IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORP. and BOSTON SCIENTIFIC NEUROMODULATION CORP.,	)	
Plaintiffs,	)	C.A. No. 16-1163 (GMS)
v.	)	
NEVRO CORP.,	)	
Defendant.	)	

DEFENDANT NEVRO CORP.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS PURSUANT TO FED. R. CIV. P. 12(B)(6)

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I. INTRODUCTION

Plaintiffs Boston Scientific Corp. and Boston Scientific Neuromodulation Corp.'s (collectively, "BSC") Complaint is devoid of facts that raise any plausible basis of infringement for any of their 10 asserted patents. The Complaint, filed on December 9, 2016, comes just 11 days after Defendant Nevro Corp. ("Nevro") filed a patent infringement suit against BSC in the Northern District of California to stop BSC's infringing use of Nevro's patented innovations on spinal cord stimulation ("SCS") technology for the treatment of chronic pain. *Nevro Corp. v. Boston Scientific Corp. et al.*, Case No. 3:16-cv-06830-VC (N.D. Cal. Nov. 28, 2016). In BSC's rush to the courthouse, they prepared a complaint evocative of abrogated Form 18, lacking the basic factual assertions required by *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). This motion is brought to dismiss all of BSC's claims under Federal Rule of Civil Procedure 12(b)(6) for failing to satisfy the *Twombly*/*Iqbal* standard.

The deficiencies in BSC's hastily prepared Complaint not only run afoul of Supreme Court precedent, but they are also inexcusable given that BSC has been fully aware of Nevro's accused Senza® system for nearly six years. Nevro's Senza® system, the SCS product that BSC accuses here, has been on the market for six years. It launched overseas in 2011 and in the U.S. in 2015, revolutionizing the treatment of chronic pain by using, for the first time, high frequency electrical pulses delivered to the spinal cord. There was much industry skepticism of Nevro's approach, which was contrary to the SCS industry's traditional reliance on low frequency electrical pulses to generate a sensation called "paresthesia" to mask pain. But Nevro's paresthesia-free high frequency approach has proven to be far more effective at treating chronic pain than traditional low frequency therapy.

Low frequency SCS is what BSC has historically marketed. Not surprisingly, 9 out of the 10 asserted patents are directed to conventional sub-components of any SCS system,

such as rechargeable batteries and electrode leads, and the only system patent in the collection is designed for traditional low frequency SCS systems employing paresthesia to mask pain. None relates to high frequency SCS technology. Indeed, before the Senza® system's U.S. launch in May 2015, BSC participated in a head-to-head clinical trial monitored by the Food & Drug Administration ("FDA"), which led to the FDA awarding Nevro's Senza® system an industry-first "superiority" label in a direct comparison to BSC's traditional low frequency system.

BSC's highly deficient Complaint does not contain any factual allegations about the accused Senza® system or how it relates to BSC's claims of infringement. BSC must have some factual basis for asserting infringement of each of the patents-in-suit. *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1300-01 (Fed. Cir. 2004). The Complaint, however, contains no such facts. Rather, BSC parrots the conclusory "make, use, sell" language of the Patent Act for each direct infringement allegation. That is no different from the Form 18 minimal pleading standard, which was abrogated over a year ago. BSC's allegations of indirect infringement, infringement based upon exported components, and willfulness are no better. In addition to their insufficiently pled underlying direct infringement claims, they fail because they are also devoid of any facts to plausibly suggest actual knowledge of the asserted patents and/or infringement that those claims require. The fact that BSC brought suit against Nevro by filing a Complaint devoid of any facts, despite having been aware of Nevro's technology for nearly six years, belies the merits of BSC's allegations in the present action.

In an attempt to avoid potentially unnecessary motion practice, Nevro has met and conferred with BSC and asked BSC to amend the Complaint to comply with the *Twombly*/*Iqbal* standard. Specifically, Nevro asked BSC whether BSC would agree to amend prior to Nevro's current January 30 deadline (D.I. 6) to respond to the Complaint. BSC has declined to amend in

advance of Nevro's deadline, leaving Nevro no choice but to proceed with the present motion. Accordingly, Nevro requests that the Court dismiss the present Complaint pursuant to Rule 12(b)(6) for failure to state any viable claim. *See* Fed. R. Civ. P. 12(b)(6).

II. NATURE AND STAGE OF THE PROCEEDING

On December 9, 2016, BSC filed the Complaint in this action against Nevro, asserting that Nevro's Senza® spinal cord stimulation system infringes 10 patents. (D.I. 1 ¶ 1). Nevro brings the present motion in response to BSC's Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) (hereinafter "Rule 12(b)(6)").

III. SUMMARY OF ARGUMENT

All of BSC's claims should be dismissed pursuant to Rule 12(b)(6) for failing to allege sufficient facts to state plausible claims of direct infringement, indirect infringement, export infringement, and willful infringement.

1. BSC's allegations of direct infringement are cursory repetitions of the statutory "make, use, sell" language. They fail to set forth basic facts concerning the accused Senza® system and how they relate to the asserted patents. Consequently, no reasonable inference of infringement may be drawn from the bare assertions in the Complaint.

2. BSC's claims of indirect infringement are even more lacking. Not only do these claims fail because any allegation of underlying direct infringement is insufficient, but there are no facts to support even an inference that Nevro knew of the asserted patents before this lawsuit and specifically intended to induce or contribute to their infringement. BSC's contributory infringement claims are additionally deficient because the Complaint does not identify any particular components that supposedly contribute to any infringement, and contains

no facts to support any inference that the accused system and its components are especially made or adapted for use in a patented combination and have no substantial non-infringing uses.

3. BSC's export infringement claims are deficient, not only due to the lack of factual allegations concerning knowledge and intent that they too demand, but also for the additional reason that the Complaint simply recites the statutory language with no factual enhancement and fails to identify infringing conduct commensurate with the scope of each patent.

4. Finally, BSC's willful infringement claims fail because the Complaint lacks factual assertions concerning Nevro's pre-suit awareness of infringement and because there are no factual allegations of any intent with respect to infringement or any egregious pre-litigation conduct.

IV. STATEMENT OF FACTS

A. The Accused Senza® System

Nevro was founded in 2006 to develop a novel SCS technology for the treatment of chronic pain. SCS therapy has been used for nearly 40 years to treat chronic pain. Before Nevro, the SCS industry relied on "low frequency" electrical waveforms to generate paresthesia —a sensation of tingling, numbness, buzzing, or pins-and-needles—to mask, not eliminate pain.

The SCS system that Nevro created, called the Senza® system,[1] uses a high frequency therapy that is paresthesia-free. The Senza® system is a medical device that is surgically implanted in a patient's back. It applies high frequency electrical pulses to the spinal

[1] As shown below BSC's Complaint does not allege any facts about the accused Senza® System or how they relate to BSC's infringement allegations. For context, Nevro provides some facts here from public sources, such as Nevro's website, or from judicially noticeable documents, such as Nevro's SEC filings and documents available on the FDA's website.

cord at a rate of 10,000 pulses per second (10,000 Hz or 10 kHz), which Nevro commercially markets as HF10™ therapy.[2] HF10™ therapy is a stark departure from traditional SCS therapies that relied on the use of low frequency electrical pulses (typically between 50 Hz and 60 Hz) to induce paresthesia. BSC has long marketed such traditional, low frequency SCS systems and paresthesia-based therapies.

Nevro's Senza® system has been on the market for years. Nevro received CE Mark in 2010 and has been selling the Senza® system in Europe and Australia since 2011. Nevro received FDA approval in May of 2015, and the Senza® system has been on the U.S. market ever since. In an FDA-monitored randomized, controlled trial pitting Nevro's Senza® system directly against BSC's paresthesia-based low frequency SCS product, Nevro's technology proved to be nearly twice as effective at relieving chronic pain as BSC's.[3] As a result, when the FDA cleared Nevro's Senza® system for sale in the U.S. on May 8, 2015, it awarded the Senza® system a "superiority" label—a rare occurrence in the medical device field and the first ever in the SCS industry.

Like other commercially available SCS systems, the Senza® system consists of an implantable pulse generator (IPG), leads, surgical tools, a clinician laptop programmer, a

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[2] *See* http://www.nevro.com/English/Physicians/Senza-System/default.aspx (last accessed January 30, 2017). Nevro's Senza® system and its HF10™ therapy are covered by over 100 U.S. and international patents. http://www.nevro.com/English/Patents/default.aspx (last accessed January 30, 2017).

[3] *See* Kapural *et al.*, "Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain," *Anesthesiology*, 123(4) (available at http://anesthesiology.pubs.asahq.org/article.aspx?articleid=2411790&resultClick=3, last accessed January 30, 2017).

patient remote control, and a mobile charger. These components of the Senza® system enable physicians to implant the leads and the IPG, and enable patients to operate the system.[4]

B. The Asserted Patents

BSC claims that Nevro's Senza® system infringes 10 of its patents: U.S. Patent No. 6,895,280 (the "'280 patent"); U.S. Patent No. 7,428,438 (the "'438 patent"), U.S. Patent No. 7,437,193 (the "'193 patent"), U.S. Patent No. 7,587,241 (the "'241 patent"), U.S. Patent No. 7,891,085 (the "'085 patent"), U.S. Patent No. 8,019,439 (the "'439 patent"), U.S. Patent No. 8,644,933 (the "'933 patent"), U.S. Patent No. 8,646,172 (the "'172 patent"), U.S. Patent No. 8,650,747 (the "'747 patent"), and U.S. Patent No. 9,370,664 (the "'664 patent") (collectively, the "asserted patents"). (D.I. 1). The 10 asserted patents mostly relate to parts or subparts of a traditional, paresthesia-based SCS system. Nine of the patents pertain to standard components of such SCS systems, such as rechargeable batteries, implantable stimulators, and leads.[5] The one system patent in the collection is directed to a system designed to carry out low frequency, paresthesia-based SCS therapy. None of BSC's asserted patents are directed to the therapeutic method and waveforms utilized in the SCS devices, which are at the heart of Nevro's revolutionary SCS technology.

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[4] *See* http://www.nevro.com/English/Physicians/Senza-System/default.aspx; *see generally documents available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130022 (last accessed January 30, 2017).

[5] The '438 patent claims a system for recharging a battery for an implantable stimulator. The '193 patent claims a rechargeable implantable stimulator. The '241 patent claims a method for monitoring and controlling an implantable device's functions based on power source. The '085, '439, '172, '747 patents all pertain to stimulation leads, including methods of manufacturing leads, particular types of leads, and an assembly for making leads. The '933 patent claims an external charger for an implantable device. The '664 patent claims an implantable medical device with error modulators that behave a particular way.

BSC asserts various theories of direct and indirect patent infringement under 35 U.S.C. §§ 271(a), (b), (c), (f), and (g), but recites scant facts as the basis for those claims. (*Id.*)

V. LEGAL PRINCIPLES

To survive a motion to dismiss under Rule 12(b)(6), a complaint must set forth sufficient factual matter that, accepted as true, "state[s] a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. Plausibility requires more than a "sheer possibility" that a defendant has acted unlawfully, it requires "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). A pleading is therefore insufficient if it merely offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" or "'naked assertion[s]' devoid of 'further factual enhancement.'" *Id.* (quoting *Twombly*, 550 U.S. at 555, 557) (alteration in original).

Given the emphasis on factual pleading, a court is not obligated to accept as true "bald assertions," *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997), "unsupported conclusions and unwarranted inferences," *Schuylkill Energy Res., Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are "self-evidently false," *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

The Federal Circuit has long held that claims other than those for direct infringement must satisfy the *Twombly*/*Iqbal* standard. *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1336 (Fed. Cir. 2012). On December 1, 2015, the Federal Rules of Civil Procedure were amended to abrogate Rule 84 and the Appendix of Forms,

including Form 18, which had set forth a sample bare-bones complaint for direct patent infringement. *See* Supreme Court of the United States, Order Regarding Amendments to the Federal Rules of Civil Procedure (Apr. 29, 2015). As a result, all allegations of patent infringement are now held to the standards set forth in *Twombly* and *Iqbal*, including direct infringement claims. *See, e.g.*, *Raindance Techs., Inc. v. 10x Genomics, Inc.*, C.A. No. 15-152-RGA, 2016 WL 927143, at *2 (D. Del. Mar. 4, 2016).

VI. ARGUMENT

The allegations in BSC's Complaint are simply formulaic recitations of the statutory elements of each cause of action devoid of factual support. They should be dismissed for failure to satisfy Federal Rule of Civil Procedure 8(a) and the *Twombly*/*Iqbal* standard.

A. BSC's Direct Infringement Claims Should Be Dismissed

BSC's allegations of direct infringement are the type of bare assertions that might have sufficed under Form 18, but have since been deemed insufficient to satisfy the *Twombly*/*Iqbal* standard. The Complaint merely identifies an accused product by the name of the system as a whole—the Senza® system—and one or more claims of 10 patents by number that are purportedly directly infringed, with no further factual allegations. (*See, e.g.*, D.I. 1 ¶¶ 1, 12, 22, 32, 42, 58, 69, 97, 98). There are no facts about the accused system or its specific components to constitute factual support for BSC's conclusions of infringement. Such averments are so broad and generic that they fail to provide Nevro with notice concerning which activities and functionalities are implicated by which patents.

District courts applying the *Twombly*/*Iqbal* standard have held that claims of direct infringement should be supported by facts reasonably establishing that the accused product falls within the scope of at least one claim. *Raindance*, 2016 WL 927143, at *2; *Atlas IP, LLC v.*

Exelon Corp., No. 15 C10746, 2016 WL 2866134, at *5 (N.D. Ill. May 17, 2016) ("factual allegations that do not permit a court to infer that the accused product infringes each element of at least one claim are not suggestive of infringement—they are merely compatible with infringement."); *Robern, Inc. v. Glasscrafters, Inc.*, No. CV 16-1815, --- F. Supp. 3d ---, 2016 WL 3951726, at *5 (D.N.J. July 22, 2016). BSC's direct infringement allegations fall far short of this mark.

The 10 asserted patents include apparatus, method of use, and method of manufacturing claims. For the patents that claim an SCS system or its components (*i.e.*, '280, '438, '193, '439, '933, '747, and '664 patents), BSC's allegations are a bare recital of the statutory language, asserting that Nevro infringes "at least" one identified claim by "making, using, offering to sell, selling, and/or importing in and into the United States" the Senza® system. (D.I. 1 ¶¶ 12, 22, 32, 58, 69, 87, 98). Moreover, the vast majority of the asserted patents are directed to components or subcomponents of an SCS system. But BSC's Complaint does not attempt to distinguish among the parts of the accused Senza® system, nor does it relate any asserted patent to the particular part accused of infringing. Indeed, there are no facts concerning the accused product at all, let alone factual assertions sufficiently related to the asserted claims from which any reasonable inference could be drawn as to whether the accused "Senza System" meets each element of at least one claim of each patent. *See Raindance*, 2016 WL 927143, at *2 (dismissing complaint because "Plaintiff makes no attempt to relate any of their factual assertions with any of the asserted claims").

BSC's allegations of direct infringement of patents that claim methods of use and manufacturing are equally deficient. For the '241 patent, which recites "a method for controlling an implantable medical device" (D.I. 1 Ex. D), the Complaint in a conclusory manner alleges

acts such as "using" the Senza® system, with no further facts to demonstrate that the alleged use meets the elements of the claimed method. (D.I. 1 ¶ 42). Similarly, for patents that claim methods of manufacture (*i.e.*, '085, '439, '172, and '747 patents), BSC alleges that Nevro is "making in the United States the Senza System, including its leads" (*id.* ¶¶ 50, 79), or importing leads made abroad (*id.* ¶¶ 51, 63, 81, 92). Again, there are no facts from which it can be reasonably inferred that Nevro is conducting activities that infringe the claimed methods of the '085, '439, and '172 patents to manufacture leads for the Senza® system.

BSC's threadbare allegations of direct infringement based solely on identifying 10 asserted patents and an accused product do not render those claims plausible. Indeed, Judge Andrews recently dismissed similarly deficient claims, writing:

> Right now, Plaintiff makes two factual allegations. One, here are ten patents we own. Two, you sell some products, which we have identified. Plaintiff makes a legal conclusion, to wit, the sales of your products infringe out patents. This is insufficient to plausibly allege patent infringement.

SIPCO, LLC v. Streetline, Inc., --- F. Supp. 3d ---, C.A. No. 16-830-RGA, 2017 WL 277398, at *3 (D. Del. Jan. 20, 2017). The allegations in BSC's Complaint similarly fail to meet the plausibility standard of *Twombly* and *Iqbal* and should be accordingly dismissed. *Id.*; *Raindance*, 2016 WL 927143, at *2; *Robern*, 2016 WL 3951726, at *5 (dismissing direct infringement claims where plaintiff made "no attempt to describe the alleged infringement and also failed to relate factual assertions to the pertinent claims" in the asserted patent); *Andrulis Pharm. Corp. v. Celgene Corp.*, C.A. No. 13-1644-RGA, 2014 WL 1572906, at *1 (D. Del. Apr. 10, 2014) (dismissing undivided direct infringement of method claims for failing to plausibly plead that the defendant performs every step of the claimed method).

B. BSC's Indirect Infringement Claims Should Be Dismissed

As an initial matter, BSC's induced and contributory infringement claims should be dismissed because BSC has not sufficiently pled the requisite underlying direct infringement as explained in Section VI.A above, and liability for indirect infringement "may arise 'if, but only if, [there is] . . . direct infringement.'" *Evolved Wireless, LLC v. Samsung Elecs. Co.*, C.A. No. 15-545-SLR-SRF, 2016 WL 1019667, at *5 (D. Del. Mar. 15, 2016), *report and recommendation adopted*, 2016 WL 1381765 (D. Del. Apr. 6, 2016) (alteration in original) (quoting *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014)).

These indirect infringement claims should be dismissed for the additional reason that they fail to set forth necessary facts showing the additional required elements of knowledge and intent.

To state a claim for induced infringement under 35 U.S.C. § 271(b), a plaintiff "must show direct infringement, and that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012) (internal quotations omitted). Not only must the factual allegations show that the alleged infringer knew of the patent, they must also show that the alleged infringer specifically intended that the patent be infringed. *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328 (Fed. Cir. 2009); *see also Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1928 (2015) ("active inducement" under § 271(b) requires "intent to bring about the desired result, which is infringement" (internal quotations omitted)); *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011) ("induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement").

Contributory infringement similarly requires knowledge of and intent to infringe by providing components that the alleged infringer knows are especially made or adapted for use

in an infringing combination and have no substantial noninfringing uses. *See* 35 U.S.C. § 271(c); *Aro Mfg. Co. v. Convertible Red Top Replacemt. Co.*, 377 U.S. 476, 488 (1964); *MONEC Holding AG v. Motorola Mobility, Inc.*, 897 F. Supp. 2d 225, 231 (D. Del. 2012). The plaintiff must further "plead facts that allow an inference that the components sold or offered for sale have no substantial noninfringing uses." *In Re Bill of Lading*, 681 F.3d at 1337.

BSC's allegations of induced and contributory infringement are devoid of facts concerning Nevro's alleged pre-suit knowledge of any asserted patent, let alone specific intent to infringe.[6]

As to knowledge, BSC alleges in each count that "Nevro has had actual and constructive knowledge of the [asserted patents] *prior* to the filing of this Complaint." (D.I. 1 ¶¶ 17, 27, 37, 45, 53, 64, 74, 82, 93, 103 (emphasis added)). This is a bald assertion unsupported by any facts from which Nevro's purported knowledge can reasonably be inferred. It should be rejected as such. *Minkus Elec. Display Sys. Inc. v. Adaptive Micro Sys. LLC*, C.A. No. 10-666-SLR, 2011 WL 941197, at *3 (D. Del. Mar. 16, 2011) (rejecting as insufficient bare allegation that "[d]efendant[s][ ] had actual notice of infringement . . . before the filing of this complaint"). Nor would mere constructive knowledge of the asserted patents be sufficient for indirect infringement. *See, e.g.*, *Global-Tech.*, 563 U.S. at 766 (knowledge for § 271(b) requires actual knowledge or willful blindness).

BSC's intent allegations fare no better. For each assertion of induced infringement, BSC identifies general sales and marketing activities with the conclusion that Nevro "actively induced" infringement by unidentified others "with the intent that one or more

[6] As all of BSC's induced and contributory infringement claims are stated in the past-tense, it is not clear whether BSC has asserted claims of post-suit induced and contributory infringement. Those claims would also be deficient given the paucity of factual assertions to support an inference that Nevro specifically intended to infringe the asserted patents.

claims" of the asserted patents "be infringed." (D.I. 1 ¶¶ 13, 23, 33, 43, 51, 59, 70, 80, 88, 99). Those activities say nothing of knowing and specific intent to infringe the asserted patents. *MONEC*, 897 F. Supp. 2d at 232-35 (allegations that defendants participated in the same market and conclusory averments concerning marketing and sales activities insufficient to establish knowledge and specific intent). The contributory infringement claims are even more conclusory. Those claims merely parrot the statutory language, asserting that Nevro knows "the Senza System and/or one or more components" is especially made or adapted for infringement, without any facts as to how Nevro acquired this supposed knowledge or when it did so. (*See* D.I. 1 ¶¶ 14, 24, 34, 44, 60, 71, 89, 100). Indeed, there are no facts from which such knowledge can be inferred.

BSC's contributory infringement claims are also deficient because they generically refer to "components" of the Senza® system without identifying either the component(s) or the patented combination of which they are a material part or any facts that would support a reasonable inference that the alleged component has no substantial noninfringing use. *Weiland Sliding Doors & Windows, Inc. v. Panda Windows & Doors, LLC*, No. 10CV677 JLS (MDD), 2011 WL 3490471, at *4 (S.D. Cal. Aug. 10, 2011) (requiring identification of component); *Philips v. ASUSTeK Computer Inc.*, C.A. No. 15-1125-GMS, 2016 WL 6246763, at *4 (D. Del. Oct. 25, 2016) (dismissing contributory infringement claims where complaint "provides no facts supporting the inference that the Accused Functionalities have no substantial non-infringing uses" beyond generic assertions that "the only use" is "infringing the patent" and that the "Defendants know" this).

Courts routinely dismiss such poorly pled claims, and the claims here should be dismissed as well. *See Bonutti Skeletal Innovations LLC v. Smith & Nephew, Inc.*, C.A. No. 12-

1111-GMS, 2013 WL 6058472, at *1 n.5 (D. Del. Nov. 18, 2013) (dismissing similarly deficient indirect infringement claims); *HSM Portfolio v. Fujitsu Ltd.*, C.A. No. 11-770-RGA, 2012 WL 2580547, at *1 (D. Del. July 3, 2012) (same).

C. BSC's Export Infringement Claims Should Be Dismissed

BSC's § 271(f) claims—the "export infringement claims"—also require knowledge and intent, which are insufficiently pled. Moreover, the claims simply recite the statutory language and are so disconnected from each asserted patent that their infringement theory is unintelligible. (*See* D.I. 1 ¶¶ 15, 16, 25, 26, 35, 36, 61, 62, 72, 73, 90, 91, 101, 102).

Export infringement claims under 35 U.S.C. §§ 271(f)(1) and (2) are an exception to "the general rule under United States patent law that no infringement occurs when a patented product is made and sold in another country." *Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437, 441 (2007). To state a claim under § 271(f)(1), a plaintiff must demonstrate that the defendant supplies or causes to be supplied from the United States "all or a substantial portion of the components of a patented invention" "in such manner as to actively induce the combination of such components outside of the United States" in a manner that would infringe were the combination done inside of the United States. 35 U.S.C. § 271(f)(1). Similarly with respect to § 271(f)(2), a plaintiff must demonstrate the supply of "any component of a patented invention that is especially made or especially adapted for use in the invention" knowing that it is such and knowing "that such component will be combined outside of the United States" in a manner that would infringe were the combination done inside of the United States. 35 U.S.C. § 271(f)(2). Both §§ 271(f)(1) and (2) thus also require knowledge of the asserted patents and intent that the exported components will be combined in an infringing manner. *See Waymark Corp. v. Porta Sys. Corp.*, 245 F.3d 1364, 1367-68 (Fed. Cir. 2001) (§ 271(f)(2) requires intent that the exported

component will be combined); *Universal City Studios v. Nissim Corp.*, No. 14-81344-CIV-KAM, 2015 WL 1124704, at *3-5 (S.D. Fla. Mar. 12, 2015).

Because knowledge and intent to infringe are required to state claims under § 271(f), these claims should be dismissed due to the lack of factual allegations concerning Nevro's supposed knowledge and intent to infringe, as discussed above in Section VI.B. *See Universal City Studios*, 2015 WL 1124704, at *5-6 (dismissing § 271(f) claims for failure to allege knowledge and intent).

On top of that deficiency, the Complaint does not identify any component or components that are allegedly exported, does not allege facts to support any inference that Nevro intended those components to be combined abroad into an infringing apparatus, and sets forth no facts to show that the manner in which the purportedly exported components are combined abroad in an infringing manner that implicates the scope of each asserted patent claim. Just like its deficient assertions of direct infringement, BSC's § 271(f) allegations parrot the statutory language and do not attempt to relate any facts about the Senza® system to the asserted claims. This failure leaves Nevro with no notice concerning BSC's § 271(f) infringement theory.

For example, BSC charges Nevro with infringement of claims 11 and 26 of the '439 patent under § 271(f)(1), which claims are directed to a "stimulation lead." (D.I. 1 ¶ 61). But BSC's allegation does not identify which components Nevro allegedly exports in uncombined form or show how those components are combined abroad to infringe the '439 patent's claimed "stimulation lead":

> Nevro has supplied and/or caused to be supplied in or from the United States, and it continues to supply and/or cause to be supplied in or from the United States, ***the Senza System and/or one or more components of the Senza System, including its leads and subcomponents thereof***, which constitute all or a substantial portion of the components of the inventions claimed in the '439

> patent, including without limitation the inventions in at least claims 11 and 26 of the '439 patent, where such components are uncombined in whole or in part, and in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe at least claims 11 and 26 of the '439 patent if such combination occurred within the United States.

(D.I. 1 ¶ 61 (emphasis added)). BSC's allegations would suggest that exporting the Senza® system—which is a system that includes an implantable pulse generator (IPG), stimulation leads, a trial stimulator, surgical tools, a clinician laptop programmer, a patient remote control, and a mobile charger—or even exporting whole stimulation leads would violate § 271(f)(1). That claim is simply implausible, as neither the Senza® system as a whole nor a completed lead could conceivably be a "component" of the "stimulation lead" claimed by the '439 patent. And BSC's vague assertion about lead "subcomponents" does not identify which subcomponents constitute the accused instrumentality.

BSC's § 271(f) claims are thus deficient, both for inadequately alleging knowledge and intent and for failing to identify infringing activities and constituent parts related to the scope of each of the asserted patents.

D. BSC's Willful Infringement Claims Should Be Dismissed

BSC's willful infringement claims should be dismissed due to BSC's failure to adequately allege any claims of infringement, as discussed above. A claim of willful infringement also requires a showing of intentional conduct, which BSC fails to make in their Complaint. Willful infringement may be found only in "egregious cases of misconduct beyond typical infringement." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1935 (2016). The Supreme Court has explained that "[t]he sort of conduct warranting enhanced damages has been variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." *Id.* at 1932.

As discussed in Section VI.B. above, BSC's conclusory assertion that "Nevro has had actual and constructive knowledge of the [asserted patents] prior to the filing of this Complaint" is unsupported by any facts from which that assertion can be inferred. (D.I. ¶¶ 17, 27, 37, 45, 53, 64, 74, 82, 93, 103). This deficiency is also fatal to BSC's willful infringement claims. *MONEC*, 897 F. Supp. 2d at 236; *U.S. Ethernet Innovations, LLC v. Netgear, Inc.*, No. 13-2262 CW, 2013 WL 4112601, at *4 (N.D. Cal. Aug. 12, 2013) (dismissing willful infringement claims premised on mere allegation that defendant had "actual or constructive knowledge" of the relevant patents). Without knowledge of the asserted patents, BSC also cannot plausibly assert that Nevro knew, had the requisite intent, or recklessly disregarded the potential for infringement. *MONEC*, 897 F. Supp. 2d at 236-37.

Besides knowledge, BSC also fails to allege any facts regarding Nevro's prelitigation conduct, let alone facts sufficient to support an inference that Nevro's behavior was egregious beyond typical allegations of infringement. *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1374 (Fed. Cir. 2007), *abrogated on other grounds by Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016) ("[I]n ordinary circumstances, willfulness will depend on an infringer's prelitigation conduct."). The Complaint copies and pastes the same conclusory allegation that "Nevro's infringement is reckless, knowing, deliberate, and willful" with no factual enhancement. (D.I. 1 ¶¶ 17, 27, 37, 45, 53, 64, 74, 82, 93, 103). That litany of adjectives is insufficient to sustain BSC's obligation to plead facts showing a plausible entitlement to relief. *See Varian Med. Sys., Inc. v. Elekta AB*, C.A. No. 15-871-LPS, 2016 WL 3748772, at *8 (D. Del. July 12, 2016), *report and recommendation adopted at D.I. 112* (dismissing, as insufficiently pled, willful infringement claims where the plaintiff did "little more than provide a formulaic recitation of the pre-*Halo* elements of a willful infringement claim"); *Princeton*

Digital Image Corp. v. Ubisoft Entm't SA, C.A. No. 13-335-LPS-CJB, 2016 WL 6594076, at *11 (D. Del. Nov. 4, 2016) (dismissing willful infringement claims where the plaintiff failed to adequately plead pre-suit knowledge or any egregious conduct after the filing of the Complaint); *HSM Portfolio*, 2012 WL 2580547, at *1 (dismissing willfulness allegations where no facts were alleged in support). As there are no other facts in the Complaint to support BSC's willful infringement claims, the Court should dismiss those claims as insufficiently pled.

VII. CONCLUSION

BSC's Complaint fails to state facts that plausibly establish any claim for relief against Nevro. Accordingly, for the foregoing reasons, Nevro respectfully requests that the Court dismiss all of BSC's claims pursuant to Rule 12(b)(6).

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January 30, 2017

CERTIFICATE OF SERVICE

I hereby certify that on January 30, 2017, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 30, 2017, upon the following in the manner indicated:

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