IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INSPIRE MEDICAL SYSTEMS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
NYXOAH, INC., and NYXOAH SA,	)	**DEMAND FOR JURY TRIAL**
	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT OR, IN THE ALTERNATIVE, DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

Plaintiff Inspire Medical Systems, Inc. ("Inspire") brings this action against Defendant Nyxoah SA and its wholly owned subsidiary Defendant Nyxoah, Inc. (collectively "Nyxoah") for infringement of or, in the alternative, declaratory judgment of infringement of, U.S. Patent Nos. 10,898,709 (the "'709 Patent"), 11,806,526 (the "'526 Patent"), and 11,850,424 (the "'424 Patent") (the "Asserted Patents" or the "Patents-in-Suit"). For its Complaint, Inspire alleges as follows:

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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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.

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.

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.

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.

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.

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

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.

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.

BACKGROUND

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.

21. Traditional OSA treatments typically involve CPAP therapy, which delivers a 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.

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.

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.

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.

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.

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).

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.

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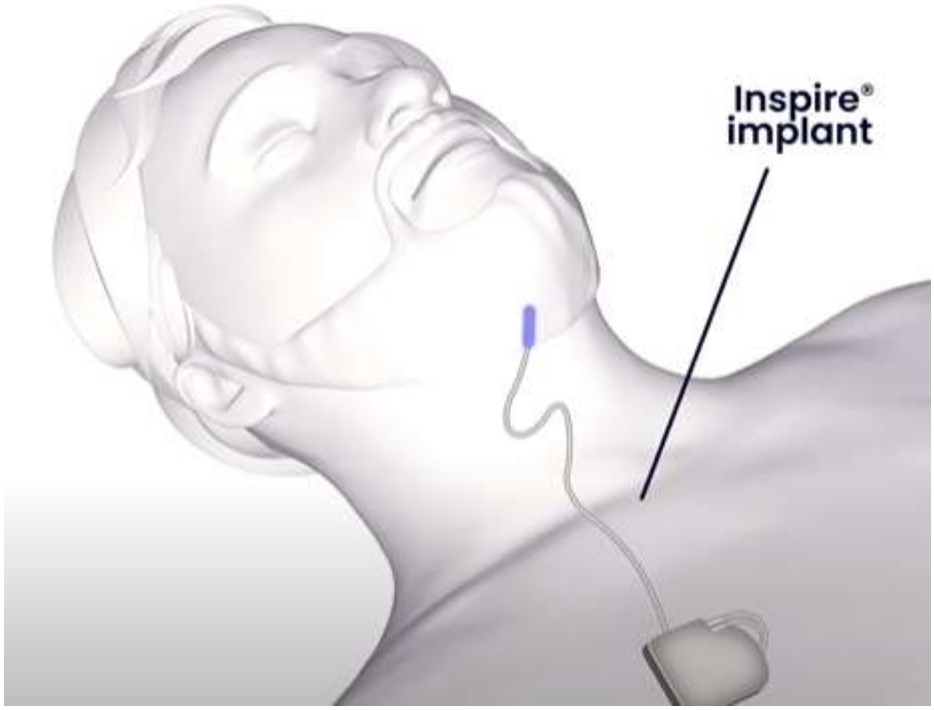


28. The Inspire system includes a breathing sensor, a stimulation cuff electrode, a generator, a patient remote, and a proprietary algorithm. These components work together to monitor and adapt to the patient's natural breathing rhythm during application of therapy (*i.e.*, at night while sleeping). 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.

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.

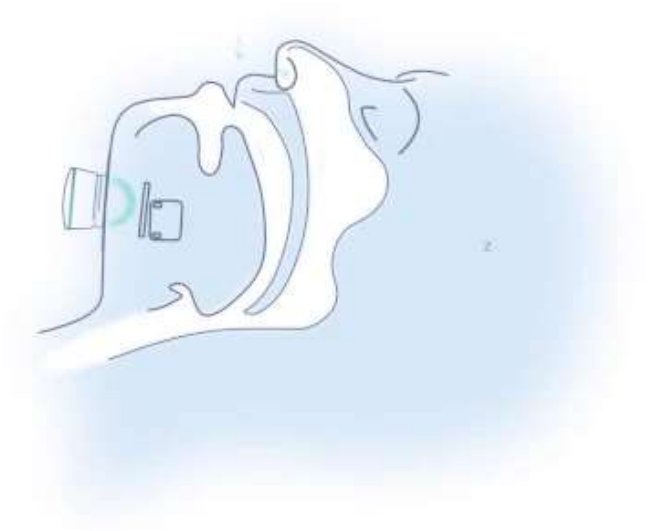
30. To date, Inspire therapy has been implanted in over 100,000 patients.

NYXOAH'S FOLLOW-ON GENIO SLEEP APNEA TREATMENT PRODUCT

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

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.

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.



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"Genio – How it works," YouTube Video, at 1:02, available at https://www.youtube.com/watch?v=I0Jh9emwOsA.

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.

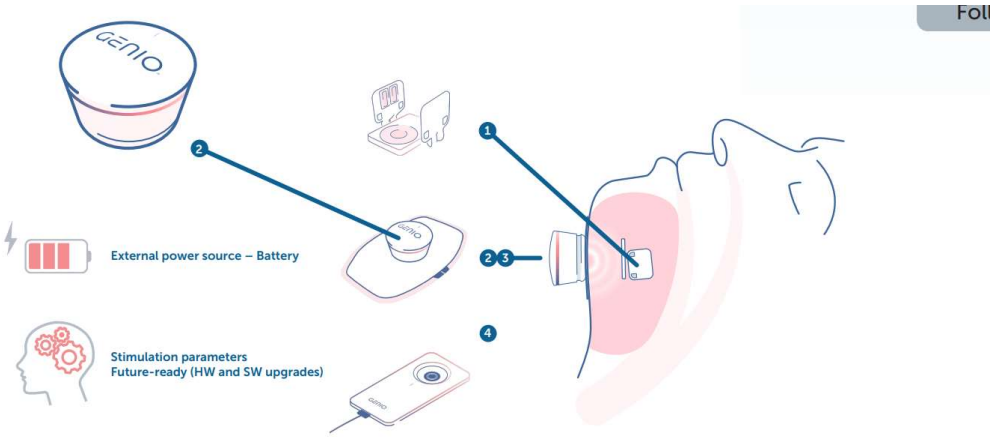

Figure 3. Figure 3. Schematic of Genio system. (**1**) Implantable stimulator (IS); (**2**) Activation chip (AC); (**3**) Disposable patch (DP); (**4**) Charging unit (CU)

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=I0Jh9emwOsA.

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.

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.

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]

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.*

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

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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.*

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.

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.

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.

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

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.

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.*

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.*

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.*

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

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.*

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.

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

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").

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.*

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.*

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.*

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/.

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.

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.*

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.

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.*

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).

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

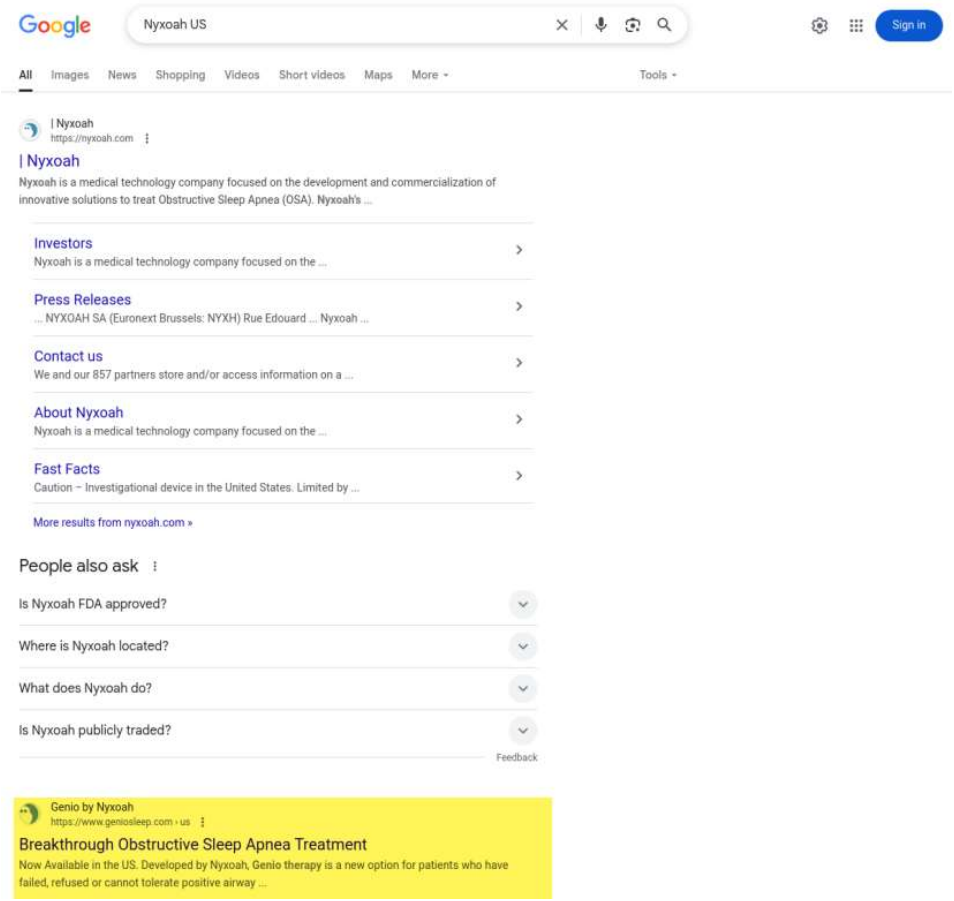
Record View	Shipment ID	Arrival Date	Submission Date	Port of Entry Division	Country of Origin	Product Code	Product Code Description	Manufacturer FEI Number	Manufacturer Legal Name
View	SCS-0708465-5/12/1	05/08/2025	05/09/2025	Division of Northeast Imports	Belgium	73MNQ	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA	3037207042	NYXOAH SA VDG SITE
View	SCS-0723482-1/12/1	05/08/2025	05/09/2025	Division of Southeast Imports	Belgium	73MNQ	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA	3037207042	NYXOAH SA VDG SITE
View	SCS-0707366-6/12/1	05/08/2025	05/09/2025	Division of Southeast Imports	Belgium	73MNQ	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA	3037207042	NYXOAH SA VDG SITE
View	SCS-0689544-0/12/1	05/08/2025	05/13/2025	Division of Southeast Imports	Belgium	73MNQ	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA	3037207042	NYXOAH SA VDG SITE
View	SCS-0116422-2/12/1	04/05/2025	04/09/2025	Division of Southeast Imports	Belgium	73MNQ	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED, APNEA	3037207042	NYXOAH SA VDG SITE
View	SCS-0115984-2/12/1	04/05/2025	04/09/2025	Division of Southeast Imports	Belgium	73MNQ	STIMULATOR, HYPOGLOSSAL NERVE, IMPLANTED,	3037207042	NYXOAH SA VDG SITE

Id.

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

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.

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:



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).

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

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.

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.

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").

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.

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

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

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.

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

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

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.

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.

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

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

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.

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.

COUNT I –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.

85. The ’709 Patent is valid.

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.

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.

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

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.

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.

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=I0Jh9emwOsA; Nyxoah 2024 Annual Report at 24–25. Through its web pages, manuals,

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and other documentation regarding Genio, Nyxoah actively encourages and instructs users, customers, and others to infringe the '709 Patent.

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.

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

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.

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.

COUNT II –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.

97. The '526 Patent is valid.

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.

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.

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

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.

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.

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=I0Jh9emwOsA; 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.

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.

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

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.

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.

COUNT III –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.

109. The ’424 Patent is valid.

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.

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.

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

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.

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.

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=I0Jh9emwOsA; 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.

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.

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

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.

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.

COUNT IV – 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.

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.

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.

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.

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.

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

126. The '709 Patent is valid.

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.

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.

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

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.

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.

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=I0Jh9emwOsA; 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.

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.

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

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.

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.

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.

COUNT V – 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.

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.

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.

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.

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.

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

144. The '526 Patent is valid.

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.

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.

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

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.

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.

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=I0Jh9emwOsA; 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.

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.

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

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.

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.

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.

COUNT VI – 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.

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.

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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.

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.

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.

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

162. The '424 Patent is valid.

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.

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.

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

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.

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.

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=I0Jh9emwOsA; 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.

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.

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

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.

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.

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.

JURY DEMAND

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

PRAYER FOR RELIEF

WHEREFORE, Inspire requests the following relief:

(a) A judgment that Nyxoah has infringed or will infringe, and/or has induced or will induce infringement of the Asserted Patents;

(b) A permanent injunction pursuant to, *inter alia*, 35 U.S.C. § 283 enjoining Nyxoah, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Nyxoah's Genio and/or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes or would infringe the Asserted Patents, or the inducement of any of the foregoing;

(c) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Nyxoah's Genio, the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Asserted Patents, respectively, will infringe, and/or actively induce infringement of the Asserted Patents;

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(d) An award of Inspire's damages, including but not limited to an award of lost profits, or other monetary relief to compensate Inspire for Nyxoah's past infringement and/or any continuing and/or future infringement of the Asserted Patents up until the date such judgment is entered, including pre- and post-judgment interest, costs, and disbursements as justified pursuant to 35 U.S.C. § 284;

(e) A declaration that this case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Inspire's costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

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