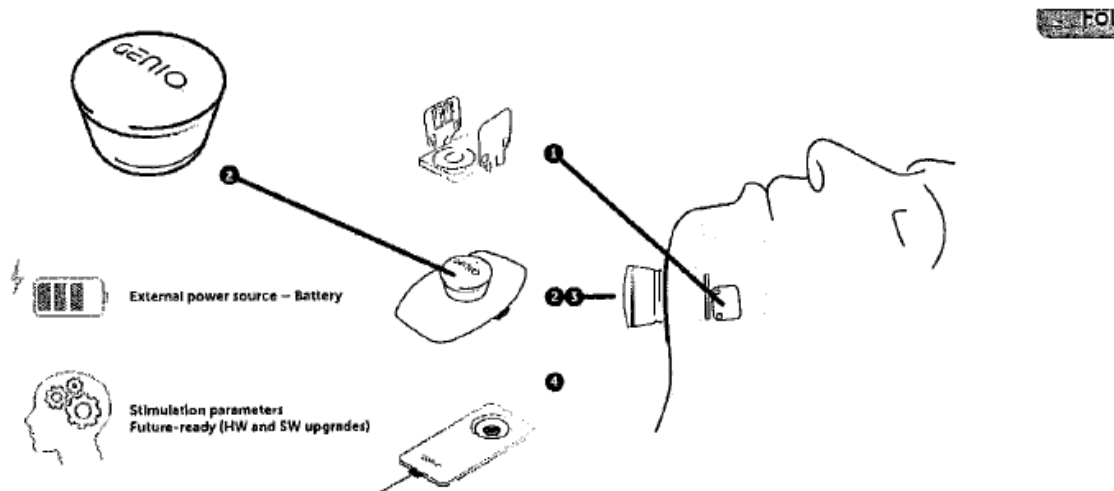


Figure 3. Figure 3. Schematic of Genio system. (1) Implantable stimulator (IS); (2) Activation chip (AC); (3) Disposable patch (DP); (4) Charging unit (CU)

Nyxoah 2024 Annual Report at 22 (annotated); DREAM Poster (June 2023), available at <https://investors.nyxoah.com/sites/default/files/2023-06/DREAM%20Poster%20-%20June%202023.pdf>; see also “Genio - How it works,” YouTube Video, at 1:02, available at <https://www.youtube.com/watch?v=IOJh9emwOsA>.

RESPONSE: Nyxoah admits that the cited Annual Report, DREAM Poster and YouTube video speak for themselves.

35. Genio uses an asynchronous stimulation protocol. Rather than stimulating based on actively-sensed breathing, Genio delivers stimulation at a predetermined programmed rate, without sensing the user's actual breathing activity.

RESPONSE: Admitted.

RESPONSE TO ALLEGATIONS REGARDING “NYXOAH’S GENIO SLEEP APNEA PRODUCT AND DOMESTIC COMMERCIALIZATION THEREOF”

36. Observing the success of Inspire, Nyxoah intends to enter the U.S. OSA treatment market – which Nyxoah identified as its “largest market opportunity.” Nyxoah’s business strategy consists of piggybacking on the hard work and innovations of Inspire in order to sell a follow-on product. “Nyxoah S.A. (NASDAQ: NYXH) Q1 2025 Earnings Call Transcript,” Insider Monkey, https://www.insidermonkey.com/blog/nyxoah-s-a-nasdaqnyxh-q1-2025-earnings-call-transcript-1534289/?utm_medium=referral&utm_source=msn-news.

RESPONSE: Nyxoah admits that the cited article speaks for itself. Nyxoah denies the remainder of the allegations in paragraph 36.

37. Indeed, in its May 2025 earnings call, Nyxoah identified itself as a “*smart follower*” of Inspire. *Id.* In Nyxoah’s words: “*It’s always nice to be second, meaning that there was a lot of heavy lifting done by competition.*” *Id.*¹

RESPONSE: Nyxoah admits that the cited article speaks for itself, without the emphasis added by Plaintiff. Nyxoah denies the remainder of the allegations in paragraph 36.

¹ Unless otherwise stated, any emphasis within a quote is added.

38. On that same earnings call, Nyxoah laid out its plan to “target high-volume hypoglossal nerve stimulation implanting centers where patients and physicians are actively seeking an alternative solution to current therapy [*i.e.*, using Inspire].” *Id.* Nyxoah further explained how it had “been planning very carefully and studying the U.S. market. It starts with heat maps that they are called like where are the high-volume sites [*i.e.*, the sites purchasing high volumes of Inspire].” *Id.*

RESPONSE: Nyxoah admits that the cited article speaks for itself. Nyxoah denies the remainder of the allegations in paragraph 36.

39. Nyxoah began its pursuit of the U.S. market in 2022 with its “DREAM Study,” a clinical trial conducted “to support the marketing authorization of the Genio hypoglossal nerve stimulation system (HGNS) in the United States.” “Nyxoah Announces DREAM U.S. Pivotal Study Meets Primary Endpoints,” Nyxoah, available at <https://nyxoah.gcs-web.com/news-releases/news-release-details/nyxoah-announces-dream-us-pivotal-study-meets-primary-endpoints>. Nyxoah’s CEO, in the public announcement of DREAM, stated the results would “pave the way for Genio to shift the OSA treatment paradigm in the U.S.” *Id.* In March 2024, Nyxoah formally announced results of DREAM. *Id.*

RESPONSE: Nyxoah admits that the DREAM Study began in 2021, and that the successful results of the study were released in March 2024. Nyxoah admits that the cited press release speaks for itself. Nyxoah denies the remainder of the allegations in paragraph 36.

40. In March 2023, Nyxoah filed for FDA approval for the marketing and sale of Genio in the U.S. by initiating the first of multiple modules for premarket approval (PMA) of Genio. Nyxoah Form 20-F at 8, filed March 20, 2025, available at <https://www.sec.gov/Archives/edgar/data/1857190/000141057825000398/nyxh->

[20241231x20f.htm](#). Nyxoah submitted the final module in June 2024. *Id.*; *see also* Nyxoah 2024 Annual Report, at 19-20.

RESPONSE: Nyxoah admits that it filed for FDA approval in or around 2023. Nyxoah further admits that it submitted the first module to the FDA in March 2023, and it submitted the final module to the FDA in June 2024.

41. In an August 2024 press release, Nyxoah represented that its “U.S. market launch of Genio® [was] planned for the beginning of 2025.” “Nyxoah Rings the Closing Bell at Nasdaq while Preparing for U.S. Market Launch of Innovative Sleep Apnea Device,” available at <https://nyxoah.gcs-web.com/news-releases/news-release-details/nyxoah-rings-closing-bell-nasdaq-while-preparing-us-market>.

RESPONSE: Nyxoah admits that the cited article speaks for itself.

42. Likewise, on March 19, 2025, Nyxoah stated that its “expect[s] to obtain marketing authorization in the United States and be commercially available in the United States in the first quarter of 2025.” Nyxoah 2024 Annual Report, at 16.

RESPONSE: Nyxoah admits that the cited document speaks for itself.

43. On March 26, 2025, Nyxoah announced that it received an approvable letter from the FDA.

RESPONSE: Admitted.

44. In an April 8, 2025 announcement, Nyxoah stated that the FDA’s approvable letter “means that Nyxoah’s application for marketing the device in the United States substantially meets the requirements” of FDA’s PMA requirement and “the FDA will approve the application subject to satisfactory completion of the manufacturing facilities, methods and controls review.” “Nyxoah Provides Update on FDA Approvable Letter for Genio System,” Nyxoah Press Release, available

at <https://nyxoah.gcs-web.com/news-releases/news-release-details/nyxoah-provides-update-fda-approvable-letter-genio-system>.

RESPONSE: Nyxoah admits that the cited article speaks for itself.

45. In the same announcement, Nyxoah stated that it is “confident that it will be able to successfully complete this validation in the near term” and it “anticipates that its application could potentially be approved in the second quarter” of 2025. *Id.*

RESPONSE: Nyxoah admits that the cited article speaks for itself.

46. In its May 14, 2025 earnings call, Nyxoah stated that it has “successfully completed the final process validation requested by the FDA.” “Nyxoah Reports First Quarter Financial and Operating Results,” Nyxoah, available at <https://nyxoah.gcs-web.com/node/7706/pdf>. Nyxoah also represented that “the last step toward FDA approval is an on-site inspection at the U.S. manufacturing site which [Nyxoah] expect[s] to be completed shortly.” *Id.*

RESPONSE: Nyxoah admits that the cited article speaks for itself.

47. Given Nyxoah’s confidence in the U.S. manufacturing site, Nyxoah’s CEO stated in a May 14, 2025 press release accompanying the earnings call that the company “continue[s] to anticipate that [its] application could potentially be approved in the second quarter of 2025.” *Id.*

RESPONSE: Nyxoah admits that the cited article speaks for itself. Nyxoah denies the remaining allegations in paragraph 47.

48. Nyxoah has undertaken significant, concrete, and meaningful preparations to commercialize Genio in the United States upon FDA approval.

RESPONSE: Admitted.

49. On April 8, 2025, Nyxoah’s CEO stated that Nyxoah “look[s] forward to launching Genio in the U.S. *upon receipt of FDA approval.*” *Id.*

RESPONSE: Nyxoah admits that it issued an announcement on April 8, 2025 containing the quotation set forth in paragraph 49, without the modification and emphasis added by Plaintiff. Otherwise denied.

50. In its 2024 Annual Report released in March 2025, Nyxoah announced that it “*expect[s]* to hire approximately 50 people in [its] commercial organization in the United States” in anticipation of FDA approval. Nyxoah 2024 Annual Report, at 21. Nyxoah, upon “obtain[ing] regulatory authorization to market the Genio system in the United States, [] *intend[s]* to build a direct sales force ... [for] marketing and selling the Genio system in the United States.” Nyxoah SEC Form 20-F at 15, filed March 20, 2025. In the same filing, Nyxoah claimed it “*expect[s]* that approximately half [of the U.S. team] will be sales representatives or territory managers and supported by clinical education specialists, pre-authorization and reimbursement support personnel, marketing resources and leadership.” *Id.* at 63.

RESPONSE: Nyxoah admits that the referenced documents speak for themselves, without the modifications and emphasis added by Plaintiff.

51. Nyxoah’s U.S. Genio sales team is already being formed, if not already formed.

RESPONSE: Admitted.

52. Nyxoah’s CEO, Olivier Taelman, relocated from Nyxoah’s European headquarters to the United States specifically “*to oversee the launch of the Genio product in the U.S.*” See Nyxoah 2024 Annual Report, at 57. On information and belief, Mr. Taelman relocated to Nyxoah’s New Jersey office. Olivier Taelman, LinkedIn Profile, <https://www.linkedin.com/in/olivier-taelman-964a5578/> (displaying, as of May 29, 2025, Mr. Taelman’s location as “Summit, New Jersey, United States”).

RESPONSE: Nyxoah admits that the referenced documents speak for themselves, without the emphasis added by Plaintiff. Otherwise denied.

53. In July 2024, Nyxoah hired Scott Holstine as Chief Commercial Officer. “Nyxoah Appoints Scott Holstine as Chief Commercial Officer,” Nyxoah, available at <https://nyxoah.gcs-web.com/news-releases/news-release-details/nyxoah-appoints-scott-holstine-chief-commercial-officer>. Nyxoah brought Mr. Holstine - who allegedly has “over 26 years of experience in the medical device industry with a proven track record in U.S. product launches” - in to help “lead the commercial operations of Nyxoah enabling a successful U.S. launch.” *Id.*

RESPONSE: Nyxoah admits that the referenced document speaks for itself.

54. As of February 2024, Nyxoah posted a position for a “Therapy Access Manager (Medical Device Healthcare Reimbursement)” in the United States. Job Posting: Therapy Access Manager (Medical Device Healthcare Reimbursement), LinkedIn, available at <https://www.linkedin.com/jobs/view/therapy-access-manager-medical-device-healthcare-reimbursement-at-nyxoah-4138233762/> (noting Nyxoah is “no longer accepting applications”). This role’s responsibilities would include working with a “Genio Patient Access Program (GPAP)” and “collaborat[ing] with Sales to identify customers needing reimbursement education for Genio.” *Id.*

RESPONSE: Nyxoah admits that the referenced document speaks for itself.

55. Similarly, as of March 2025, Nyxoah posted a position for a “Training & Education Manager (Sleep Implant)” in the United States. Job Posting: Training & Education Manager (Sleep Implant), LinkedIn, available at <https://www.linkedin.com/jobs/view/training-education-manager-sleep-implant-at-nyxoah-4157894162/> (noting Nyxoah is “no longer accepting applications”). According to Nyxoah, this employee’s responsibilities would include “train[ing]

and certify[ing] Genio® implanters, proctors, and field experts, while supporting implantation and titration activities.” *Id.*

RESPONSE: Nyxoah admits that the referenced document speaks for itself.

56. In February 2025, Nyxoah hired Amy Sullivan as Regional Business Director. Amy Sullivan, LinkedIn Profile, available at <https://www.linkedin.com/in/amy-sullivan-b1b3161/>. That same month, Nyxoah also hired John Patrick Lynch as “Supply Chain Expert with focus on Sales & Operations Planning,” whose job description includes “support in launch of new products.” John Patrick Lynch, LinkedIn Profile, available at <https://www.linkedin.com/in/john-patrick-lynch/>.

RESPONSE: Nyxoah admits that the referenced documents speak for themselves.

57. In a March 13, 2025 press release summarizing Nyxoah’s work in 2024, Nyxoah noted it had “[a]ssembled [a] U.S. executive leadership team with deep industry experience” and had a “[f]ull U.S. commercial organization, including sales, marketing, and market access teams, *in place.*” “Nyxoah Reports Fourth Quarter and Financial Year 2024 Financial and Operating Results,” Nyxoah, available at <https://nyxoah.gcs-web.com/news-releases/news-release-details/nyxoah-reports-fourth-quarter-and-financial-year-2024-financial>.

RESPONSE: Nyxoah admits that the referenced article speaks for itself, without the modifications and emphasis added by Plaintiff.

58. In its May 2025 earnings call, Nyxoah announced it is “*ready* to launch in the U.S. with 50 commercial team members *who are all hired and trained* ... compris[ing] [] sales, marketing, market access professionals.” “Nyxoah S.A. (NASDAQ: NYXH) Q1 2025 Earnings Call Transcript,” Insider Monkey, available at https://www.insidermonkey.com/blog/nyxoah-s-a-nasdaqnyxh-q1-2025-earnings-call-transcript-1534289/?utm_medium=referral&utm_source=msn-news. Nyxoah additionally stated that, “[i]n preparation of our U.S. commercial launch, *we have*

built a world-class team in support of our U.S. go-to-market strategy. In addition, we have put in place industry-leading talents with a track record in neuromodulation and/or Obstructive Sleep Apnea, or OSA, across our sales, marketing, reimbursement and medical affairs teams in the U.S.” *Id.*

RESPONSE: Nyxoah admits that the referenced article speaks for itself, without the emphasis added by Plaintiff.

59. Nyxoah is also prepared on the manufacturing front, as Nyxoah already has sites in the United States ready to manufacture and/or currently manufacturing Genio.

RESPONSE: Nyxoah admits that it has one such site. Otherwise denied.

60. In its May 2025 earning call, Nyxoah explained that it has made “investments in the U.S. commercial organization in preparation for FDA approval and subsequent commercial launch.” *Id.*

RESPONSE: Nyxoah admits that the referenced article speaks for itself.

61. On information and belief, Nyxoah is currently commercially manufacturing, using, and/or importing Genio devices in the U.S. in anticipation of its U.S. commercial launch, unrelated to its FDA submissions. At least some of such importations include importations of Genio and/or components thereof after completion of Nyxoah’s DREAM Study (March 2024).

RESPONSE: Denied.

62. As reported in the FDA’s Import Entry Database (as of May 30, 2025), Nyxoah imported Genio and/or components thereof into the United States on at least 35 occasions from August 6, 2020 to May 8, 2025. U.S. Food & Drug Administration Imports Entry Data Search.² In

² To view Nyxoah’s importation record, a search using Product Code “73MNQ” and Manufacturer Legal Name “Nyxoah” at <https://datadashboard.fda.gov/oii/cd/impentry-table.htm>

particular, Nyxoah imported Genio at least 13 times in 2025 alone, the most recent being May 8, 2025:

Record View	Shipment ID	Arrival Date	Submission Date	Port of Entry Division	Country of Origin	Product Code	Product Code Description	Manufacturer FEI Number	Manufacturer Legal Name
View	SCS-0708465-5/12/1	05/08/2025	05/09/2025	Division of Northeast Imports	Belgium	73MNO	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA	3037207042	NYXOAH SA VDO SITE
View	SCS-0723482-1/12/1	05/08/2025	05/09/2025	Division of Southeast Imports	Belgium	73MNO	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA	3037207042	NYXOAH SA VDO SITE
View	SCS-0707366-8/12/1	05/08/2025	05/09/2025	Division of Southeast Imports	Belgium	73MNO	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA	3037207042	NYXOAH SA VDO SITE
View	SCS-0680544-0/12/1	05/08/2025	05/13/2025	Division of Southeast Imports	Belgium	73MNO	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA	3037207042	NYXOAH SA VDO SITE
View	SCS-0116422-2/12/1	04/05/2025	04/09/2025	Division of Southeast Imports	Belgium	73MNO	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA	3037207042	NYXOAH SA VDO SITE
View	SCS-0115984-1/12/1	04/05/2025	04/09/2025	Division of Southeast Imports	Belgium	73MNO	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA	3037207042	NYXOAH SA VDO SITE

Id.

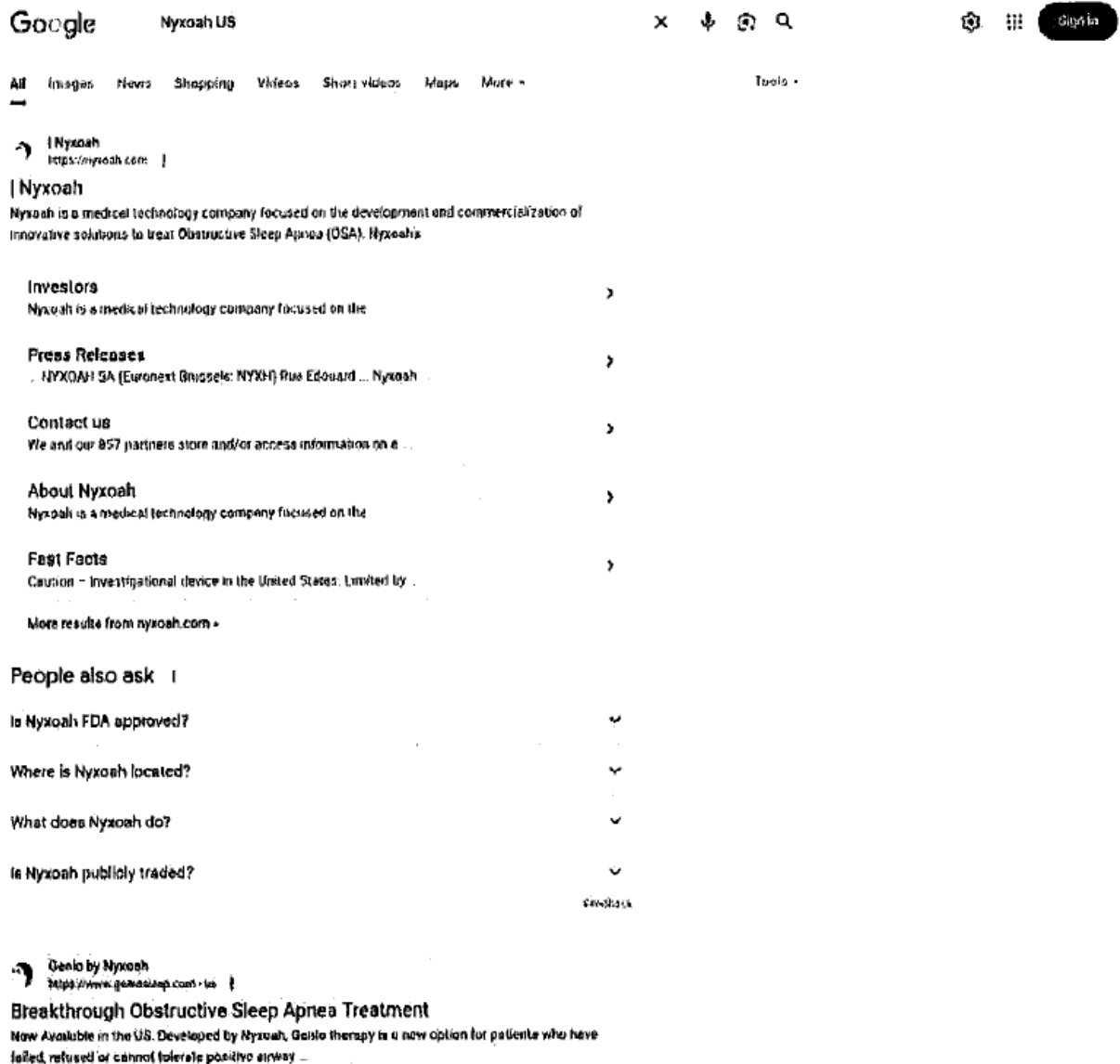
RESPONSE: Nyxoah admits that the referenced document speaks for itself. Nyxoah denies the remaining allegations in paragraph 62.

63. On information and belief, given Nyxoah's conduct and statements during at least the past five years, Nyxoah will commercialize Genio in the United States as soon as possible once Genio is FDA-approved.

RESPONSE: Nyxoah admits that it has recently received FDA approval for Genio and has begun to commercialize Genio in the United States. Nyxoah denies the remaining allegations in paragraph 63.

64. As recently as May 21, 2025, a Google search of "Nyxoah US" reveals at least one Nyxoah domain already staged for online commercialization of Genio in the United States:

reveals Nyxoah's repeated importation of "STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA."



RESPONSE: Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 64, and on that basis denies those allegations.

65. Nyxoah has raised tens of millions of dollars in the past year alone in preparation for Genio's United States commercial launch:

Nyxoah raises \$27M for US commercialization of sleep apnea technology



By Shani Alexander Oct. 17, 2024



Nyxoah SA recently raised \$27 million, after selling three million shares, in a bid to shore up its capital base as it prepares to commercialize Genio — its obstructive sleep apnea technology — in the U.S. The company hopes to get regulatory clearance by the end of the year following positive data from the Dream pivotal study.

Nyxoah sold the three million shares to a single U.S.-based health care investor as part of the company's at-the-market offering to raise \$50 million. The \$27 million raised takes the

total funds raised by the company so far this year to \$120 million, as it comes on the back of \$52.5 million it previously raised in equity offering and the \$40.5 million loan it secured from the European Investment Bank.

“Nyxoah raises \$27M for US commercialization of sleep apnea technology,” BioWorld, available at <https://www.bioworld.com/articles/713165-nyxoah-raises-27m-for-us-commercialization-of-sleep-apnea-technology> (annotated).

RESPONSE: Nyxoah admits that the cited article speaks for itself. Nyxoah denies the remaining allegations in paragraph 65.

66. A real, established, and immediate controversy exists between Inspire and Nyxoah concerning Nyxoah’s commercialization of Genio in the United States.

RESPONSE: Nyxoah denies that a justiciable controversy existed between Plaintiff and Nyxoah as of the date when Plaintiff filed its Complaint.

67. Nyxoah is aware of Inspire’s Asserted Patents. On information and belief, Nyxoah has been aware of Inspire’s Asserted Patents since their issuance or, at the latest, shortly thereafter. As the above-cited references and others make clear, Nyxoah has studied Inspire and its activities intently, given its business model to be a “smart follower” of Inspire and to piggyback off Inspire’s

hard work and success. It is implausible that, as a well-funded second entrant into the market that Inspire created, Nyxoah has not assessed Inspire's patent portfolio.

RESPONSE: Denied.

68. Moreover, on information and belief, Nyxoah has regularly monitored Inspire's patent filings and developments. For example, Nyxoah's own issued patents cite Inspire-owned patents and patent applications that generally relate to sleep apnea treatment. *See, e.g.*, U.S. Patent Nos. 9,463,318, 11,730,469, 10,814,137, and 11,253,712.

RESPONSE: Nyxoah admits that several patents and patent applications are listed on the face of U.S. Patent Nos. 9,463,318, 11,730,469, 10,814,137, and 11,253,712. Nyxoah lacks knowledge or information sufficient to form a belief about whether any of such patents and patent applications are owned by Inspire, and on that basis denies those allegations. Nyxoah denies the remaining allegations in paragraph 68.

69. Additionally, Inspire notified Nyxoah of its Asserted Patents and Genio's infringement thereof by electronic mail and certified letter sent to CEO Mr. Taelman and General Counsel An Moonen (the "Inspire Notice Letter").

RESPONSE: Nyxoah admits that it received a letter from Michael A. Morin of Latham & Watkins and addressed to Olivier Taelman and An Moonen, dated May 28, 2025—two days before the instant Complaint was filed. Nyxoah denies the remaining allegations of paragraph 69.

RESPONSE TO ALLEGATIONS REGARDING "THE ASSERTED PATENTS"

U.S. Patent No. 10,898,709

70. The '709 Patent is titled "Stimulation for treating sleep disordered breathing" and was duly and legally issued by the U.S. Patent and Trademark Office ("USPTO") on January 26, 2021. A true and accurate copy of the '709 Patent is attached as Exhibit 1.

RESPONSE: Nyxoah admits that the '709 Patent is entitled on its face "Stimulation for treating sleep disordered breathing"; that the patent bears a date of January 26, 2021 on its face; and that a copy of the patent is attached to the complaint as Exhibit 1. Nyxoah denies the remaining allegations of paragraph 70.

71. The named inventors listed on the '709 Patent are Darrell Wagner, Quan Ni, John Rondoni, and David Dieken.

RESPONSE: Nyxoah admits that the '709 Patent lists Darrell Wagner, Quan Ni, John Rondoni, and David Dieken as inventors on its face.

72. The '709 Patent issued from Application No. 15/562,714, filed on March 16, 2016.

RESPONSE: Nyxoah admits that the '709 Patent lists on its face the Application No. 15/562,714, and a PCT application filing date of March 16, 2016.

73. Inspire owns the entire right, title, and interest in and to the '709 Patent, including all rights to sue and recover for infringement thereof.

RESPONSE: Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 73, and on that basis denies those allegations.

U.S. Patent No. 11,806,526

74. The '526 Patent is titled "Stimulation for treating sleep disordered breathing" and was duly and legally issued by the USPTO on November 7, 2023. A true and accurate copy of the '526 Patent is attached as Exhibit 2.

RESPONSE: Nyxoah admits that the '526 Patent is entitled on its face "Stimulation for treating sleep disordered breathing"; that the patent bears a date of November 7, 2023 on its face; and that a copy of the patent is attached to the complaint as Exhibit 2. Nyxoah denies the remaining allegations of paragraph 74.

75. The named inventors listed on the '526 Patent are Darrell Wagner, Quan Ni, John Rondoni, and David Dieken.

RESPONSE: Nyxoah admits that the '526 Patent lists Darrell Wagner, Quan Ni, John Rondoni, and David Dieken as inventors on its face.

76. The '526 Patent issued from Application No. 17/012,481, filed on September 4, 2020.

RESPONSE: Nyxoah admits that the '526 Patent lists on its face the Application No. 17/012,481, and a filing date of September 4, 2020.

77. The '526 Patent is a continuation of the '709 Patent and does not include any new subject matter not already described in the '709 Patent.

RESPONSE: Nyxoah admits that the '526 Patent states on its face that it issued from an application that is a continuation of the application that led to issuance of the '709 Patent. Nyxoah denies the remaining allegations of paragraph 77.

78. Inspire owns the entire right, title, and interest in and to the '526 Patent, including all rights to sue and recover for infringement thereof.

RESPONSE: Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 78, and on that basis denies those allegations.

U.S. Patent No. 11,850,424

79. The '424 Patent is titled "Stimulation for treating sleep disordered breathing" and was duly and legally issued by the USPTO on December 26, 2023. A true and accurate copy of the '424 Patent is attached as Exhibit 3.

RESPONSE: Nyxoah admits that the '424 Patent is entitled on its face "Stimulation for treating sleep disordered breathing"; that the patent bears a date of December 26, 2023 on its face;

and that a copy of the patent is attached to the complaint as Exhibit 3. Nyxoah denies the remaining allegations of paragraph 79.

80. The named inventors listed on the '424 Patent are Darrell Wagner, Quan Ni, John Rondoni, and David Dieken.

RESPONSE: Nyxoah admits that the '424 Patent lists Darrell Wagner, Quan Ni, John Rondoni, and David Dieken as inventors on its face.

81. The '424 Patent issued from Application No. 17/348,852, filed on March 16, 2016.

RESPONSE: Nyxoah admits that the '424 Patent lists on its face the Application No. 17/348,852. Nyxoah denies the remaining allegations of paragraph 81.

82. The '424 Patent is a continuation of the '526 Patent and does not include any new subject matter not already described in the '526 Patent or the '709 Patent.

RESPONSE: Nyxoah admits that the '424 Patent states on its face that it issued from an application that is a continuation of the application that led to issuance of the '526 Patent. Nyxoah denies the remaining allegations of paragraph 82.

83. Inspire owns the entire right, title, and interest in and to the '424 Patent, including all rights to sue and recover for infringement thereof.

RESPONSE: Nyxoah lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 83, and on that basis denies those allegations.

RESPONSE TO COUNT I – ALLEGED “INFRINGEMENT OF U.S. PATENT NO. 10,898,709”

84. Inspire repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

RESPONSE: Nyxoah repeats the responses contained in the preceding paragraphs 1 through 83 as though set forth herein.

85. The '709 Patent is valid.

RESPONSE: Denied.

86. As shown in the claim chart in Exhibit 4, Nyxoah's Genio meets each and every limitation of at least Claim 1 of the '709 Patent, either literally and/or under the doctrine of equivalents.

RESPONSE: Denied. Nyxoah further denies the allegations made in the claim chart in Exhibit 4.

87. Nyxoah has infringed and continues to infringe (directly and/or by inducement) one or more claims of the '709 Patent by making, using, offering to sell, selling, importing into the United States, and/or instructing others regarding the making, use, sale, or importation of certain medical devices (*e.g.*, Genio) that infringe (literally or under the doctrine of equivalents) the '709 Patent.

RESPONSE: Denied.

88. Nyxoah's infringing activities violate one or more subsections of 35 U.S.C. § 271.

RESPONSE: Denied.

89. On information and belief, Nyxoah directly infringes in violation of 35 U.S.C. § 271(a) at least Claim 1 of the '709 Patent, literally or under the doctrine of equivalents, by configuring Genio in an infringing manner in the United States, including during Nyxoah's testing, developing, marketing, commercial manufacture, or other use of Genio.

RESPONSE: Denied.

90. Additionally, on information and belief, Nyxoah knowingly and intentionally induces one or more persons in the United States, including but not limited to customers,

distributors, physicians, or other users of Genio, to directly infringe one or more claims of the ‘709 Patent in violation of 35 U.S.C. § 271(b) by configuring Genio in an infringing manner.

RESPONSE: Denied.

91. For example, Nyxoah provides significant support and documentation, such as manuals, guides, webpages, and videos that instruct users to use Genio in an infringing manner. *See, e.g.,* Genio 2.1 Technical Sleep Lab Instructions for Use, available at <https://www.geniosleep.com/en/safety:> DREAM Poster (June 2023), available at <https://investors.nyxoah.com/sites/default/files/2023-06/DREAM%20Poster%20-%20June%202023.pdf>; “Genio- How it works,” YouTube <https://www.youtube.com/watch?v=IOJh9emwOsA>; Nyxoah 2024 Annual Report at 24-25. Through its web pages, manuals, and other documentation regarding Genio, Nyxoah actively encourages and instructs users, customers, and others to infringe the ‘709 Patent.

RESPONSE: Denied.

92. On information and belief, Nyxoah was aware of the ‘709 Patent or acted with willful blindness as to its existence, and Nyxoah thus knew or should have known, and intended, that its conduct would result in direct infringement of the ‘709 Patent.

RESPONSE: Denied.

93. In addition, Inspire placed Nyxoah on notice of its infringement in the Inspire Notice Letter.

RESPONSE: Denied.

94. Unless enjoined by this Court, Nyxoah will continue to infringe the ‘709 Patent and as a direct result Inspire will suffer harm, including irreparable harm for which there is no adequate

remedy at law and which is not fully compensable by money damages. Accordingly, Inspire is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

RESPONSE: Denied.

95. Inspire has suffered and/or will suffer damage as a direct and proximate result of Nyxoah's infringement of the '709 Patent. Thus, in addition to injunctive relief, Inspire is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial, including but not limited to an award of lost profits.

RESPONSE: Denied.

RESPONSE TO COUNT II – ALLEGED “INFRINGEMENT OF U.S. PATENT NO. 11,806,526”

96. Inspire repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

RESPONSE: Nyxoah repeats the responses contained in the preceding paragraphs 1 through 95 as though set forth herein.

97. The '526 Patent is valid.

RESPONSE: Denied.

98. As shown in the claim chart in Exhibit 5, Nyxoah's Genio meets each and every limitation of at least Claim 1 of the '526 Patent, either literally and/or under the doctrine of equivalents.

RESPONSE: Denied. Nyxoah further denies the allegations made in the claim chart in Exhibit 5.

99. Nyxoah has infringed and continues to infringe (directly and/or by inducement) one or more claims of the '526 Patent by making, using, offering to sell, selling, importing into the United States, and/or instructing others regarding the making, use, sale, or importation of certain

medical devices (*e.g.*, Genio) that infringe (literally or under the doctrine of equivalents) the '526 Patent.

RESPONSE: Denied.

100. Nyxoah's infringing activities violate one or more subsections of 35 U.S.C. § 271.

RESPONSE: Denied.

101. On information and belief, Nyxoah directly infringes in violation of 35 U.S.C. § 271(a) at least Claim 1 of the '526 Patent, literally or under the doctrine of equivalents, by configuring Genio in an infringing manner in the United States, including during Nyxoah's testing, developing, marketing, commercial manufacture, or other use of Genio.

RESPONSE: Denied.

102. Additionally, on information and belief, Nyxoah knowingly and intentionally induces one or more persons in the United States, including but not limited to customers, distributors, physicians, or other users of Genio, to directly infringe one or more claims of the '526 Patent in violation of 35 U.S.C. § 271(b) by configuring Genio in an infringing manner.

RESPONSE: Denied.

103. For example, Nyxoah provides significant support and documentation, such as manuals, guides, webpages, and videos that instruct users to use Genio in an infringing manner. *See, e.g.*, Genio 2.1 Technical Sleep Lab Instructions for Use, available at <https://www.geniosleep.com/en/safety>; DREAM Poster (June 2023), available at <https://investors.nyxoah.com/sites/default/files/2023-06/DREAM%20Poster%20-%20June%202023.pdf>; “Genio – How it works,” YouTube <https://www.youtube.com/watch?v=IOJh9emwOsA>; Nyxoah 2024 Annual Report at 24-25.

Through its web pages, manuals, and other documentation regarding Genio, Nyxoah actively encourages and instructs users, customers, and others to infringe the '526 Patent.

RESPONSE: Denied.

104. On information and belief, Nyxoah was aware of the '526 Patent or acted with willful blindness as to its existence, and Nyxoah thus knew or should have known, and intended, that its conduct would result in direct infringement of the '526 Patent.

RESPONSE: Denied.

105. In addition, Inspire placed Nyxoah on notice of its infringement in the Inspire Notice Letter.

RESPONSE: Denied.

106. Unless enjoined by this Court, Nyxoah will continue to infringe the '526 Patent and as a direct result Inspire will suffer harm, including irreparable harm for which there is no adequate remedy at law and which is not fully compensable by money damages. Accordingly, Inspire is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

RESPONSE: Denied.

107. Inspire has suffered and/or will suffer damage as a direct and proximate result of Nyxoah's infringement of the '526 Patent. Thus, in addition to injunctive relief, Inspire is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial, including but not limited to an award of lost profits.

RESPONSE: Denied.

RESPONSE TO COUNT III – ALLEGED “INFRINGEMENT OF U.S. PATENT NO. 11,850,424”

108. Inspire repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

RESPONSE: Nyxoah repeats the responses contained in the preceding paragraphs 1 through 107 as though set forth herein.

109. The '424 Patent is valid.

RESPONSE: Denied.

110. As shown in the claim chart in Exhibit 6, Nyxoah's Genio meets each and every limitation of at least Claim 1 of the '424 Patent, either literally and/or under the doctrine of equivalents.

RESPONSE: Denied. Nyxoah further denies the allegations made in the claim chart in Exhibit 6.

111. Nyxoah has infringed and continues to infringe (directly and/or by inducement) one or more claims of the '424 Patent by making, using, offering to sell, selling, importing into the United States, and/or instructing others regarding the making, use, sale, or importation of certain medical devices (*e.g.*, Genio) that infringe (literally or under the doctrine of equivalents) the '424 Patent.

RESPONSE: Denied.

112. Nyxoah's infringing activities violate one or more subsections of 35 U.S.C. § 271.

RESPONSE: Denied.

113. On information and belief, Nyxoah directly infringes in violation of 35 U.S.C. § 271(a) at least Claim 1 of the '424 Patent, literally or under the doctrine of equivalents, by configuring Genio in an infringing manner in the United States, including during Nyxoah's testing, developing, marketing, commercial manufacture, or other use of Genio.

RESPONSE: Denied.

114. Additionally, on information and belief, Nyxoah knowingly and intentionally induces one or more persons in the United States, including but not limited to customers, distributors, physicians, or other users of Genio, to directly infringe one or more claims of the '424 Patent in violation of 35 U.S.C. § 271(b) by configuring Genio in an infringing manner.

RESPONSE: Denied.

115. For example, Nyxoah provides significant support and documentation, such as manuals, guides, webpages, and videos that instruct users to use Genio in an infringing manner. *See, e.g.,* Genio 2.1 Technical Sleep Lab Instructions for Use, available at <https://www.geniosleep.com/en/safety:> DREAM Poster (June 2023), available at <https://investors.nyxoah.com/sites/default/files/2023-06/DREAM%20Poster%20-%20June%202023.pdf>; “Genio – How it works,” YouTube <https://www.youtube.com/watch?v=IOJh9emwOsA>; Nyxoah 2024 Annual Report at 24-25. Through its web pages, manuals, and other documentation regarding Genio, Nyxoah actively encourages and instructs users, customers, and others to infringe the '424 Patent.

RESPONSE: Denied.

116. On information and belief, Nyxoah was aware of the '424 Patent or acted with willful blindness as to its existence, and Nyxoah thus knew or should have known, and intended, that its conduct would result in direct infringement of the '424 Patent.

RESPONSE: Denied.

117. In addition, Inspire placed Nyxoah on notice of its infringement in the Inspire Notice Letter.

RESPONSE: Denied.

118. Unless enjoined by this Court, Nyxoah will continue to infringe the '424 Patent and as a direct result Inspire will suffer harm, including irreparable harm for which there is no adequate remedy at law and which is not fully compensable by money damages. Accordingly, Inspire is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

RESPONSE: Denied.

119. Inspire has suffered and/or will suffer damage as a direct and proximate result of Nyxoah's infringement of the '424 Patent. Thus, in addition to injunctive relief, Inspire is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial, including but not limited to an award of lost profits.

RESPONSE: Denied.

RESPONSE TO COUNT IV – ALLEGATIONS REGARDING “DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,898,709”

120. Inspire repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

RESPONSE: Nyxoah repeats the responses contained in the preceding paragraphs 1 through 119 as though set forth herein.

121. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, as well as the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq.

RESPONSE: Nyxoah admits that Count IV purports to state a claim arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, as well as the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq.

122. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution.

RESPONSE: Nyxoah denies that a justiciable controversy existed between Plaintiff and Nyxoah as of the date when Plaintiff filed its Complaint.

123. Defendants have made and will continue to make, substantial preparation to manufacture, sell, offer to sell, and/or import Genio in the United States.

RESPONSE: Denied.

124. Defendants' actions and statements indicate a strong likelihood of continuing on its path to manufacture, sell, offer to sell, and/or import Genio in the United States.

RESPONSE: Denied.

125. Defendants' commercialization (*e.g.*, manufacture, sale, offer to sell, and/or importation into the United States) of Genio is imminent.

RESPONSE: Denied.

126. The '709 Patent is valid.

RESPONSE: Denied.

127. As shown in the claim chart in Exhibit 4, Nyxoah's Genio meets each and every limitation of at least Claim 1 of the '709 Patent, either literally and/or under the doctrine of equivalents.

RESPONSE: Denied. Nyxoah also denies the allegations in the claim chart in Exhibit 4.

128. Nyxoah's imminent manufacture, use, sale, offer to sell, or importation of Genio or any similar product will constitute direct infringement of at least one claim of the '709 Patent and/or active inducement of infringement by others of at least one claim of the '709 Patent literally or under the doctrine of equivalents.

RESPONSE: Denied.

129. Nyxoah's infringing activities will violate one or more subsections of 35 U.S.C. § 271.

RESPONSE: Denied.

130. On information and belief, Nyxoah will directly infringe in violation of 35 U.S.C. § 271(a) at least Claim 1 of the '709 Patent, literally or under the doctrine of equivalents, by configuring Genio in an infringing manner in the United States, including during Nyxoah's testing, developing, marketing, commercial manufacture, or other use of Genio.

RESPONSE: Denied.

131. Additionally, on information and belief, Nyxoah will knowingly and intentionally induce one or more persons in the United States, including but not limited to customers, distributors, physicians, or other users of Genio, to directly infringe one or more claims of the '709 Patent in violation of 35 U.S.C. § 271(b) by configuring Genio in an infringing manner.

RESPONSE: Denied.

132. For example, on information and belief, Nyxoah will provide significant support and documentation, such as manuals, guides, webpages, and videos that demonstrate how to configure Genio to infringe the '709 Patent. *See, e.g.*, Genio 2.1 Technical Sleep Lab Instructions for Use, available at <https://www.geniosleep.com/en/safety>; DREAM Poster (June 2023), available at <https://investors.nyxoah.com/sites/default/files/2023-06/DREAM%20Poster%20-%20June%202023.pdf>; "Genio – How it works," YouTube <https://www.youtube.com/watch?v=IOJh9emw0sA>; Nyxoah 2024 Annual Report at 24-25. Through its web pages, manuals, and other documentation regarding Genio, Nyxoah will actively encourage and instruct users, customers, and others to infringe the '709 Patent.

RESPONSE: Denied.

133. On information and belief, Nyxoah is aware of the '709 Patent or has acted with willful blindness as to its existence, and Nyxoah thus knows or should know, and intends, that its conduct will result in direct infringement of the '709 Patent.

RESPONSE: Denied.

134. In addition, Inspire placed Nyxoah on notice of its infringement in the Inspire Notice Letter.

RESPONSE: Denied.

135. Inspire is entitled to a declaratory judgment that Nyxoah's commercial manufacture, use, offer for sale, sale, and/or importation of Genio prior to patent expiration will infringe the '709 Patent.

RESPONSE: Denied.

136. Unless enjoined by this Court, Nyxoah will infringe the '709 Patent and as a direct result Inspire will suffer harm, including irreparable harm for which there is no adequate remedy at law and which is not fully compensable by money damages. Accordingly, Inspire is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

RESPONSE: Denied.

137. Inspire will suffer damage as a direct and proximate result of Nyxoah's imminent infringement of the '709 Patent. Thus, in addition to injunctive relief, Inspire is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial, including but not limited to an award of lost profits.

RESPONSE: Denied.

RESPONSE TO COUNT V – ALLEGATIONS REGARDING “DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,806,526”

138. Inspire repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

RESPONSE: Nyxoah repeats the responses contained in the preceding paragraphs 1 through 137 as though set forth herein.

139. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, as well as the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

RESPONSE: Nyxoah admits that Count V purports to state a claim arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, as well as the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

140. There is an actual case or controversy such that the Court may entertain Plaintiff’s request for declaratory relief consistent with Article III of the United States Constitution.

RESPONSE: Nyxoah denies that a justiciable controversy existed between Plaintiff and Nyxoah as of the date when Plaintiff filed its Complaint.

141. Defendants have made and will continue to make, substantial preparation to manufacture, sell, offer to sell, and/or import Genio in the United States.

RESPONSE: Denied.

142. Defendants’ actions and statements indicate a strong likelihood of continuing on its path to manufacture, sell, offer to sell, and/or import Genio in the United States.

RESPONSE: Denied.

143. Defendants’ commercialization (*e.g.*, manufacture, sale, offer to sell, and/or importation into the United States) of Genio is imminent.

RESPONSE: Denied.

144. The '526 Patent is valid.

RESPONSE: Denied.

145. As shown in the claim chart in Exhibit 5, Nyxoah's Genio meets each and every limitation of at least Claim 1 of the '526 Patent, either literally and/or under the doctrine of equivalents.

RESPONSE: Denied. Nyxoah also denies the allegations made in the claim chart in Exhibit 5.

146. Nyxoah's imminent manufacture, use, sale, offer to sell, or importation of Genio or any similar product will constitute direct infringement of at least one claim of the '526 Patent and/or active inducement of infringement by others of at least one claim of the '526 Patent literally or under the doctrine of equivalents.

RESPONSE: Denied.

147. Nyxoah's infringing activities will violate one or more subsections of 35 U.S.C. § 271.

RESPONSE: Denied.

148. On information and belief, Nyxoah will directly infringe in violation of 35 U.S.C. § 271(a) at least Claim 1 of the '526 Patent, literally or under the doctrine of equivalents, by configuring Genio in an infringing manner in the United States, including during Nyxoah's testing, developing, marketing, commercial manufacture, or other use of Genio.

RESPONSE: Denied.

149. Additionally, on information and belief, Nyxoah will knowingly and intentionally induce one or more persons in the United States, including but not limited to customers,

distributors, physicians, or other users of Genio, to directly infringe one or more claims of the '526 Patent in violation of 35 U.S.C. § 271(b) by configuring Genio in an infringing manner.

RESPONSE: Denied.

150. For example, on information and belief, Nyxoah will provide significant support and documentation, such as manuals, guides, webpages, and videos that demonstrate how to configure Genio to infringe the '526 Patent. *See, e.g.*, Genio 2.1 Technical Sleep Lab Instructions for Use, available at <https://www.geniosleep.com/en/safety>; DREAM Poster (June 2023), available at <https://investors.nyxoah.com/sites/default/files/2023-06/DREAM%20Poster%20-%20June%202023.pdf>; “Genio – How it works,” YouTube <https://www.youtube.com/watch?v=IOJh9emw0sA>; Nyxoah 2024 Annual Report at 24-25. Through its web pages, manuals, and other documentation regarding Genio, Nyxoah will actively encourage and instruct users, customers, and others to infringe the '526 Patent.

RESPONSE: Denied.

151. On information and belief, Nyxoah is aware of the '526 Patent or has acted with willful blindness as to its existence, and Nyxoah thus knows or should know, and intends, that its conduct will result in direct infringement of the '526 Patent.

RESPONSE: Denied.

152. In addition, Inspire placed Nyxoah on notice of its infringement in the Inspire Notice Letter.

RESPONSE: Denied.

153. Inspire is entitled to a declaratory judgment that Nyxoah's commercial manufacture, use, offer for sale, sale, and/or importation of Genio prior to patent expiration will infringe the '526 Patent.

RESPONSE: Denied.

154. Unless enjoined by this Court, Nyxoah will infringe the '526 Patent and as a direct result Inspire will suffer harm, including irreparable harm for which there is no adequate remedy at law and which is not fully compensable by money damages. Accordingly, Inspire is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

RESPONSE: Denied.

155. Inspire will suffer damage as a direct and proximate result of Nyxoah's imminent infringement of the '526 Patent. Thus, in addition to injunctive relief, Inspire is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial, including but not limited to an award of lost profits.

RESPONSE: Denied.

RESPONSE TO COUNT VI – ALLEGATIONS REGARDING “DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,850,424”

156. Inspire repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

RESPONSE: Nyxoah repeats the responses contained in the preceding paragraphs 1 through 155 as though set forth herein.

157. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, as well as the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

RESPONSE: Nyxoah admits that Count VI purports to state a claim arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, as well as the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

158. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution.

RESPONSE: Nyxoah denies that a justiciable controversy existed between Plaintiff and Nyxoah as of the date when Plaintiff filed its Complaint.

159. Defendants have made and will continue to make, substantial preparation to manufacture, sell, offer to sell, and/or import Genio in the United States.

RESPONSE: Denied.

160. Defendants' actions and statements indicate a strong likelihood of continuing on its path to manufacture, sell, offer to sell, and/or import Genio in the United States.

RESPONSE: Denied.

161. Defendants' commercialization (*e.g.*, manufacture, sale, offer to sell, and/or importation into the United States) of Genio is imminent.

RESPONSE: Denied.

162. The '424 Patent is valid.

RESPONSE: Denied.

163. As shown in the claim chart in Exhibit 6, Nyxoah's Genio meets each and every limitation of at least Claim 1 of the '424 Patent, either literally and/or under the doctrine of equivalents.

RESPONSE: Denied. Nyxoah also denies the allegations made in the claim chart in Exhibit 6.

164. Nyxoah's imminent manufacture, use, sale, offer to sell, or importation of Genio or any similar product will constitute direct infringement of at least one claim of the '424 Patent and/or active inducement of infringement by others of at least one claim of the '424 Patent literally or under the doctrine of equivalents.

RESPONSE: Denied.

165. Nyxoah's infringing activities will violate one or more subsections of 35 U.S.C. § 271.

RESPONSE: Denied.

166. On information and belief, Nyxoah will directly infringe in violation of 35 U.S.C. § 271(a) at least Claim 1 of the '424 Patent, literally or under the doctrine of equivalents, by configuring Genio in an infringing manner in the United States, including during Nyxoah's testing, developing, marketing, commercial manufacture, or other use of Genio.

RESPONSE: Denied.

167. Additionally, on information and belief, Nyxoah will knowingly and intentionally induce one or more persons in the United States, including but not limited to customers, distributors, physicians, or other users of Genio, to directly infringe one or more claims of the '424 Patent in violation of 35 U.S.C. § 271(b) by configuring Genio in an infringing manner.

RESPONSE: Denied.

168. For example, on information and belief, Nyxoah will provide significant support and documentation, such as manuals, guides, webpages, and videos that demonstrate how to configure Genio to infringe the '424 Patent. *See, e.g.*, Genio 2.1 Technical Sleep Lab Instructions for Use, available at <https://www.geniosleep.com/en/safety>; DREAM Poster (June 2023), available at <https://investors.nyxoah.com/sites/default/files/2023-06/DREAM%20Poster%20-%20June%202023.pdf>; “Genio – How it works,” YouTube <https://www.youtube.com/watch?v=IOJh9emw0sA>; Nyxoah 2024 Annual Report at 24-25. Through its web pages, manuals, and other documentation regarding Genio, Nyxoah will actively encourage and instruct users, customers, and others to infringe the '424 Patent.

RESPONSE: Denied.

169. On information and belief, Nyxoah is aware of the '424 Patent or has acted with willful blindness as to its existence, and Nyxoah thus knows or should know, and intends, that its conduct will result in direct infringement of the '424 Patent.

RESPONSE: Denied.

170. In addition, Inspire placed Nyxoah on notice of its infringement in the Inspire Notice Letter.

RESPONSE: Denied.

171. Inspire is entitled to a declaratory judgment that Nyxoah's commercial manufacture, use, offer for sale, sale, and/or importation of Genio prior to patent expiration will infringe the '424 Patent.

RESPONSE: Denied.

172. Unless enjoined by this Court, Nyxoah will infringe the '424 Patent and as a direct result Inspire will suffer harm, including irreparable harm for which there is no adequate remedy at law and which is not fully compensable by money damages. Accordingly, Inspire is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

RESPONSE: Denied.

173. Inspire will suffer damage as a direct and proximate result of Nyxoah's imminent infringement of the '424 Patent. Thus, in addition to injunctive relief, Inspire is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial, including but not limited to an award of lost profits.

RESPONSE: Denied.

RESPONSE TO JURY DEMAND

174. Pursuant to Fed. R. Civ. P. 38, Inspire demands a trial by jury on all issues triable as such.

RESPONSE: Nyxoah admits that Plaintiff requests a trial by jury. Nyxoah similarly requests a trial by jury on all issues so triable.

RESPONSE TO PRAYER FOR RELIEF

Defendants deny that Plaintiff is entitled to any of the relief requested in any of paragraphs (a) through (g) of its Prayer for Relief.

AFFIRMATIVE DEFENSES

Defendants assert the following affirmative defenses without prejudice to the denials in this answer and without admitting any allegations of the complaint not otherwise admitted. Defendants expressly reserve the right to allege additional defenses as they become known through the course of discovery.

FIRST AFFIRMATIVE DEFENSE

The complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The complaint fails to state a claim upon which relief can be granted for indirect patent infringement, including contributory infringement and inducement of infringement.

THIRD AFFIRMATIVE DEFENSE

The complaint fails to state a claim upon which relief can be granted for declaratory judgment.

FOURTH AFFIRMATIVE DEFENSE

Each claim of the patents-in-suit is invalid for failure to comply with the requirements for patentability as set forth in Title 35, United States Code, including in particular Sections 101, 102, 103, and/or 112 thereof, and/or under other judicially-created bases for invalidity.

FIFTH AFFIRMATIVE DEFENSE

Defendants are not infringing and have not infringed, directly or indirectly, any valid and enforceable claim of the patents-in-suit, either literally or under the doctrine of equivalents.

SIXTH AFFIRMATIVE DEFENSE

Defendants are not willfully infringing and have not willfully infringed any valid and enforceable claim of the patents-in-suit.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrine of prosecution history estoppel.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's right to seek damages is limited, including without limitation by 35 U.S.C. §§ 286 and 287.

NINTH AFFIRMATIVE DEFENSE

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

TENTH AFFIRMATIVE DEFENSE

Defendants have engaged in all relevant activities in good faith, thereby precluding Plaintiff, even if it prevails, from recovering its reasonable attorneys' fees and/or costs under 35 U.S.C. § 285.

WHEREFORE, Defendants pray for judgment in their favor and against Plaintiff for their fees, costs, and expenses, and for such other relief as the Court deems just and proper.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Counter-Plaintiffs Nyxoah, Inc. and Nyxoah SA (collectively "Nyxoah" or "Counter-Plaintiffs"), by way of their attorneys

Duane Morris LLP, hereby state for their Counterclaims against Counter-Defendant Inspire Medical Systems, Inc. (“Inspire” or “Counter-Defendant”) the following:

1. This is an action for a declaratory judgment of non-infringement and invalidity of one or more claims of United States Patent Nos. 10,898,709 (the “’709 Patent”), 11,806,526 (the “’526 Patent”), and 11,850,424 (the “’424 Patent”) (collectively, the “Asserted Patents”).

THE PARTIES

2. Nyxoah, Inc. is a corporation incorporated and existing under the laws of Delaware, with its principal place of business at 350 Springfield Ave, Suite 200, Summit, New Jersey 07901.

3. Nyxoah SA is a business entity organized and existing under the laws of Belgium, with its principal place of business at Rue Edouard Belin 12 1435 Mont-Saint-Guibert, Belgium.

4. On information and belief, Inspire is a company incorporated and existing under the laws of Delaware, with its corporate offices and principal place of business at 5500 Wayzata Blvd., Suite 1600, Golden Valley, Minnesota 55416.

JURISDICTION

5. This Court has subject matter jurisdiction over these non-infringement and invalidity Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338 with respect to claims arising under the Patent Act, 35 U.S.C. § 101 *et seq.*, and pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*

6. This Court has personal jurisdiction over Inspire, as Inspire is a corporation incorporated and existing under the laws of Delaware, and as Inspire has availed itself of this Court by filing its Complaint for alleged infringement of the Asserted Patents.

7. Venue is proper in this judicial district pursuant to, *inter alia*, 28 U.S.C. § 1391(b). Inspire has also consented to venue in this Court by bringing this action against Nyxoah in this district and thus venue for Nyxoah’s Counterclaims is proper in this judicial district.

STATEMENT OF CLAIMS

COUNT I – DECLARATION OF NON-INFRINGEMENT OF THE '709 PATENT

8. Nyxoah incorporates by reference each of the preceding Counterclaim paragraphs as if fully set forth herein.

9. Inspire has brought a patent infringement action against Nyxoah.

10. Inspire has alleged that it is the owner of the entire right, title, and interest in and to the '709 Patent.

11. Inspire has alleged and continues to allege that Nyxoah has infringed at least claim 1 of the '709 Patent.

12. Nyxoah's accused Genio product has not infringed any claims of the '709 Patent, including claim 1, at least because the accused Genio product does not have "a non-cardiac stimulation element to engage and to stimulate an upper-airway-patency-related nerve," and does not utilize "a reference respiratory cycle compris[ing] at least one of: a historical patent-specific average respiratory cycle for stable respiration; and a multi-patient average respiratory cycle for stable respiration."

13. An actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, has arisen and now exists between Inspire and Nyxoah concerning whether Nyxoah has infringed (directly or indirectly) any valid and enforceable claim of the '709 Patent.

14. Nyxoah has never made, used, imported, offered for sale and/or sold in the United States any products or services that infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '709 Patent.

15. Nyxoah has never contributed to the infringement of, or induced others to infringe, any valid and enforceable claim of the '709 Patent.

16. By virtue of the foregoing, Nyxoah desires a judicial determination of its rights and duties with respect to any alleged infringement of the '709 Patent.

17. A judicial declaration is necessary and appropriate at this time so that the parties may proceed in accordance with their respective rights and duties determined by the Court.

COUNT II – DECLARATION OF INVALIDITY OF THE '709 PATENT

18. Nyxoah incorporates by reference each of the preceding Counterclaim paragraphs as if fully set forth herein.

19. Inspire has brought a patent infringement action against Nyxoah.

20. An actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, has arisen and now exists between Inspire and Nyxoah regarding the invalidity of one or more claims of the '709 Patent.

21. The claims of the '709 Patent are invalid for failure to comply with one or more of the requisite statutory and/or decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation 35 U.S.C. §§ 101, 102, 103, and/or 112, the rules, regulations, and laws pertaining thereto, and/or under other judicially-created bases for invalidity.

22. The claims of the '709 Patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least PCT Application No. WO 2015/051140.

23. By virtue of the foregoing, Nyxoah desires a judicial determination of its rights and duties with respect to any alleged validity of the '709 Patent.

24. A judicial declaration is necessary and appropriate at this time so that the parties may proceed in accordance with their respective rights and duties determined by the Court.

COUNT III – DECLARATION OF NON-INFRINGEMENT OF THE '526 PATENT

25. Nyxoah incorporates by reference each of the preceding Counterclaim paragraphs as if fully set forth herein.

26. Inspire has brought a patent infringement action against Nyxoah.

27. Inspire has alleged that it is the owner of the entire right, title, and interest in and to the '526 Patent.

28. Inspire has alleged and continues to allege that Nyxoah has infringed at least claim 1 of the '526 Patent.

29. Nyxoah's accused Genio® product has not infringed any claims of the '526 Patent, including claim 1, at least because the accused Genio product does not have "a non-cardiac stimulation means for stimulating an upper airway patency-related nerve," and does not utilize a stimulation period whose "duration . . . is based on a reference respiratory-related parameter."

30. An actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, has arisen and now exists between Inspire and Nyxoah concerning whether Nyxoah has infringed (directly or indirectly) any valid and enforceable claim of the '526 Patent.

31. Nyxoah has never made, used, imported, offered for sale and/or sold in the United States any products or services that infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '526 Patent.

32. Nyxoah has never contributed to the infringement of, or induced others to infringe, any valid and enforceable claim of the '526 Patent.

33. By virtue of the foregoing, Nyxoah desires a judicial determination of its rights and duties with respect to any alleged infringement of the '526 Patent.

34. A judicial declaration is necessary and appropriate at this time so that the parties may proceed in accordance with their respective rights and duties determined by the Court.

COUNT IV – DECLARATION OF INVALIDITY OF THE '526 PATENT

35. Nyxoah incorporates by reference each of the preceding Counterclaim paragraphs as if fully set forth herein.

36. Inspire has brought a patent infringement action against Nyxoah.

37. An actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, has arisen and now exists between Inspire and Nyxoah regarding the invalidity of one or more claims of the '526 Patent.

38. The claims of the '526 Patent are invalid for failure to comply with one or more of the requisite statutory and/or decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation 35 U.S.C. §§ 101, 102, 103, and/or 112, the rules, regulations, and laws pertaining thereto, and/or under other judicially-created bases for invalidity.

39. The claims of the '526 Patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least PCT Application No. WO 2015/051140.

40. By virtue of the foregoing, Nyxoah desires a judicial determination of its rights and duties with respect to any alleged validity of the '526 Patent.

41. A judicial declaration is necessary and appropriate at this time so that the parties may proceed in accordance with their respective rights and duties determined by the Court.

COUNT V – DECLARATION OF NON-INFRINGEMENT OF THE '424 PATENT

42. Nyxoah incorporates by reference each of the preceding Counterclaim paragraphs as if fully set forth herein.

43. Inspire has brought a patent infringement action against Nyxoah.

44. Inspire has alleged that it is the owner of the entire right, title, and interest in and to the '424 Patent.

45. Inspire has alleged and continues to allege that Nyxoah has infringed at least claim 1 of the '424 Patent.

46. Nyxoah's accused Genio® product has not infringed any claims of the '424 Patent, including claim 1, at least because the accused Genio product does not have "a means for stimulating a hypoglossal nerve," and does not utilize a stimulation period whose "duration . . . is based on a reference respiratory-related parameter."

47. An actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, has arisen and now exists between Inspire and Nyxoah concerning whether Nyxoah has infringed (directly or indirectly) any valid and enforceable claim of the '424 Patent.

48. Nyxoah has never made, used, imported, offered for sale and/or sold in the United States any products or services that infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '424 Patent.

49. Nyxoah has never contributed to the infringement of, or induced others to infringe, any valid and enforceable claim of the '424 Patent.

50. By virtue of the foregoing, Nyxoah desires a judicial determination of its rights and duties with respect to any alleged infringement of the '424 Patent.

51. A judicial declaration is necessary and appropriate at this time so that the parties may proceed in accordance with their respective rights and duties determined by the Court.

COUNT VI – DECLARATION OF INVALIDITY OF THE '424 PATENT

52. Nyxoah incorporates by reference each of the preceding Counterclaim paragraphs as if fully set forth herein.

53. Inspire has brought a patent infringement action against Nyxoah.

54. An actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, has arisen and now exists between Inspire and Nyxoah regarding the invalidity of one or more claims of the '424 Patent.

55. The claims of the '424 Patent are invalid for failure to comply with one or more of the requisite statutory and/or decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation 35 U.S.C. §§ 101, 102, 103, and/or 112, the rules, regulations, and laws pertaining thereto, and/or under other judicially-created bases for invalidity.

56. The claims of the '424 Patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least PCT Application No. WO 2015/051140.

57. By virtue of the foregoing, Nyxoah desires a judicial determination of its rights and duties with respect to any alleged validity of the '424 Patent.

58. A judicial declaration is necessary and appropriate at this time so that the parties may proceed in accordance with their respective rights and duties determined by the Court.

PRAYER FOR RELIEF

WHEREFORE, Counter-Plaintiffs pray that the Court:

- A. Enter judgment in favor of Counter-Plaintiffs and against Counter-Defendant, and dismiss Inspire's complaint with prejudice;
- B. Declare that each of the Asserted Patents are invalid;
- C. Declare that Nyxoah has not infringed, either literally or under the doctrine of equivalents, nor contributed to infringement by others, nor actively induced others to infringe, any claim of the Asserted Patents;

D. Declare that Nyxoah has not willfully infringed, either literally or under the doctrine of equivalents, nor willfully contributed to infringement by others, nor willfully actively induced others to infringe, any claim of the Asserted Patents;

E. Declare this to be an exceptional case pursuant to 35 U.S.C. § 285 and award Counter-Plaintiffs their reasonable attorneys' fees;

F. Award Counter-Plaintiffs all of their costs in this action; and

G. Grant to Counter-Plaintiffs such further necessary or proper relief as the Court may deem just.

DEMAND FOR JURY TRIAL

Counter-Plaintiffs demand a jury trial on all issues so triable in this action.

Dated: August 25, 2025

Respectfully submitted,

OF COUNSEL:

L. Norwood Jameson*
DUANE MORRIS LLP
1075 Peachtree Street, NE, Suite 1700
Atlanta, GA 30309-3929
wjameson@duanemorris.com

Anthony J. Fitzpatrick*
Charlotte Drew*
DUANE MORRIS LLP
100 High Street, Suite 2400
Boston, MA 02110-1724
ajfitzpatrick@duanemorris.com
cdrew@duanemorris.com

Jarrad M. Gunther*
DUANE MORRIS LLP
30 South 17th Street
Philadelphia, PA 19103-4196
Telephone: (215) 979-1837
JMGunther@duanemorris.com

*admitted *pro hac vice*

DUANE MORRIS LLP

/s/ Monté T. Squire
Monté T. Squire (No. 4764)
1201 N. Market Street, Suite 501
Wilmington, DE 19801
Telephone: (302) 657-4900
mtsquire@duanemorris.com

Attorneys for Nyxoah, Inc. and Nyxoah SA