UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	SACV 12-00327-JVS (MLGx)	Date	March 7, 2013
Title	Medtronic Inc. v. Edwards Lifesciences Corp. Et al.		

Present: The Honorable	James V. Selna	
Karla J. Tunis		Not Present
Deputy Clerk		Court Reporter
Attorneys Present for Plaintiffs:		Attorneys Present for Defendants:
Not Present		Not Present

Proceedings: (IN CHAMBERS) Order re Claim Construction

Plaintiff/Counter-Defendant Medtronic, Inc. ("Medtronic") and Defendants/Counter-Claimants Edwards Lifesciences, Corp.; Edwards Lifesciences, LLC; and Edwards Lifesciences (USA), Inc. (collectively, "Edwards") have submitted proposed claim constructions to the Court for certain language contained in Medtronic's U.S. Patent No. 7,184,829 ("the '829 Patent"), entitled "Method and System for Nerve Stimulation Prior to and During a Medical Procedure; and U.S. Patent No. 8,036,741 ("the '741 Patent"), entitled "Method and System for Nerve Stimulation and Cardiac Sensing Prior to and During a Medical Procedure." (Medtronic's Opening Markman Brief ("Pl. Markman Br."), Docket No. 57; Edwards' Opening Claim Construction Brief ("Def. Markman Br."), Docket No. 52; Joint Claim Construction Chart & Prehearing Statement ("Prehearing Statement"), Docket No. 49-1.) The parties also submitted reply briefs. (Medtronic's Reply Markman Brief ("Pl. Reply."), Docket No. 70; Edwards' Reply Claim Construction Brief ("Def. Reply."), Docket No. 76.) The Court construes the relevant claim language below.

I. BACKGROUND

The two patents-in-suit were issued to inventors Michael Hill, Scott Jahns, and James Keogh, and assigned to Medtronic. ('829 Patent, Declaration of Sharon Roberg-Perez ("Roberg-Perez Decl.") Ex. B, Docket No. 54-2; '741 Patent, Roberg-Perez Decl. Ex. A, Docket No. 54-1.) Medtronic alleges that Edwards infringes the patents through the use of its transcatheter heart valve ("THV"), the SAPIEN, in conjunction with its Retroflex 3 Delivery System. (Complaint ¶¶ 13, 20, Docket No. 1; Medtronic's Disclosure of Asserted Claims and Infringement Contentions, Declaration of Kripa Rama ("Raman Decl.") Ex. H, Docket No. 52-10, at 3–4.) Specifically, Medtronic alleges that

the asserted claims of the patents relate to the "critical steps that Edwards instructs physicians to take in order to safely and effectively deploy the SAPIEN at the site of the native aortic valve" through rapid pacing. (Pl. Markman Br., at 2.)

A. The '829 Patent

The '829 Patent discloses "methods for performing a medical procedure" and, more particularly, "methods and systems of stimulating a nerve in order to modify the beating of a heart to allow a medical procedure to be performed or for blood flow to be controlled." ('829 Patent, 1:25–30.) First, a nerve is stimulated to "adjust the beating of a heart to a first condition, such as a stopped or slowed condition." (Id. at Abstract.) Second, the stimulation is stopped to "adjust the beating of the heart to a second condition, such as a beating condition." (Id.) Additionally, the heart itself may be stimulated to a beating condition. (Id.) The invention's purpose is "to provide a method for controllably stopping or slowing the heart intermittently for diagnostic," therapeutic, blood flow control, and medical procedure purposes. (Id. at 2:22–35.) This addresses the shortcomings of the prior art, which either involves stopping the heart while the patient is on a cardiopulmonary bypass ("CPB") circuit; or more prolonged heart stoppages using, for example, drugs, that limit the heart's ability to supply blood circulation during surgery. (See id. at 1:42–2:21; Pl. Markman Br., at 1.)

B. The '741 Patent

The '741 Patent discloses similar methods and systems to adjust the beating of the heart or for stimulating the heart itself by pacing. ('741 Patent, 1:37–44, 3:1–3.) It also relates to "methods and systems for sensing imminent cardiac contractions" during a procedure and for "monitoring and controlling . . . physiological and/or chemical parameters of a fluid such as blood or oxygen in the systemic and/or pulmonary circulatory systems during a medical procedure." (Id. at 1:44–51.) These help determine whether blood and oxygen flow is sufficient and help avoid interference from unexpected heart contractions. (Id. at 2:36–47.)

II. LEGAL STANDARD

It is well-settled that claim construction is "exclusively within the province of the court." Markman v. W. Instruments, Inc., 517 U.S. 370, 372 (1996). Such construction

"begins and ends" with the claim language itself, Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001), but extrinsic evidence may also be consulted "if needed to assist in determining the meaning or scope of technical terms in the claims," Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed. Cir. 1995).

In construing the claim language, the Court begins with the principle that "the words of a claim are generally given their ordinary and customary meaning." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). Further, this ordinary and customary meaning "is the meaning that the [claim] term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1313. "[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id.

"In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances general purpose dictionaries may be helpful." Id. at 1314. In other cases, "determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art." Id. In those cases, "the court looks to those sources available to the public that show what a person of skill in the art would have understood the disputed claim language to mean." Id. These sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id. (internal quotation marks omitted).

It is improper to read limitations from the specification into the claim. Callicrate v. Wadsworth Mfg., Inc., 427 F.3d 1361, 1368 (Fed. Cir. 2005) ("'[I]f we once begin to include elements not mentioned in the claim, in order to limit such claim . . ., we should never know where to stop.'" (quoting Phillips, 415 F.3d at 1312)). "We do not import limitations into claims from examples or embodiments appearing only in a patent's written description, *even when a specification describes very specific embodiments of the invention* or even describes only a single embodiment, unless the specification makes clear that 'the patentee . . . intends for the claims and the embodiments in the

specification to be strictly coextensive.'" JVW Enters., Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1335 (Fed. Cir. 2005) (internal citations omitted) (emphasis added).

III. DISCUSSION

Medtronic alleges that Edwards infringes (1) independent claims 10 and 28, and dependent claims 11–13, 15–18, and 20–21, of the '741 Patent; and (2) claim 43 of the '829 Patent. (Pl. Markman Br., at 6.) First, the Court sets forth claim 10 of the '741 Patent and discusses the disputed terms therein. Then, the Court discusses claims 17 and 20 of the '741 Patent. Finally, the Court examines claim 43 of the '829 Patent.

A. Claim 10 of the '741 Patent

Claim 10 of the '741 Patent recites:

> A method of performing a cardiac medical procedure, comprising: a) obtaining a stent device; b) electrically stimulating a heart to adjust beating of the heart to a first condition; c) delivering the stent device to the stimulated heart when the beating of the stimulated heart has been adjusted to the first condition, when the heart is beating in the first condition; and d) reducing electrical stimulation of the heart to adjust beating of the heart to a second condition after delivering the stent device.

('741 Patent, 37:33–45.) The Court discusses each disputed term separately and identifies the additional claims in which the disputed term occurs.

1. "**stent device**" (Claims 10–13, 15–18, 20–21, 28)

Medtronic's Proposed Construction	Edwards' Proposed Construction
Option 1: No construction required; use ordinary meaning Option 2: device providing support within the space of a tubular structure in the body	stent devices insertable by surgical or non-surgical means other than heart valve replacement medical devices insertable using a steerable catheter device

Edwards proposes that the Court construe "stent device" to exclude "heart valve replacement medical devices insertable using a steerable catheter device." (Def. Markman Br., at 11–13.) Edwards does not rely on the claim term, the context in which it is used, or the specification, which lack any limitation that supports its construction.[1] See Phillips, 415 F.3d at 1314 (citing Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001) ("Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.") Edwards justifies the limitation as "embod[ying] the [Patent] Examiner's interpretation of . . . 'stent device' . . . and effectuat[ing his] clear directive that the claimed invention cannot possibly cover 'a heart valve replacement medical device insertable into a steerable catheter device.'" (Def. Markman Br., at 11 (citation omitted) (quoting '741 Patent File History – 03/07/2011 Non-Final Rejection ("March Non-Final Rejection"), Raman Decl. Ex. G, at 848).)

During prosecution, Medtronic presented five claims directed to systems for transcatheter replacement of a native heart valve comprising, *inter alia*, a "heart valve replacement medical device." ('741 Patent File History, 06/18/2010 Second Preliminary Amendment, Raman Decl. Ex. G, at 819–20.) The Examiner issued a non-final rejection of an amendment to change the scope of the replacement heart valve element to include a valve "insertable into the steerable catheter device." (March Non-Final Rejection, at 848.) He reasoned that "the specification fails to teach a heart valve replacement medical device insertable into a steerable catheter device," so "the claim constitutes new matter." (Id.) Edwards suggests that because of this and Medtronic's "acquiesce[nce]" to the rejection by "abandoning" these claims, it follows that "stent device" cannot cover a replacement heart valve insertable into a steerable catheter device. (Def. Markman Br., at 13.)

Contrary to Edwards' position, there is no "clear directive" that the claimed methods "cannot possibly cover 'a heart valve replacement medical device insertable into a steerable catheter device.'" (Def. Markman Br., at 11.) The Examiner gave Medtronic

[1]Claims recite that "the stent device is a replacement heart valve." (E.g., '741 Patent, 38:23–24 (claim 21), 37:29–32 (claims 8 and 9), 38:36–37 (claim 24).) Per the specification, a "medical procedure" may be a "heart valve repair" or replacement. (Id. at 24:25–28.)

the opportunity to cite to "sufficient support in the original disclosure" to rebut his conclusion. (March Non-Final Rejection, at 848.) In response, Medtronic canceled the claims and explicitly stated that this action was "without prejudice to or disclaimer of the subject matter therein." ('741 Patent File History – 09/11/09 Amendment and Reply, Raman Decl. Ex. G, at 860.) The Examiner never addressed the amended claims again. Thus, the Court does not know if he would have adhered to his position at the time of allowance.

Medtronic's cancellation also is not an affirmative representation that "stent device" does not cover a heart valve replacement medical device insertable into a steerable catheter device. "[T]he prosecution history limits interpretation of claims terms so as to exclude any interpretation that was disclaimed during prosecution." Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 994 (Fed. Cir. 2003) (citation omitted). Therefore, "[a] patentee may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement." Id. at 995. Medtronic, however, made no statement affirmatively "yield[ing] claim scope in order to secure allowance of the patent." MarcTec, LLC v. Johnson & Johnson, 394 F. App'x 685, 687 (Fed. Cir. 2010); Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc., 182 F. App'x 994, 997 (Fed Cir. 2006) ("A clear and unmistakable disavowal in the prosecution history may narrow claim scope.").

Further, the rejected claims were for a system for transcatheter replacement of a native heart valve. The Court perceives a difference between this claimed system and the disputed claimed method for "delivering" a stent device and declines to treat the method claims as equivalent to the cancelled system claims. Cf. Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.), 687 F.3d 1266, 1277 (Fed. Cir. 2012) (holding that asserted system claims were no different for asserted method claims for patent eligibility purposes where there was no material difference between the claims in the asserted patents). Prosecution history estoppel thus does not prevent Medtronic from asserting that "stent device" should not be limited, and the Court declines to adopt Edwards' construction.

The Court finds that "stent device" requires construction. Medtronic proposes to construe "stent device" as a "device providing support within the space of a tubular structure in the body." (Pl. Markman Br., at 8.) No intrinsic evidence defines "stent

device," so the Court looks to extrinsic evidence to determine its ordinary meaning "as defined by a person having ordinary skill in the art." Phillips, 415 F.3d at 1319. Stedman's Medical Dictionary defines "stent" as, *inter alia*, a "[s]lender threat, rod, or catheter, lying within the lumen of tubular structures, used to provide support . . . or to ensure patency of an intact but contracted lumen"; and defines lumen as "the space in the interior of a tubular structure." (Prehearing Statement, at 32–33 (quoting Stedman's Medical Dictionary (26th ed. 1995)).) Accordingly, the Court adopts Medtronic's proposed construction, which is consistent with the ordinary meaning of "stent device."

2. "**electrically stimulating a heart to adjust beating of the heart to a first condition**"[2] (Claims 10–13, 15–18, 20–21, 28)

Medtronic's Proposed Construction	Edwards' Proposed Construction
stimulating the heart to adjust beating of the heart so that there is reduced heart motion and/or blood flow	electrically stimulating a heart to adjust beating of the heart to a stopped or slowed beating of the heart

"First condition"or "first rate" refers to an adjusted beating of the heart; the stent device may be delivered to the heart while it is in this condition. (E.g., '741 Patent, 37:39–40, 38:48–51.) The parties dispute whether the "first condition" (1) is limited to "a stopped or slowed beating of the heart," as Edwards proposes; or (2) encompasses any adjustment to the beating if it results in reduced heart motion and/or blood flow, as Medtronic proposes. Edwards believes its construction follows the mandated metric—a "rate"—by defining the term with reference to the measure of the beating of the heart, and is the only one supported by the specification, which only refers to a stopped or slowed beating. (Def. Markman Br., at 14–15 (quoting '741 Patent, 2:57–67, 18:5–12).) Medtronic counters that the claims and specification do not limit "first condition" to a stopped or slowed beating of the heart. (Pl. Markman Br., at 9–10 (citing '741 Patent, 1:41–44, 11:67–12:2).)

[2]The claim construction also applies to the construction of "first rate" in claim 28 of the '741 Patent, which recites in relevant part: "**electrically stimulating the heart to adjust beating of the heart to a first rate.**" ('741 Patent, 38:48–49.) The Court uses "first condition" to refer to "first condition" and "first rate."

Claim 10 does not recite that the heart beat must be stopped or slowed, and the claim context supports a broader reading although it does not explicitly associate "first condition" with an increased beating of the heart. Under the doctrine of claim differentiation, there is a presumption that differences in claim language are significant, so a court should not construe terms in ways that render the language of a claim superfluous. Phillips, 415 F.3d at 1314–15 ("[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim."). Claim 14 recites, "wherein the first condition is a slowed condition." ('741 Patent, 37:54–55). Therefore, reading a stopped or slowed limitation into claim 10 would render this additional modifier superfluous, which weighs against doing so. Similarly, claim 17 recites, "wherein stimulating comprises pacing the heart to achieve the first condition." ('741 Patent, 38:4–5.) On its face, and regardless of the parties' disagreement over the meaning of "pacing," this does not establish that "pacing" means slowing or stopping the heart beat.

More importantly, although the disclosed embodiments refer to a slowed or stopped beating in the "first condition," the specification does not explicitly associate the "first condition" with increased beating of the heart. (E.g., '741 Patent, 2:57–67, 18:5–12; 26:53–28:53 (explaining that heart may be stilled via nerve stimulation or use of drugs but not mentioning pacing).) Edwards believes this repeated discussion defines the invention. (Def. Markman Br., at 15.) However, "the interpretive process may not import limitations from the specification into the defining language of the claims," Leggett & Platt, Inc. v. Hickory Springs Mfg. Co., 285 F.3d 1353, 1357 (Fed. Cir. 2002), unless "the specification manifests a clear intent to limit the term by using it in a manner consistent with only a single meaning," Arlington Indus., Inc. v. Bridgeport Fittings, Inc. 632 F.3d 1246, 1254 (Fed. Cir. 2011). Disclosure of a particular embodiment "is not enough . . . to limit the patentee's clear, broader claims" where "the patentee did not act as his own lexicographer or disavow claim scope." Kara Tech., Inc. v. Stamps.com Inc., 582 F.3d 1341, 1347 (Fed. Cir. 2009).

In Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340 (Fed. Cir. 2004), the Federal Circuit analyzed the specifications of three patents and concluded that repeated, clear statements describing a particular way of practicing the invention led to the "inescapable conclusion" that the "communications between the local and remote sites of the claimed inventions must occur directly over a telephone line" even though the claim

language was not as limited. Id. at 1348. The "Summary of the Invention," as well as other language, "characterize[d] the entire 'personal communications system' as enabling communications between a local site and a remote site over a telephone line." Id. The specification never suggested the use of another network and used restrictive language. Id. Similarly, in Watts v. XL Sys., Inc., 232 F.3d 877, 883 (Fed. Cir. 2000), the court determined that the specification limited the invention to structures that utilize misaligned taper angles by stating that "[t]he present invention utilizes [the varying taper angle] feature." In SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337 (Fed. Cir. 2001), the court explained that a compelling portion of specification limiting the claims to specific embodiments was the "broad and unequivocal" recitation that a previously defined sleeve structure is "the basic sleeve structure for *all embodiments of the present invention contemplated and disclosed herein*." Id. at 1343–44 (emphasis in original).

The Court finds that the '741 Patent's specification consistently uses permissive language to define the scope of the methods. Thus, "while it is clear that the patentee was primarily focused on an embodiment of his invention" wherein the "first condition" is a slowed or stopped beating of the heart, "nothing in the patent limits the claims to that embodiment." SunRace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1305 (Fed. Cir. 2003).

For example, the specification teaches that "[t]he first condition *may* be"—not *must* be—"a stopped or slowed condition." ('741 Patent, 2:66–67 (emphasis added).) This may be achieved by a method "includ[ing] stimulating a nerve" to inhibit beating, which is followed either by ceasing nerve stimulation or stimulating the entire heart to adjust beating to the "second condition." (Id. at 2:57–3:2.) The specification also teaches that "[a]nother aspect of the present invention provides a method for performing a medical procedure wherein the beating of the heart is inhibited" through nerve stimulation or automatically when the cardiac tissue is non-contracting. (Id. at 6:34–43.) This language does not preclude other methods for electrically stimulating the heart to allow a medical procedure to be performed.[3] The specification also uses the term "presently preferred embodiments" and repeatedly uses the terms "in one embodiment,"

[3]The language of the claim also does not require "electrically stimulating a nerve" but, more broadly, "electrically stimulating a heart."

"may be," "permits," and "another aspect." Medtronic's careful, consistent use of phrases like "in one embodiment" and "may be," rather than restrictive language, and its explicit qualification "the invention is not necessarily so limited [to the particular embodiments and examples described in the specification], and that numerous other embodiments . . . are intended to be encompassed by the claims," weigh in favor of a broader construction than Edwards advocates. Accord Rexnord Corp, 274 F.3d at 1345 (noting that inventor used similar phrases, including the qualification, and finding that invention embraces, through "portion," structures that may be "integral" or "separate," not just "separate").

At oral argument, Edwards dismissed the patentee's use of such explicit qualification language as mere boilerplate. This approach deprives the patentee of the benefit of the careful word-smithing in which it engaged, and Edwards offers no authority for the proposition that express language—however labeled—may be ignored. Moreover, no such panoply of qualifiers was present in Microsoft to impede the Federal Circuit's conclusion that the "repeated[] and consistent[]" references to telephone lines produced the "inescapable conclusion" that the invention was limited to transmission over telephone lines.[4] Microsoft, 357 F.3d at 1347–48 (internal quotation marks omitted). There also is nothing in the present patent analogous to the express statement in the SciMed specification that the restrictive element—the basic sleeve structure—is the same "for *all embodiments of the present invention contemplated and disclosed herein*." 242 F.3d at 1343 (emphasis in original).

Thus, the Court finds that the patentee did not set out the embodiments intending that they be strictly coextensive with the claims, Phillips, 415 F.3d at 1323, or intend to limit the claim scope by using words of manifest exclusion or restriction, Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 905–06 (Fed. Cir. 2004); see also Martek Biosciences Corp. v. Nutrivona, Inc., 579 F.3d 1363, 1380–81 (Fed. Cir. 2009). Therefore, the Court declines to limit "first condition" to a "stopped or slowed beating of the heart."[5]

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[4]Numerous qualifiers appear regularly in Edwards' quotations from the specification in the PowerPoint presentation it used during oral argument.

[5]Edwards urges the Court to consider the patent inventors' project summaries as extrinsic evidence to clarify the meaning of "first condition." (See Def. Reply, at 6.) This would be inappropriate because the patent and specification sufficiently

Consequently, the Court concludes that the preferred construction of "first condition" should track the intended purpose of the method: reducing or eliminating heart motion and/or blood flow to allow a medical procedure to be performed. The specification teaches that when the heart is in the first condition either the medical procedure can be performed because the heart is stilled, or blood flow can be controlled. (E.g., '741 Patent, 1:41–44, 18:5–12 ("The present invention permits the heart to be stilled for selected and controllable periods of time in order to permit a cardiac or other medical procedure to be performed.").) An effect of the adjustment to the "first condition" may be that heart motion and/or blood flow are reduced or eliminated. (Id. at 11:65–12:2.) These two effects are not one and the same. Edwards argues that such a construction "jettisons 'rate' in favor of a new metric not used in the claim language." (Def. Reply, at 16.) The Court disagrees. This construction is not "divorced entirely from the concept of heart rate." (Id.) Instead, without specifying an exact rate or range, it establishes that the heart rate in the "first condition" must be one that results in reduced or eliminated heart motion and/or blood flow. (See Pl. Reply, at 9.) Further, at oral argument, Edwards asserted that the Court's adoption of the phrase "results in reduced heart motion and/or reduced blood flow" amounts to an impermissible restriction from a single embodiment, and pointed to a nerve stimulation embodiment described at col. 11:65–12:6. To be sure, the description is there, but the description is applicable to every embodiment in whole or in part in order for the invention to achieve its stated purpose.

Accordingly, the Court adopts the following construction of the disputed term: "electrically stimulating the heart to adjust beating of the heart to a rate that results in reduced heart motion and/or blood flow."

3. "**delivering the stent device to the stimulated heart when the**

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establish the meaning of "first condition." Interactive, 256 F.3d at 1332 ("Relying on extrinsic evidence to construe a claim is "proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence," although it "may always be consulted . . . to assist in understanding the underlying technology." (internal quotation marks and citation omitted)). Furthermore, any statements in the inventors' project summaries about "asystole" would be unhelpful in construing "first condition," and the project summaries themselves are not comparable to "the testimony of scientific witnesses." AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239, 1249 (Fed. Cir. 2001).

beating of the stimulated heart has been adjusted to the first condition, when the heart is beating in the first condition"[6] (Claims 10–13, 15–18, 20–21, 28)

Medtronic's Proposed Construction	Edwards' Proposed Construction
Option 1: No construction required; limitations should be accorded their ordinary meaning, in the context of the claim language and the constructions of other limitations of the claims Option 2: placing the stent device at its intended target or destination while the heart is stimulated so that heart motion and/or blood flow is reduced	delivering the stent device from the point of entry to the heart while it is stimulated to beat a stopped or slowed beating of the heart

Edwards' proposed construction embraces its reading of "first condition" and defines "delivering" as beginning from the entry of the stent device into the body and lasting until delivery to the heart. Edwards argues that this captures the "geographical" aspect of "delivery" and the temporal limitation that the delivery occur when the heart is in the "first condition." (Def. Markman Br., at 16–17.) It contends that the plain meaning of "delivering" is not "limited to only the act of reaching the final destination" but rather "the traversal of the entire path of the object in going from one point to another." (Id. at 16–17.)

A court generally should assign claim terms their ordinary meaning, "according to the customary understanding of a person of ordinary skill in the art who reads them in the context of the intrinsic record." Agilent Techs., Inc. v. Affymetrix, Inc., 567 F.3d 1366, 1376 (Fed. Cir. 2009). The dictionary definitions provided by Edwards define "deliver" with reference to its end point—an intended recipient, place, target, or destination. (Prehearing Statement, at 59–60 (citations omitted.) They do not define "deliver" also

[6]The claim construction also applies to the construction of claim 28 of the '741 Patent, which recites in relevant part: **"delivering a stent device to the heart when the heart is beating at the first rate."** ('741 Patent, 38:50–51.)

with reference to a "point of entry" or "starting point."

The claim language and specification also reveal no special meaning for the phrase "delivering . . . to the heart." Claims 10 and 28 do not require the heart to be in the "first condition" before the stent enters the body and/or from the point of entry until it is delivered to the heart.[7] (E.g. '741 Patent, 37:35–42 (defining no other step between obtaining stent device, stimulation to "first condition," and delivery to heart).) The specification also does not require this. It teaches that one aspect of the invention provides a method that includes stimulating a nerve to adjust to a first condition, after which a medical procedure is performed on an organ. (Id. at 2:57–3:1.) The focus is on the organ's (heart's) condition when it is operated upon, not necessarily during any preceding steps. In essence, the delivery path and location where the stent enters the body are immaterial; any infringement turns on whether the beating of the heart is in the "first condition" when the stent device reaches the intended destination, not on the choice of a delivery path.[8] Thus, the evidence reveals that the meaning of "delivering," as understood by one skilled in the art, is apparent even to lay persons.[9] Construction would involve "little more than the application of the widely accepted meaning of [a] commonly understood" word. Phillips, 415 F.3d at 1314. The Court finds that it is better to allow the claim language to speak for itself, especially when adopting Edwards' construction adds a

[7]The Court notes that Edwards' actual language, "from the point of entry to the heart," could also be read to mean the point of entry *into* the heart, not *into* the body.

[8]Intrinsic evidence relating to the delivery of drugs does not militate against this understanding. Drugs may be delivered via intravenous, intracoronary, or intraventricular administration, or other methods. ('741 Patent, 19:36-46.) The specification does not mention a "point of entry." Instead, it explains how, for example, a catheter may be delivered endovascularly—through the insertion into a blood vessel—such that drugs may use it as a delivery device. (Id. at 19:36-38, 55-61.) The focus remains on the intended destination. (See id. at 31:5-7 ("Both delivery components . . . may be any suitable means for delivering drugs to a site of a medical procedure.").)

[9]For example, the postal carrier "delivers" a letter when she puts it in the recipient's mailbox—not when she picks it up from a drop-box.

new term to the claim and could create more ambiguity in other claim terms.[10] E.g., O2 Micro Int'l v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1362 (Fed. Cir. 2008). Accordingly, construction is unnecessary.

4. "**reducing electrical stimulation of the heart to adjust beating of the heart to a second condition after delivering the stent device**"[11] (Claims 10–13, 15–18, 20–21, 28)

Medtronic's Proposed Construction	Edwards' Proposed Construction
reducing or eliminating stimulation of the heart to adjust beating of the heart so that heart motion and/or blood flow returns to normal	reducing electrical stimulation of the heart to adjust beating of the heart to a higher rate after delivering the stent device

The parties dispute the meaning of "second condition" and "second rate," which they agree are defined in relation to the adjusted beating of the heart in the "first condition." (Def. Markman Br., at 19–20; Pl. Markman Br., at 14–15.) Under Edwards' originally proposed construction, the beating of the heart must be faster in the "second condition" than in the "first condition." This requirement is not supported by the Patent for the reasons discussed in the "first condition" analysis, *supra*, although the disclosed embodiments refer to the "second condition" as a beating condition and in relation to "stopped or slowed" beating in the "first condition." The claim language also is inconclusive as to whether the "second condition" must be a "higher beating" or "slower beating" condition; it only establishes that electrical stimulation of the heart is reduced to adjust from the "first condition." ('741 Patent, 37:43–45; see 37:56–57 (Dependent Claim

[10]The Court agrees with Edwards that replacing "delivering" with the term "placing" is inappropriate; "placing" is neither part of nor consistent with the definitions cited for "delivery," much less the intrinsic evidence in the '741 Patent. (See Def. Reply, at 18–19.)

[11]The claim construction also applies to the construction of "second rate" in claim 28 of the '741 Patent, which recites in relevant part: "**reducing electrical stimulation of the heart to adjust beating of the heart to a second rate after delivering the stent device**." ('741 Patent, 38:52–54.) The Court uses "second condition" to refer to"second condition" and "second rate."

15 recites, "wherein the second condition is a beating condition.").) The heart itself may be stimulated to adjust beating to the "second condition."[12] (Id. at 38:1–3.) The Court therefore declines to adopt Edwards' original construction.

At oral argument, Edwards proposed an alternative construction based on the Court's construction of "first condition": "reducing electrical stimulation of the heart to adjust beating of the heart to a normal beating rate." The implication, in light of the Court's construction of "first condition," is that heart motion (*e.g.*, contractions) and/or blood flow will return to normal at this beating rate. The Court finds that this alternative construction adequately tracks the meaning of the claim and the purpose of the method and the '741 Patent. Accordingly, the Court construes "second condition" as: "reducing electrical stimulation of the heart to adjust beating of the heart to a normal beating rate."

B. Claim 17 of the '741 Patent

Claim 17 of the '741 Patent recites, with the disputed term in bold: "17. The method of claim 10, wherein stimulating comprises **pacing the heart to achieve the first condition**." ('741 Patent, 38:4–5.)

Medtronic's Proposed Construction	Edwards' Proposed Construction
Option 1: No construction required; use ordinary meaning Option 2: wherein stimulating comprises setting or regulating the rhythm of the heart to achieve the first condition	changing the pace of the heart to achieve a stopped or slowed beating of the heart

The only remaining dispute is whether to construe "pacing the heart." The Court already has construed "first condition" such that the heart can be based either to a slower or stopped heart rate, or a higher heart rate. Edwards proposes that "pacing" means

[12] One disclosed embodiment teaches that, "[i]f appropriate, the heart may be stimulated to ensure that contractions occur" and that the heart contracts normally. (E.g., '741 Patent, 25:40–53.) The stimulation may occur through pacing pulses, (id. at 25:47–48), but the specification does not limit the stimulation only to that method.

"changing the pace of," while Medtronic proposes either no construction or to construe it as "wherein stimulating comprises setting or regulating the rhythm of the heart."[13]

The Court finds that "pacing" should be construed in accordance with its plain and ordinary meaning. The language of the claims belies Edwards' proposal that it only means "changing the pace" or, more specifically, "changing the rate"[14]—a proposal that assumes the patentee acted as its own lexicographer. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history."). Edwards' construction ostensibly renders this dependent claim superfluous, because it does not contemplate any particular method of stimulation. In essence, it would read, "wherein stimulating comprises changing the heart rate to achieve a stopped or slowed beating of the heart" or heart rate. Yet, the claims do not treat "pacing" and "changing the heart rate" interchangeably. (See, e.g., '741 Patent, 37:37–38, 38:1–5 (making "pacing" a distinct form of stimulation), 38:38–39 ("wherein stimulating the heart comprises pacing the heart").) The Court's construction of "first condition" also rejects any requirement that "pacing" stop or slow beating.

The specification also supports a broader understanding of "pacing." Previously disclosed methods indicate that "pacing" may be used to start the beating of the heart. ('741 Patent, 2:18–19.) Such language would not make sense if "pacing" merely meant toggling between two heart rates rather than a form of stimulation that affects the heart rate and therefore heart movement and/or blood flow. The specification also teaches that "the heart may be paced with an electrical pacing system, thereby maintaining a normal cardiac output." (Id. at 10:62–64.) "Pacing pulses" also may be applied to the heart to encourage it to contract normally. (Id. at 18:1–4.) Such language indicates that "pacing"

[13]Although Edwards faults Medtronic for "fail[ing] to specify the meaning of the phrase 'first condition,'" (Reply, at 22), the Court need not construe "first condition" again.

[14]Edwards equates "pace" with "heart rate." (See Def. Reply, at 21 ("'[P]acing' in this claim term to achieve the first condition means changing from a higher heart rate, such as the normal heart rate to a 'first condition' where the heart is stopped or slowed.").)

need not only involve stimulation that changes the heart rate, but stimulation that regulates and maintains a particular cardiac output. At oral argument, Edwards stressed that this language uses "pacing" in a different context: restoring an underperforming heart. True enough, but it gives meaning to "pacing" and indicates that it refers to speeding up the heart and/or stimulating contractions. Extrinsic evidence also supports an understanding of "pacing" beyond "changing the rate." Dictionaries define "pace" as "to set or regulate the pace of" or "to set or regulate the rate of speed for." (Prehearing Statement, at 114 (citations omitted).) Merriam-Webster defines "pacing" as "the act or process or regulating or changing the timing or intensity of cardiac contractions." Merriam-Webster Medical Dictionary, http://www.merriam-webster.com/medical/pacing (last visited February 12, 2013). Thus, "pacing" affects both beating of the heart and/or movement of the heart, *e.g.*, cardiac contractions or cardiac output, and could involve speeding up the heart to achieve the "first condition."

Accordingly, the Court construes "pacing" in accordance with its ordinary meaning and with reference to the specification: "changing or regulating the beating of the heart or movement of the heart to achieve the first condition."

C. Claim 20 of the '741 Patent

Claim 20 of the '741 Patent recites, with the disputed term in bold: "The method of claim 10, **wherein the stimulating of the heart comprises stimulating the Purkinje fibers**." ('741 Patent, 38:21–22.)

Medtronic's Proposed Construction	Edwards' Proposed Construction
stimulating an area of the heart that includes Purkinje fibers	wherein the stimulating of the heart involves stimulating the Purkinje fibers directly

The parties dispute whether this claim (1) requires stimulating the Purkinje fibers[15]

[15]Purkinje fibers are "a specialized cardiac muscle cell that conducts impulses through the walls of the ventricles" of the heart. (Academic Press Dictionary of Science and Technology, Roberg-Perez Decl. Ex. H, at 81.)

"directly," as proposed by Edwards, (Def. Markman Br., at 21); or (2) requires that the stimulation of the heart be in an area that includes the fibers, as proposed by Medtronic, (Pl. Markman Br., at 18.) Edwards argues that any other construction would render claim 20 superfluous to claim 10 and that Medtronic improperly broadens the area that can be stimulated. (Def. Markman Br., at 21; Def. Reply, at 23–24.) Medtronic counters that the claim language does not limit the method of the stimulation, this is a "comprising claim" that only requires "that the stimulation of the heart includes stimulation of the Purkinje fibers," and "directly" creates unnecessary ambiguity. (Pl. Markman Br., at 18–19.)

"Comprising"—and, by extension, "comprises" or "comprised of"—is a "term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997); see also CIAS, Inc. v. Alliance Gaming Corp., 504 F.3d 1356, 1361 (Fed. Cir. 2007) ("In the patent claim context the term 'comprising' is well understood to mean including but not limited to." (internal quotation marks omitted)). While "comprising" permits additional elements not required by a claim, it "does not remove the limitations that are present." Power Mosfet Techs., L.L.C. v. Siemens AG, 378 F.3d 1396, 1409 (Fed. Cir. 2004). Applying those principles, the Court concludes that the stimulation recited in claim 20 requires the stimulation of the Purkinje fibers, although it may include the stimulation of other areas of the heart. Therefore, Medtronic's proposed construction, which only requires stimulating an area that *includes* Purkinje fibers but not actual stimulation *of* the fibers, is too narrow to be supported by the claim language.

Edwards' proposed construction also is too narrow. The meaning of "comprising" precludes any construction "that it is the Purkinje fibers, directly *and alone*, that are to be stimulated here." (Def. Reply, at 23 (emphasis added).) Further, Edwards provides no support for its conclusion that "indirect stimulation of Purkinje fibers would amount simply to stimulation of the heart generally." (Def. Markman Br., at 21.) The patent language does not require or exclude direct or indirect stimulation of the Purkinje fibers. It is possible to conceive of situations where indirect stimulation of the fibers may be necessary or preferable to "direct" stimulation. The patent language also does not mandate that the stimulation of the Purkinje fibers must be purposeful rather than

incidental, so long as it occurs.[16] Further, it is not evident that a broader construction would render claim 20 superfluous, because it is not coextensive with claim 10, which recites, "electrically stimulating a heart. . . ." ('741 Patent, 37:37.) The specification teaches that several parts of the heart may be stimulated, including the carotid sinus nerve, the fat pad associated with the sinoatrial ("SA") node, the fat pad associated with the atrioventricular ("AV") node , the junction of the AV node, the Bundle of His, and the Purkinje fibers. (Id. at 11:59–64.) Claim 20 merely requires that the Purkinje fibers be stimulated to adjust the beating of the heart, unlike the more general stimulation in claim 20.

Accordingly, the Court adopts the following construction: "wherein the stimulating of the heart includes stimulating the Purkinje fibers."

D. Claim 43 of the '829 Patent

Claim 43 of the '829 Patent recites:

> A method of electrically manipulating cardiac rhythm during a medical procedure, comprising: providing a stimulator, the stimulator comprising a stimulation electrode; positioning the stimulation electrode in a position suitable for stimulating Purkinje fibers to stop or slow cardiac rhythm; [and] intermittently starting and stopping stimulation of the Purkinje fibers multiple times in order to manipulate cardiac rhythm during a medical procedure.

('829 Patent, 20:47–56.) The Court discusses each disputed term separately.

1. **"positioning the stimulation electrode in a position suitable for stimulating Purkinje fibers to stop or slow cardiac rhythm**"

[16] At the Technology Tutorial, the parties acknowledged that stimulating one nerve or part of the heart would not necessarily stimulate another nerve.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. SACV 12-00327-JVS (MLGx) Date March 7, 2013

Title Medtronic Inc. v. Edwards Lifesciences Corp. Et al.

Medtronic's Proposed Construction	Edwards' Proposed Construction
positioning the stimulation electrode to allow for the stimulation of the region of the Purkinje fibers	placing the stimulation electrode in a position that stimulates the Purkinje fibers so as to stop or slow the heart beat

The parties dispute the meaning of "suitable for" and how that affects the required placement of the stimulation electrode. Medtronic proffers a broad construction that focuses on positioning and does not mention stopping or slowing cardiac rhythm. (Pl. Markman Br., at 20–21.) Edwards contends that the claim must be construed to give full meaning to the positioning's expressed purpose and to "cardiac rhythm." (Def. Markman Br., at 9–10; Def. Reply, at 8–12.)

First, contrary to the implication in Edwards' proposal, nothing in the claim language or specification justifies excluding any placement of the stimulation electrode that could either stop, slow, or quicken cardiac rhythm when the Purkinje fibers are stimulated. Contrary to Medtronic's language, nothing justifies broadening "suitable for" to "allow for" or "Purkinje fibers" to "the region of the Purkinje fibers," or reading out "to stop or slow cardiac rhythm." In Vizio, Inc. v. Int'l Trade Comm'n, 605 F.3d 1330, 1340 (Fed. Cir. 2010) (emphasis added), the Federal Circuit reasoned that "suitable for use" "suggest[s] that [the method or object] must actually *be capable* of being used for the claimed function." As Edwards contends, adopting Medtronic's proposed expansion of "Purkinje fibers" to "the region of the Purkinje fibers" would incorporate a new term and could encompass placements that would not be suitable for stopping or slowing cardiac rhythm. (Def. Reply, at 10–11.) Medtronic's proffered definitions for "suitable"—"adapted to a use or purpose" or "well-fitted for the purpose, appropriate"—suggest a middle ground between the proposed constructions. (Prehearing Statement, at 1 (quoting Merriam-Webster's Collegiate Dictionary (10th ed. 1997); The Oxford Compact English Dictionary (1996).) Therefore, based on the plain meaning of "suitable," the Court construes "positioning the stimulation electrode in a position suitable for stimulating Purkinje fibers" as "positioning the stimulation electrode in a position capable of and appropriate for stimulating the Purkinje fibers."

Turning to the second part of the phrase, "cardiac rhythm," the parties agree that to "manipulate cardiac rhythm" includes "adjustments to the beating of the heart." (See Def. Markman Br., at 10; Pl. Markman Br., at 23 (agreeing that to "manipulate cardiac

rhythm" involves "repeated adjustments to the beating of the heart").) Medtronic, however, disagrees that "cardiac rhythm" and "the heart beat" are coextensive. (See, e.g., Pl. Markman Br., at 23 ("[A]ny manipulation of cardiac rhythm in response to intermittent stimulation falls within the scope of the claims, so long as the manipulation includes stopping or slowing the rhythm.").)

The claim language and specification do not reveal a special meaning for "cardiac rhythm," and the Court finds that it is not used interchangeably with "heart beat." See Hyperphrase Techs., LLC v. Google, Inc., 260 F. App'x 274, 278–79 (Fed. Cir. 2007) (interchangeable use of two terms is akin to definition equating them). One embodiment teaches that nerve stimulation can be used "to temporarily stop or slow the beating heart," a manipulation that eliminates or reduces heart motion and/or blood flow. ('829 Patent, 5:52–56.) The specification explains that the SA node function as "the pacemaker" in healthy individuals, and that "[n]ormal heart rhythm associated with the SA node is typically referred to as sinus rhythm." ('829 Patent, 5:31–33.) The specification goes on to detail the heart rate when the SA node or the AV node fail, but it does not indicate that such a heart rate is equivalent to "cardiac rhythm." (See, e.g., id. at 5:33–37 ("When the SA node fails, the AV node generally takes over creating a heart rate of approximately 35 to 60 beats per minute. Heart rhythm associated with the AV node is typically referred to as nodal rhythm.").) One court notes that "[t]he cardiac rhythm normally takes its origin in" the sinoatrial node, "a microscopic collection of atypical cardiac muscle fibers (Purkinje fibers)."[17] Kolakowski v. Sec. of Health & Human Servs., No. 99-0625V, 2010 WL 5672753, at *31 n.57 (Fed. Cl. 2010). Extrinsic evidence also supports a broader understanding of "cardiac rhythm." "Cardiac" means "relating to" or "pertaining to" the heart. (Prehearing Statement, at 17.) Merriam-Webster's Medical Dictionary defines rhythm as, *inter alia*, "the pattern of recurrence of the cardiac cycle." Merriam-Webster Medical Dictionary, http://www.merriam-webster.com/medical/ (last visited February 12, 2013). "Sinus rhythm" means "the rhythm of the heart produced by impulses from the sinoatrial node." Id. (last visited February 12, 2013). Therefore, the Court concludes that it is preferable to give the general term "cardiac rhythm" its full meaning, let the claim speak for itself, and not restrict it to the beating of the heart or the rhythm of the beating of the heart. See Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989

[17]For a more comprehensive explanation of the electrical system of the heart, see In re Propulsid Prods. Liability Litig., 261 F. Supp. 2d 603, 606–08 (E.D. La. 2003).

(Fed. Cir. 1999).

Accordingly, the Court adopts the following construction of the disputed term: "positioning the stimulation electrode in a position capable of and appropriate for stimulating the Purkinje fibers to stop or slow cardiac rhythm."

2. "**intermittently starting and stopping stimulation of the Purkinje fibers multiple times in order to manipulate cardiac rhythm during a medical procedure**."

Medtronic's Proposed Construction	Edwards' Proposed Construction
discontinuous stimulation of the Purkinje fibers that contributes to repeated adjustments to the beating of the heart, including stimulation that stops or slows cardiac rhythm	intermittently starting stimulation of the Purkinje fibers so as to stop or slow heart beat during the stimulation and stopping stimulation of the Purkinje fibers so as to allow the heart beat to recover multiple times during the performance of a single medical procedure

The parties dispute whether stimulation of the Purkinje fibers must stop or slow cardiac rhythm during stimulation and allow it to "recover" when stimulation ceases, and the meaning of "a." Edwards contends that its construction sets forth a "specific logical sequence" that first requires stimulation to stop or slow the heart beat—the only embodiment disclosed in the specification—and that "a" means a "single, medical procedure." (Def. Markman Br., at 10–11.) Medtronic counters that the intrinsic evidence does not specify or limit the nature of the adjustments to the beating of the heart, require "recovery," or limit the intermittent stimulation to an ambiguous "single" procedure. (Pl. Markman Br., at 23–24.)

First, the parties generally agree on the meaning of "intermittently," which extrinsic evidence defines as "occurring at intervals, not continuous," or "alternately ceasing and beginning again." (Id. (quoting The Oxford Compact English Dictionary (1996)); Random House Webster's Unabridged Dictionary (2d ed. 1999)).) Thus, the Court will let that claim language speak for itself and not construe "intermittently." O2 Micro Int'l, 521 F.3d at 1362.

Second, the parties generally agree that to "manipulate cardiac rhythm," in this context, involves adjustments to the beating of the heart. The question is whether the stimulation of the Purkinje fibers is limited only to stimulation that stops or slows the heartbeat, or whether it encompasses stimulation that speeds up the heart beat but also can concurrently result in stopping or slowing the rhythm. (See Pl. Markman Br., at 23 (arguing that any manipulation of cardiac rhythm in response to intermittent stimulation is within claim scope "so long as the manipulation includes stopping or slowing the rhythm").)

Claim 43 does not, on its face, require the intermittent stimulation to stop or slow the heart beat and then allow it to recover. Given the use of "suitable for" in the preceding phrase, the language is broad enough to encompass slowing, stopping, or speeding up the heart beat, assuming it includes stopping or slowing cardiac rhythm.

The claim context supports this interpretation. The immediately surrounding claims (42, 44–46) do not require positioning a stimulator in a position suitable for stimulating "to stop or slow cardiac rhythm." (Compare '829 Patent, 20:51–53 ("suitable for stimulating Purkinje fibers to stop or slow cardiac rhythm) with id. at 20:61–63 ("positioning the stimulation electrode in a position suitable for stimulating a junction of an AV node and a His bundle to manipulate cardiac rhythm").) Other claims, however, expressly recite that their claimed method is "for controllably stopping or slowing a heart intermittently during a medical procedure," (id. at 17:12–20 (claim 1)), or "stimulating the vagal nerve to reduce heart rate" (id. at 18:15–17 (claim 15)).[18]

Relatedly, disclosed embodiments refer to intermittently stopping or slowing the beating of a heart or the heart itself through nerve stimulation. (E.g., id. at Figure 3, 15:29–34.) But "[i]t is important not to import into a claim limitations that are not part of the claim," so "a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." SuperGuide Corp. v. DirecTV Enters., 358 F.3d 870, 875 (Fed. Cir. 2004). The specification states that in one method, the "first condition," during which a medical procedure is performed, "*may* be a stopped or slowed condition." (829 Patent, 2:40–43.) In another method, "[a] nerve is stimulated transvenously to reduce the beating of a heart" so heart surgery can be

[18] Claims 1, 12, 15, 29, 38, 29, 40, and 41 all require stimulation of a vagal nerve.

performed. (Id. at 3:59–62.) The permissive language contrasts with the restrictive language, but the restrictive language is not directed to claim 43.

More importantly, the specification states that "[t]he nerve being stimulated may be vagus nerve fibers, hypoglossal nerve fibers, phrenic nerve fibers, parasympathetic nerve fibers, and sympathetic nerve fibers, a vagal nerve, a carotid sinus nerve, a fat pad." (Id. at 3:3–6.) The Purkinje fibers are never defined as a nerve. There is no evidence that the patentee acted as its own lexicographer and equated the two.[19] This language also indicates that, at least under the '829 Patent, sympathetic nerves may be stimulated to adjust the beating of the heart, which weighs against Edwards' construction. At the Technology Tutorial, Edwards stated that parasympathetic nerves may be stimulated to inhibit the beating of the heart, but there is no ability to stimulate sympathetic nerves to speed up the beating of the heart. Even though the specification confirms that stimulation of the vagus nerve and carotid sinus nerve can reduce the sinus rate and produce asystole, conflicting information precludes the Court from relying on the assertion about sympathetic nerves, which is unsupported by record. In In re Propulsid, the court explained that the two nerves affecting cardiac function in humans are sympathetic and vagal nerves. 261 F. Supp. 2d at 607. Vagal nerves are "inhibitory": they slow heart rate and conduction through the AV node and prolong ventricular refractoriness. Id. "Sympathetic nerve stimulation, on the other hand, speeds the heart rate, improves AV conduction, increases cardiac contraction, and increases blood pressure. The two nerves reciprocate each other." Id. Thus, the exact dynamics of heart rate response to sympathetic nerve stimulation may not be as straightforward as Edwards describes.

More to the point, the consequences of vagal or carotid sinus nerve or other nerve stimulation do not dictate the consequences of Purkinje fiber stimulation covered by the claimed method. Even if they did, the '829 Patent contemplates nerve stimulation that may increase the heart rate. And the patentee chose when to differentiate between methods directed only to slowing or stopping the heart rate and those that encompass increasing the heart rate, both of which may stop or slow cardiac rhythm. Simply put, claim 43 is not as limiting as, for example, claims 1 or 15 or 41, and the claim language

[19] In one embodiment of a system, the '829 Patent states that a "nerve stimulator" may be used to electrically manipulate cardiac rhythm by, *inter alia*, stimulating the Purkinje fibers. ('829 Patent, 5:46–51.) This does not equate the Purkinje fibers with nerves.

and the specification do not justify limiting the stimulation of the Purkinje fibers to stimulation that only stops or slows the heart beat to stop or slow cardiac rhythm.

Therefore, in light of the claim language and the specification, the Court adopts the following construction of this part of the disputed claim: "intermittently starting and stopping stimulation of the Purkinje fibers to adjust the beating of the heart multiple times, where the stimulation stops or slows cardiac rhythm."

Finally, Edwards argues that "a" means "single," but there is no intrinsic support for this construction. In patent parlance, an indefinite article, such as "a," means "'one or more' in open-ended claims containing the transitional phrase 'comprising,'" and is generally read as meaning "one" when following the phrase "consisting of." IEZ Corp. v. Blue Pumpkin Software, Inc., 122 F. App'x 458, 467 (Fed. Cir. 2005) (quoting KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000)); Digene Corp. v. Third Wave Techs., Inc., 322 F. App'x 902, 909 (Fed. Cir. 2009) (citation omitted). "Unless the claim is specific as to the number of elements, the article 'a' receives a singular interpretation only in rare circumstances when the patentee evinces a clear intent to so limit the article." KCJ Corp., 223 F.3d at 1356.

"Comprising" does not precede "a" in claim 43, but the claim language and the specification do not limit the method to a "single" medical procedure or indicate Medtronic's intent to limit it to singular form. Instead, the specification implies that "a medical procedure" more accurately refers to a medical procedure which may have multiple steps or a series of concurrent procedures.[20] (E.g., '829 Patent, 3:59–65

[20]The '829 Patent claims repeatedly recite "a medical procedure," and the Court finds no reason to believe that the meaning of the term varies from claim to claim. See Digital-Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc., 672 F.3d 1270, 1275–76 (Fed. Cir. 2012) (explaining that claim term must be construed the same way each time it is used in patent). Claims 14 and 25 also establish that the medical procedure in independent claims 1 and 25 in the '829 Patent "is selected from the group consisting of: surgical procedures, non-surgical procedures, endoscopic procedures," cardiac surgery with or without cardiopulmonary bypass circuits, brain surgery, heart valve repair, heart valve replacement, beating heart surgery, etc. ('829 Patent, 17:63–18:12, 18:58–19:7.) These cannot all be distilled into "a single medical procedure."

(providing method of performing heart surgery where nerve is stimulated to reduce beating of heart, heart is stimulated to cause beating, and nerve is "restimulated to re-inhibit beating of the heart and surgery is continued").) One portion of the specification teaches that while the heart is contracting as desired when stimulation of the heart either is stopped or started to encourage contractions, "it may be determined if additional medical procedures or additional stages of the medical procedure need to be performed." (Id. at 16:1–6.) If so, contractions may be inhibited again and "[a]dditional surgery, additional steps in the medical procedure or additional medical procedures may again be performed." (Id. at 16:15–17.) "This cycle may be repeated until the procedure, *such as the surgery*, is completed." (Id. at 16:22–23 (emphasis added).) This language shows that intermittent stimulation is not limited to completion of a "single" procedure, so there is no need to depart from the Federal Circuit's general rule. Therefore, the Court rejects Edwards' proposal and adopts the customary meaning of "a"—"one or more."

Accordingly, the Court adopts the following construction of the disputed term: "intermittently starting and stopping stimulation of the Purkinje fibers to adjust the beating of the heart multiple times, where the stimulation stops or slows cardiac rhythm during a series of one or more medical procedures."

IV. CONCLUSION

Disputed Claim Term	**Court's Construction**
stent device	device providing support within the space of a tubular structure in the body
electrically stimulating a heart to adjust beating of the heart to a first condition/electrically stimulating the heart to adjust beating of the heart to a first rate	electrically stimulating the heart to adjust beating of the heart to a rate that results in reduced heart motion and/or blood flow

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. SACV 12-00327-JVS (MLGx) Date March 7, 2013

Title Medtronic Inc. v. Edwards Lifesciences Corp. Et al.

delivering the stent device to the stimulated heart when the beating of the stimulated heart has been adjusted to the first condition, when the heart is beating in the first condition/delivering a stent device to the heart when the heart is beating at the first rate	(no construction needed in the context of the claim language and the Court's previous constructions)
reducing electrical stimulation of the heart to adjust beating of the heart to a second condition after delivering the stent device/reducing electrical stimulation of the heart to adjust beating of the heart to a second rate after delivering the stent device	reducing electrical stimulation of the heart to adjust beating of the heart to a normal beating rate
pacing the heart to achieve the first condition	changing or regulating the beating of the heart or movement of the heart to achieve the first condition
wherein the stimulating of the heart comprises stimulating the Purkinje fibers	wherein the stimulating of the heart includes stimulating the Purkinje fibers
positioning the stimulation electrode in a position suitable for stimulating Purkinje fibers to stop or slow cardiac rhythm	positioning the stimulation electrode in a position capable of and appropriate for stimulating the Purkinje fibers to stop or slow cardiac rhythm
intermittently starting and stopping stimulation of the Purkinje fibers multiple times in order to manipulate cardiac rhythm during a medical procedure	intermittently starting and stopping stimulation of the Purkinje fibers to adjust the beating of the heart multiple times, where the stimulation stops or slows cardiac rhythm during a series of one or more medical procedures

IT IS SO ORDERED.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	SACV 12-00327-JVS (MLGx)	Date	March 7, 2013
Title	Medtronic Inc. v. Edwards Lifesciences Corp. Et al.		

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