IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEVRO CORP. Plaintiff, v. BOSTON SCIENTIFIC CORP. AND BOSTON SCIENTIFIC NEUROMODULATION CORP., Defendants.	C.A. No. 21-258-CFC

DEFENDANTS' OPENING BRIEF
IN SUPPORT OF THEIR MOTION TO DISMISS FOR LACK OF PATENTABLE SUBJECT MATTER

Dated: April 19, 2021

Of Counsel (pro hac to be filed):

Michael P. Kahn
Michael N. Petegorsky
AKIN GUMP STRAUSS HAUER & FELD LLP
One Bryant Park, Bank of America Tower
New York, NY 10036-6745
(212) 872-1000
mkahn@akingump.com
mpetegorsky@akingump.com

Rachel J. Elsby
AKIN GUMP STRAUSS HAUER & FELD

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
FARNAN LLP
919 Market Street
12th Floor
Wilmington, Delaware 19801
(302) 777-0300
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Defendants Boston Scientific Corporation and Boston Scientific Neuromodulation Corp.

LLP
Robert S. Strauss Tower
2001 K Street, N.W.
Washington, DC 20006-1037
(202) 887-4000
relsby@akingump.com

Steven D. Maslowski
AKIN GUMP STRAUSS HAUER & FELD LLP
Two Commerce Square
2001 Market Street, Suite 4100
Philadelphia, PA 19103-7013
(215) 965-1200
smaslowski@akingump.com

Matthew M. Wolf
ARNOLD & PORTER KAYE SCHOLER LLP 601 Massachusetts Ave., NW
Washington, DC 20001-3743
(202) 942-5000
matthew.wolf@arnoldporter.com

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I. NATURE AND STAGE OF THE PROCEEDINGS

Defendants Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. (collectively, "BSC") respectfully move to dismiss Plaintiff Nevro Corp.'s ("Nevro") complaint for infringement of U.S. Patent Nos. 10,556,112 ("the '112 patent"); 10,576,286 ("the '286 patent"); 8,892,209 ("the '209 patent"); 8,792,988 ("the '988 patent"); and 9,333,357 ("the '357 patent") (collectively, "Asserted Patents") under Rule 12(b)(6) for failure to state a claim upon which relief can be granted because the asserted claims are invalid under 35 U.S.C. § 101.

II. SUMMARY OF ARGUMENT

Spinal cord stimulation (SCS) therapy has been around for decades, and works by sending programmed electrical signals to a patient's spine to alleviate pain. Some SCS therapies produce a natural reaction in the body referred to as paresthesia or tingling, while others do not—whether a given patient experiences paresthesia is just a natural phenomenon. The Supreme Court's decisions in *Alice* and *Mayo* make clear that natural phenomena are not entitled to patent protection, and "simply appending conventional steps, specified at a high level of generality" to the claimed discovery does not make ineligible subject matter patentable. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 82 (2012). But that is exactly the situation this case presents. Nevro's asserted claims to "paresthesia-free" devices

and methods are directed to a natural phenomenon paired with conventional instructions.

Nevro's asserted claims lack any innovative concept to transform the natural phenomenon into a patentable invention. Nevro does not even purport to have invented a new SCS device or way of programming it. As Nevro must admit, all of the remaining limitations in the asserted claims were ordinary and conventional features when Nevro filed its patent applications. Nevro's only alleged "distinguishing feature" is the absence of paresthesia. But even assuming Nevro discovered a "paresthesia-free" phenomenon, which it did not, that alleged discovery tied to conventional devices does not qualify for patenting: "Under the *Mayo/Alice* framework, a claim directed to a newly discovered law of nature (or natural phenomenon or abstract idea) cannot rely on the novelty of that discovery for the inventive concept necessary for patent eligibility." *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016). The asserted claims are directed to a natural phenomenon and lack any "inventive concept" sufficient to satisfy the requirements of Section 101. And Nevro knows it.

This isnot the parties' first dispute about the patentability of Nevro's claims to paresthesia-free therapies. In response to an earlier wave of litigation brought by Nevro in California, BSC challenged the patentability of Nevro's "high frequency" patent claims. Nevro defended those claims, identifying their "high frequency"

waveforms, i.e., from 1.5 kHz to 100 kHz, as an "inventive concept." But here, Nevro abandoned its touted "high frequency" claims, and seeks to preempt the entire SCS field from using well-known waveform parameters, such as frequency, amplitude and pulse widths, that have been used, by Nevro's admission, "for decades," based solely on the absence of paresthesia. The absence of paresthesia is a natural phenomenon, not a patentable invention and the asserted claims are invalid.

III. STATEMENT OF FACTS

A. Nevro's Serial Litigation Strategy

This litigation is the third in an on-going campaign by Nevro to obtain in the courtroom what it failed to achieve in the market—a monopoly on the absence of paresthesia. Initially, Nevro pursued claims to "high frequency" programming, but now its asserted claims go much broader to the phenomenon itself—Nevro is asserting claims for which the only purported point of novelty is whether a particular patient experiences paresthesia.

1. *Case No. 1* – Nevro Sues BSC in California Over "High Frequency" Paresthesia-Free Claims

Nevro started this multi-front legal battle on November 28, 2016, when it sued BSC in the Northern District of California over six patents, including two asserted here—the '357 and the '988 patents ("California Action").[1] In that case, Nevro

[1] Nevro later added a seventh patent in the California Action.

alleged that its SCS therapy "uses a unique 'high frequency' electrical waveform to provide pain relief *without* generating paresthesia,[2]" and the patents were "directed to high-frequency, paresthesia-free therapy." D.I. 1 at ¶14. On July 24, 2018, the district court in that case awarded summary judgment in BSC's favor on twelve claims for indefiniteness and found the remaining six method claims not infringed.[3] Nevro appealed only indefiniteness. Following a decision from the Federal Circuit, Nevro stipulated to dismiss the claims at risk in the California Action, with prejudice. Notably, in the 2016 California case, Nevro also initially asserted claim 1 of the '357 patent (which it asserts here), but dropped that claim in early 2018 in the face of an invalidity challenge only to reassert it here alongside two similarly broad claims in related patents.

2. *Case No. 2* – Nevro Counterclaims in Delaware Over 1.2 kHz "Paresthesia-Free" Programming

On December 9, 2019, while the appeal of the California Action was still pending, Nevro filed counterclaims against BSC in Delaware ("Delaware II") for infringement of five additional patents, including U.S. Patent No. 10,149,978 ("the '978 patent"). Like the California patents, the '978 patent is directed to paresthesia-free therapy; however, it does not recite "high frequency" parameters. Instead, it

[2] *Nevro Corp. v. Boston Scientific Corp.*, C.A. No. 3:16-cv-06830, D.I. 158 at ¶5 (N.D. Cal. Nov. 16, 2017) ("California Action") (cited at FN4 of the complaint).
[3] California Action, D.I. 449.

recites a single, conventional frequency of 1.2 kHz capable of being delivered using conventional SCS systems that were commercialized by BSC long before Nevro existed. Notably, public records show that physicians used Boston Scientific devices to provide SCS therapy at 1.2 kHz without paresthesia well-before Nevro's asserted work in this area. Nonetheless, Nevro tried again.

3. *Case No. 3* – Nevro Files a New Case Over Broader "Paresthesia-Free" SCS

Understanding that its '978 patent is narrowly limited to a single frequency and anticipated by BSC's prior use, Nevro filed the instant complaint, presumably with the hope of using the five Asserted Patents to resuscitate its failed attempt from California and failing efforts with the '978 patent. Two of the five Asserted Patents are direct relatives and slightly broader versions of the '978 patent that Nevro prosecuted in the Patent Office during the California Action and Delaware II litigation (the '112 and '286 patents). Of the remaining three patents, two were asserted by Nevro in California, dismissed and then re-asserted here (the '988 and '357 patents). The third is a direct relative of the two patents from California (the '209 patent). None of the asserted claims recite a "high frequency" limitation. Rather, all of the asserted claims are, like the '978 patent, directed to a patent ineligible natural phenomenon couched in old technology. And, like the '978 patent, the new claims cover devices and methods in use and on sale well-before Nevro's work.

B. The Patents-in-Suit

The Alataris Patents: As mentioned above, the '209, '988, and '357 patents (collectively, "the Alataris patents") are all related, and list a common priority date of April 22, 2009. *See* D.I. 1, Ex. 5 at cover. The written description of the Alataris patents states that its inventions are generally directed to "systems and methods for inhibiting pain via waveforms with ***high frequency*** elements or components"—elements and components that are not recited in any asserted claim. D.I. 1, Ex. 5 at 2:54-55. The asserted claims of the Alataris patents recite no frequency limitations.

Instead, the asserted claims recite parameters that the Alataris patents themselves regard as conventional. For example, claim 1 of the '209 patent is directed to SCS devices configured to generate a signal with pulse widths of 10 to 333 microseconds. Similarly, claim 1 of the '357 patent is directed to SCS systems programmed to provide therapy at pulse widths of 10 to 333 microseconds and amplitudes of 0.5 to 10 mA. Finally, claim 1 of the '988 patent is directed methods of programming SCS devices with biphasic pulses having a pulse width of 25-166 microseconds. And each claim appends "non-paresthesia-producing" to these conventional parameters.

According to the written description, "standard SCS treatment" utilized "a frequency of less than 1500 Hz (e.g., 60-80 Hz), a pulse width of 100-200microseconds, and a duty cycle of 100%." *Id*. at 6:43-48. Amplitudes for

standard SCS treatment varied from about 3 to about 10 mA, and "w[ere] then changed by the patient on an as-desired basis during the course of the study as is typical for standard SCS therapies." *Id*. at 6:48-53. In other words, the asserted claims of the Alataris patents recite ranges that the patents themselves refer to as "standard SCS treatment"—and then add that the signal is "non-paresthesia-producing."

The Park Patents: Nevro also alleges that the accused devices infringe at least claim 1 of the '112 and '286 patents (collectively, "the Park patents"). The Park patents name a single inventor, Wesley Park, and are in the same family as the '978 patent, mentioned above. D.I. 1 at ¶33. The Park patents claim a priority date of November 7, 2013—after Mr. Park left Boston Scientific to join Nevro. Like the Alataris patents, the Park patents recite conventional SCS parameters. Nevro prosecuted these claims alongside litigation over the '978 patent. Claim 1 of the '112 patent is directed to an SCS system wherein a portion of the therapy signal is at a frequency from 500 to 1,200 Hz,[4] pulse width from 10-50 microseconds and an amplitude of 0.5 to 7 mA. Similarly, claim 1 of the '286 patent is directed to a method of programming an SCS device to generate a therapy signal at a frequency

[4] In Delaware II, Nevro is trying to add a doctrine of equivalents contention for the '978 patent (specifying 1.2 kHz) to cover this precise range of frequencies. Nevro moved for leave to amend its contentions to add this new theory in February 2021. That motion currently is before Magistrate Judge Burke. D.I. 511.

of 500 to 1,200 Hz, pulse width from 10-50 microseconds and an amplitude of 0.5 to 20 mA. And, like the others, the claims add "non-paresthesia-producing" to these standard parameters.

The written description of the Park patents discloses that "[i]n general, the short pulse width characteristics of the signal, alone or in combination with other signal parameters (e.g., frequency and/or amplitude) can produce pain relief without using the generation of paresthesia to mask the patient's sensation of pain." D.I. 1, Ex. 1 at 2:28-33. While the Park patents describe the invention as short pulse widths (10-50 microseconds) for the treatment of pain, Nevro's complaint alleges that they should be read to cover a broader range of conventional SCS parameters. Specifically, Nevro alleges that the range of conventional pulse widths from 50-200 microseconds is "equivalent" and should be found to infringe. D.I. 1, Ex. 2 at 12.

During prosecution, the PTO expressly recognized that the Park claims recite conventional SCS devices and programming. In particular, the PTO determined that the prior art discloses an SCS system with all of the programming parameters recited in the claims, "wherein at least a portion of the therapy signal is at a frequency in the frequency range from about 500 Hz to about 1200 Hz . . . with a pulse width in a pulse width range from 10 microseconds to 50 microseconds . . . and a current amplitude in a current amplitude range from 0.5 mA to 20 mA . . . and transmit[s] the therapy signal to the dorsal column of the patient's spinal cord." Elsby Dec. Ex.

A at 3 (June 25, 2019 Non-Final Rejection). In response, Nevro cancelled the rejected claims. Elsby Dec. Ex. B at 2 (Sept. 25, 2019 Applicant Response and Amendement). As to the remaining claims, which also included those conventional parameters (*compare* Elsby Dec. Ex. C at (claim 2) to *id* at (claim 14)), the Patent Office determined that the only feature distinguishing them over the prior art was the "concept" of paresthesia free therapy. Elsby Dec. Ex. D at 7 ('286 patent, Notice of Allowance). Nonetheless, in February 2021, even though Nevro knew the limitations of the '978 patent, it filed this complaint.

C. The Accused Products and Conventional SCS Technology

As described in the Asserted Patents, SCS therapy works by applying electrical signals generally defined by their frequency, pulse width, and amplitude to a patient's spinal cord. Conventional SCS systems include an implantable pulse (or signal) generator that is electrically coupled to leads that are typically implanted in a patient's epidural space. *See, e.g.*, D.I. 1, Ex. 1 at 1:30-39. Well prior to Nevro's existence, BSC independently developed its own SCS technologies and treatment protocols to provide patients with enhanced pain relief both with and without paresthesia. *See* D.I. 1 at FN1 ("Oakley 2007") (attached as Elsby Dec. Ex E).

The parameters described as "standard" in the Asserted Patents and recited in the asserted claims were found in BSC's devices from the company's inception, as confirmed by the Oakley 2007 reference cited in the complaint, BSC's FDA

approved label, and Nevro's previous statements in California and the related appeal. BSC's first device, the Precision™ SCS System received marketing approval from the FDA in 2004 and operated at the parameters in the asserted claims and within the same range of waveform parameters as the Accused Devices.[5] Elsby Dec. Ex. F. In particular, BSC's prior art Precision SCS System operated at a frequency range of 2-1200 Hz, a pulse width range of 20-1000 microseconds, and an amplitude range of 0-20 milliamps. Elsby Dec. Ex. G at 3 (Summary of Safety and Effectiveness)[6]; D.I. 1 Ex. 2 at 23. The operating capabilities of BSC's prior art Precision SCS System are also disclosed in the Oakley 2007 reference cited in the complaint. Elsby Dec. Ex. E at 263. BSC's first Precision™ SCS System also included the ability of the device to produce biphasic pulses. Elsby Dec. Ex. G at 3; *see also* Ex. E at 263 ("The system…has the capacity to deliver up to 12.7 mA current-controlled, asymmetrical, biphasic, charge-balanced stimulation pulses...").

[5] Matters of public record may be considered without converting a motion to dismiss into a motion for summary judgment. *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993). Courts in this District regularly take judicial notice of public records of the FDA attached to a motion to dismiss. *See, e.g.*, *Freed v. St. Jude Med., Inc.*, C.A. No. 17-1128, 2017 WL 4102583, at *2 (D. Del. Sept. 15, 2017).

[6] The Court may take judicial notice of the contents of the FDA's Summary of Safety and Effectiveness. It is a publicly available document that sets forth the operational capabilities of the Precision SCS System and the bases for the FDA's approval. Its contents are not subject to reasonable dispute. *See* Fed. R. Evid. 201 (b).

IV. ARGUMENT

A. Legal Standards

Section 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. However, Section 101 "contains an important implicit exception: '[L]aws of nature, natural phenomena, and abstract ideas' are not patentable.'" *Mayo*, 566 U.S. at 70 (alteration in original) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

Determining whether a claim is directed to patent-ineligible subject matter involves two steps. Step One "evaluate[s] 'the focus of the claimed advance over the prior art' to determine if the claim's 'character as a whole' is directed to excluded subject matter.'" *Intellectual Ventures I LLC v. Capital One Fin. Corp.*, 850 F.3d 1332, 1338 (Fed. Cir. 2017) (quoting *Affinity Labs of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1257 (Fed. Cir. 2016)); *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014). Step Two "look[s] with more specificity at what the claim elements add, in order to determine 'whether they identify an 'inventive concept' in the application of the ineligible subject matter' to which the claim is directed." *Capital One*, 850 F.3d at 1338 (quoting *Affinity Labs*, 838 F.3d at 1258). Claims directed to natural phenomena are ineligible for patenting when, apart from the natural

phenomenon, "[they] involve well-understood, routine, conventional activity previously engaged in by researchers in the field." *Mayo*, 566 U.S. at 73.

To state a claim on which relief can be granted, a complaint must set forth enough facts, accepted as true, to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (citation omitted). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). When assessing the merits of a Rule 12(b)(6) motion to dismiss, a court must accept as true all factual allegations in the complaint and in documents explicitly relied upon in the complaint, and it must view those facts in the light most favorable to the plaintiff. *See Umland v. PLANCO Fin. Servs.*, 542 F.3d 59, 64 (3d Cir. 2008); *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (internal quotation marks omitted).

Because patent eligibility is ultimately a question of law, the Federal Circuit has repeatedly held that Section 101 arguments may be resolved at the pleading stage. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018).

B. The Asserted Claims Are Directed to a Patent Ineligible Natural Phenomenon under the *Alice/Mayo* Test

1. *Alice* Step 1 – The Asserted Claims Are Directed to the Patient Response to Standard SCS Therapy

The asserted claims[7] are directed to the natural phenomenon of paresthesia-free therapy with conventional instructions to apply it. Although the asserted claims recite devices and methods of programming, there are no technical details or improved functionality underlying the claims—they are just directed to the paresthesia-free natural phenomenon delivered by standard devices in standard ways. *See WhitServe LLC v. Dropbox, Inc.*, Civ. No. 18-665-CFC, 2019 WL 3342949, at *5 (D. Del. Jul. 25, 2019).

Nevro admits that paresthesia-free therapy is the "key distinguishing feature" of its claims. According to Nevro, it has "patent claims *directed to lower frequency paresthesia-free therapy*" (D.I. 1 at ¶17), and "[i]f BSC is permitted to continue selling *paresthesia-free device[s],* Nevro will lose *its key distinguishing feature*…" *Id*. at ¶18 (emphasis added); *see also id.* at ¶33 (regarding Nevro's assertion of the '978 patent, which Nevro described as "another patent *directed to paresthesia-free therapy*.") (emphasis added).

[7] The Complaint specifically alleges infringement of only claim 1 of each of the Asserted Patents, which are each representative of the claims that Nevro may assert against the accused devices.

The written descriptions of the Asserted Patents confirm the claims are directed to a natural phenomenon and nothing more. For example, the Park patents disclose the application of a signal at known pulse widths and "appropriate" amplitudes to provide therapy without paresthesia in some patients, but identify no other technological process or limitation required to achieve the natural phenomenon. D.I. 1, Ex. 1 at 9:26-31 ("an expected benefit of short pulse width waveforms (e.g., having pulse widths within the ranges described above) is that when applied at the appropriate amplitude, to the appropriate neural population, such pulses can effectively reduce or eliminate patient pain without the signal producing, creating, or generating paresthesia.").

The Alataris patents similarly explain: "The present technology is directed generally to spinal cord modulation and associated systems and methods for inhibiting pain via waveforms . . . generally with reduced or eliminated side effects," e.g., paresthesia. D.I. 1, Ex. 5 at 2:52-56. Tellingly, following a series of rejections, cancellations and amendments, the examiner only allowed claims due to the reliance on "the concept of generat[ing] a non-paresthesia-producing therapy signal." Elsby Dec. Ex. D at 7. Again, the programming was ordinary, and it was the "concept," i.e., the natural phenomenon, that got the claims to issue.

In this way, the asserted claims are indistinguishable from other claims found to recite laws of nature and natural phenomena. For example, the Supreme Court in

Mayo found methods of optimizing a therapy that relied on "relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm" to set forth a law of nature:

> While it takes a human action (the administration of a [] drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. … And so a patent that simply describes that relation sets forth a natural law.

Mayo, 566 U.S. at 77. So too here—while programming an SCS system requires human action, the absence of paresthesia is a consequence of the body's natural reaction to SCS stimulation that exists separate and apart from any human action. Thus, claims that simply recite the absence of paresthesia in response to standard programming are directed to only the natural phenomenon.

Similarly, in *INO Therapeutics LLC v. Praxair Distribution, Inc.*, the Federal Circuit held claims to methods that specified natural conditions under which certain patients should be excluded from treatment were directed to a natural phenomenon; namely, the relationship between administering nitric oxide and the occurrence of pulmonary edema in certain patients. 782 F. App'x 1001 (Fed. Cir. 2019). Like the patent in *INO*, the claims here rely on the relationship between conventional electrical stimulation and its tendency to cause a particular human response in some patients—paresthesia or tingling. Such a response is the natural consequence of physiology that exists apart from any human action. And because the asserted claims

are directed to conventional programming of conventional SCS devices, all that is left is the observation of the natural phenomenon.

2. *Alice* Step 2 – The Additional Limitations are Routine and Conventional

At Step Two, "simply appending conventional steps, specified at a high level of generality" to the claimed discovery does not make ineligible subject matter patentable. *Mayo*, 566 U.S. at 82. To satisfy Section 101, claims must recite "significantly more" than routine and conventional programming or features to transform the natural phenomenon into patent eligible subject matter.[8] Here, BSC's prior art devices, Nevro's previous litigation positions, the written descriptions of the Asserted Patents and their prosecution histories all confirm that the parameters, devices and methods recited in the claims are all part of the prior art, and differentiated only by the "concept" of paresthesia-free therapy.

[8] In the California Action, Nevro asserted other claims of the '988 and '357 patents that are not asserted here. Those claims, however, recited the additional limitation related to Nevro's "high frequency" work (which Nevro now admits BSC does not practice). The subject matter eligibility of claim 18 of the '988 patent, one such "high frequency" claim, was addressed in *Nevro Corp. v. Boston Scientific Corp.*, C.A. No. 3:16-cv-06830, D.I. 449. The district court granted Nevro's motion for summary adjudication that claim 18 of the '988 patent was not patent ineligible because it recited ***high frequency*** signals using ***a special purpose device***, i.e., SCS devices capable of operating above previously-approved range of 0-1,200 Hz. *Id.*; *see also* D.I. 342 at 28-29. No such features are recited in the asserted claims here. To the contrary, the asserted claim of the '988 patent here has ***no*** frequency requirement, and no special purpose device. The district court did not address the eligibility of the claims of the '357 patent.

The Asserted Patents do not even purport to cover novel SCS devices, and Nevro makes no attempt to plead otherwise in the complaint—the only feature Nevro identifies as allegedly differentiating its asserted claims from the prior art is the concept of paresthesia-free therapy. And, as mentioned above with respect to Step One, there is no unique technological process by which Nevro generates "paresthesia-free therapy." This fact was confirmed during the claim construction hearing for the '978 patent where Nevro argued that the "programming" language in the claims refers to plain and ordinary programming.[9] Put simply, there is no "special sauce" set forth in the claims or the written description for Nevro's claimed paresthesia-free programming.

Nevertheless, Nevro alleges that it developed "unique programming" to "provide pain relief without generating paresthesia." D.I. 1 at ¶6. But using conventional devices programmed at well-known parameters to perform their ordinary function does not amount to an inventive concept. *See Solutran, Inc. v. Elavon, Inc.*, 931 F.3d 1161, 1169 (Fed. Cir. 2019) ("Merely using a general-purpose computer and scanner to perform conventional activities in the way they always have, as the claims do here, does not amount to an inventive concept."). Nevro's so-

[9] *Boston Scientific Corp. v. Nevro Corp.*, C.A. No. 16-1163, D.I. 438 at 44-46 (D. Del. Dec, 9, 2020) ("The remainder of this term should be given its plain and ordinary meaning as the words "programmed"/"programming" are well-known to those in the art and easily understood.").

called "unique programming" parameters were all routine and conventional at the time Nevro filed its patent applications, and therefore, fail to provide an inventive concept as a matter law under. *See* Elsby Dec. Ex. H (claim chart).

More specifically, the waveform parameters recited in the asserted claims were available, approved by the FDA, and used in commercial SCS devices before Nevro's earliest priority date. For example, as described in Oakley 2007 (relied on by Nevro in the Complaint) and shown below, BSC's Precision SCS System operated at all of the claimed parameters and was approved to do so in 2004 (5 years before the filing of the Alataris patents and 9 years before the filing of the Park patents)[10]:

<table>
<tr><th>Patents-in-Suit</th><th>BSC's 2004 Precision™ SCS System</th></tr>
<tr><td>'112 Patent Claim 1: A spinal cord stimulation system … the system comprising:
• amplitude from 0.5 mA to 7 mA
• frequency of from 500 Hz to 1,200 Hz
• pulse width from 10 microseconds to 50 microseconds,</td><td>
<table>
<tr><th>Parameter</th><th>Range</th><th>Default</th></tr>
<tr><td>Areas (Channels)</td><td>4</td><td>—</td></tr>
<tr><td>Amplitude</td><td>0 – 20 mA[a]</td><td>0 mA</td></tr>
<tr><td>Rate</td><td>0 – 1200 pps</td><td>40 pps</td></tr>
<tr><td>Width</td><td>0 – 1000 µsec</td><td>210 µsec</td></tr>
</table>
</td></tr>
</table>

During a prior appeal to the Federal Circuit in the California Action, Nevro admitted as much. *Nevro Corp. v. Boston Scientific Corp.*, C.A. No. 2018-2220, D.I.

[10] Because no individual claim contains limitations that raise distinct issues for determining that claim's § 101 eligibility, it is appropriate to treat them collectively. *See Content Extraction & Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343, 1348 (Fed. Cir. 2014) (holding that substantially similar claims directed to the same abstract idea can be considered together for subject matter eligibility).

29 at 7 (Fed. Cir. Nov. 15, 2018) ("[T]raditional low-frequency spinal cord stimulation have been marketed for decades. Appx9725-9726. The FDA has approved such low-frequency systems for use between 2 and 1,200 Hz."). The prosecution histories for both the Alataris and Park patents confirm that Nevro's claimed parameters fall within the range of known and conventional parameters. Elsby Dec. Exs. A at 4, D at 7, J at 5. Thus, it is not just the individual parameters that were known, the "ordered combinations" were known as well. Nevro cannot disputed that all of the claimed programming parameters fall within the prior art of record during prosecution and were found in FDA-approved devices on the market before Nevro's earliest priority date.

Aside from the conventional waveform parameters, only three other limitations remain among the asserted claims: (1) the signal delivery device is coupled to the implantable signal generator to deliver the therapy signal to the dorsal column (Park patents); (2) biphasic pulses (Alataris patents); and (3) the T9-T12 vertebral location (claim 1 of the '988 patent). All of these are similarly conventional and long a part of standard SCS therapy. *See* Elsby Dec. Ex. H.

***Dorsal column*:** The prosecution history of the '286 patent makes clear this limitation was routine and ordinary before the Park patents were filed. Elsby Dec. Ex. A at 4. And, as the Alataris patents recognize, even paresthesia-based therapy transmits signals to the dorsal column: "One effect [of standard SCS therapy] is an

orthodromic effect transmitted along the *dorsal column*…" D.I. 1, Ex. 5 at 14:28-30. Oakley 2007 reinforces the conventional nature of dorsal column stimulation, explaining that implantation of leads in the epidural space is done at the midline to "recruit more fibers in the dorsal column." Elsby Dec. Ex. E at 274.

***Biphasic pulses*:** BSC's Precisions SCS System features similarly shows biphasic pulses were conventional in the SCS field. Elsby Dec. Ex. G at 3. In fact, this limitation was incorporated in BSC's earliest 2004 SCS devices—it is neither new nor unique to paresthesia-free therapy:

> Implantable Pulse Generator - Model SC-1100
>
> The IPG enclosure is made of titanium alloy, with the dimensions of 55 mm (height), 46 mm (width) and 11 mm (thickness). It is hermetically sealed. The IPG is designed to produce a capacitively coupled monophasic or biphasic rectangular output pulse. The IPG is current regulated and includes programmable coverage areas with each individual electrode contact limited to 12.7 mA. A programming interlock is enforced to limit the coverage area output current to 20 mA or less. The IPG is capable of producing pulse widths between 20 and 1000 µs and frequencies between 2 and 1200 Hz.

Id. Again, Oakley 2007 confirms this feature was standard in BSC's prior art Precision SCS System. Elsby Dec. Ex. E at 263.

***Vertebral Locations*:** Nevro's recited lead locations, to the extent they are limiting, do not amount to an inventive concept. First, a vertebral location is not a feature of an SCS device or a parameter that Nevro conceived—it is a physical location on the body. Second, as the Alataris patents disclose, the lead location is not an inventive aspect of the claims: "the presently disclosed techniques are relatively insensitive to lead position." D.I. 1, Ex. 5 at 18:31-32. Third, as found by

the examiner during prosecution of the '286 patent, "different patients respond to stimulation different, and discovering the optimal parameters of stimulation requires only *routine skill* in the art." Elsby Dec. Ex. A at 4-5 (emphasis added).

Finally, even if taken as a whole, Nevro's purportedly "unique programming" merely recites well-known program parameters used in their ordinary course with conventional SCS devices that Nevro attempts to distinguish from the prior art only by the addition of the words "paresthesia-free." Under *Alice* and *Mayo*, that natural phenomenon, even if treated as new, is not enough to render the asserted claims patentable. *Genetic Techs.*, 818 F.3d at 1376.

V. CONCLUSION

For the foregoing reasons, the Court should grant BSC's Motion and dismiss Nevro's claims because they are directed to patent ineligible subject matter.

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Respectfully submitted,

FARNAN LLP

/s/ Michael J. Farnan

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 Market Street
12th Floor
Wilmington, Delaware 19801
(302) 777-0300
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Defendants Boston Scientific Corporation and Boston Scientific Neuromodulation Corp.

Of Counsel (pro hac to be filed):

Michael P. Kahn
Michael N. Petegorsky
AKIN GUMP STRAUSS HAUER & FELD LLP
One Bryant Park, Bank of America Tower
New York, NY 10036-6745
(212) 872-1000
mkahn@akingump.com
mpetegorsky@akingump.com

Rachel J. Elsby
AKIN GUMP STRAUSS HAUER & FELD LLP
Robert S. Strauss Tower
2001 K Street, N.W.
Washington, DC 20006-1037
(202) 887-4000
relsby@akingump.com

Steven D. Maslowski
AKIN GUMP STRAUSS HAUER & FELD LLP
Two Commerce Square
2001 Market Street, Suite 4100
Philadelphia, PA 19103-7013
(215) 965-1200
smaslowski@akingump.com

Matthew M. Wolf
ARNOLD & PORTER KAYE SCHOLER LLP 601 Massachusetts Ave., NW
Washington, DC 20001-3743
(202) 942-5000
matthew.wolf@arnoldporter.com

CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order for All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 2,483 words, excluding the case caption, signature block, table of contents and table of authorities.

/s/ Michael J. Farnan
Michael J. Farnan (Bar No. 5165)

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