IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MEDTRONIC, INC. Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, and MIROWSKI FAMILY VENTURES L.L.C. Defendants.	)	Civ. No. 07-823-SLR

Arthur G. Connolly III, Esquire of Connolly Bove Lodge & Hutz LLP, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Martin R. Lueck, Esquire, Jan M. Conlin, Esquire and Stacie E. Oberts, Esquire of Robins, Kaplan, Miller & Ciresi L.L.P., Minneapolis, Minnesota.

Richard L. Horowitz, Esquire, David Ellis Moore, Esquire of Potter Anderson & Corroon, LLP, Wilmington, Delaware. Counsel for Defendant Mirowski Family Ventures, L.L.C. Of Counsel: Arthur J. Neustadt, Esquire, Thomas J. Fisher, Esquire and John F. Presper, Esquire of Oblon, Spivak, McClelland, Maier & Neustadt, L.L.P., Alexandria, Virginia.

Frederick L. Cottrell, III, Esquire and Anne Shea Gaza, Esquire of Richards, Layton & Finger, Wilmington, Delaware. Counsel for Defendants Boston Scientific Corporation and Guidant Corporation. Of Counsel: J. Michael Jakes, Esquire and Naveen Modi, Esquire of Finnegan Henderson Farabow Garrett & Dunner LLP, Washington, District of Columbia.

OPINION

Dated: March 30, 2011
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

Plaintiff Medtronic, Inc. ("Medtronic" or "plaintiff") filed this complaint on December 17, 2007, against Boston Scientific Corporation ("BSC"), Guidant Corporation ("Guidant"), and Mirowski Family Ventures LLC ("MFV," collectively "defendants") for declaratory judgment of non-infringement and invalidity of United States Reissued Patent Nos. RE 38,119 ("the '119 patent") and RE 39,897 ("the '897 patent," collectively "the reissue patents"). (D.I. 1) Thereafter, plaintiff amended its complaint twice, first to add a defense of prosecution laches, and then to assert non-infringement of two new products. (D.I. 84; D.I. 108) BSC and Guidant filed an answer on February 2, 2008, and thereafter amended it twice. (D.I. 18; D.I. 88; D.I. 115) MFV also filed an answer on February 2, 2008 and amended it twice. (D.I. 20; D.I. 89; D.I. 114) On December 2, 2009, the parties submitted their joint claim construction chart. (D.I. 144) The court conducted a *Markman* hearing on January 7, 2010.

A bench trial was held January 25-28 and March 13, 2010 on validity and enforceability of the reissue patents and whether any of the accused products infringe any valid asserted claim. On March 30, 2010, the parties stipulated that in post-trial briefing, plaintiff would file opening and reply briefs, and defendants would file only an answering brief. (D.I. 187) On February 7, 2011, the court ordered that defendants may file a sur-reply brief addressing only the issue of infringement as discussed in plaintiff's reply post-trial brief. (D.I. 253) Pursuant to the court's order, defendants filed a sur-reply brief on February 22, 2011. (D.I. 254) The issues at bar have been fully briefed post-trial. The court has jurisdiction pursuant to 35 U.S.C. §§ 1 et seq. and 28

U.S.C. §§ 1331, 1338(a), 1400(b) and 2201. Having considered the documentary evidence and testimony, the court makes the following findings of fact and conclusions of law pursuant to Fed. R. Civ. P. 52(a).

II. FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Background

1. The parties and litigation history

1. Medtronic, BSC, and Guidant are all leading manufacturers and sellers of medical devices. (D.I. 86 at 2) Medtronic is a Minnesota corporation with a principal place of business in Minneapolis, Minnesota. (D.I. 115 at 1) Medtronic is engaged in the business of manufacturing, promoting, offering for sale, and selling certain implantable cardiac stimulation devices that are capable of providing cardiac resynchronization therapy ("CRT"). (D.I. 114 at 1; D.I. 115 at 1) BSC is a Delaware corporation with a principal place of business in Natick, Massachusetts. (D.I. 115 at 1) Guidant is an Indiana corporation with a principal place of business in Carmel, Indiana, and is a wholly-owned subsidiary of BSC. (*Id.*) Guidant is the exclusive licensee of the reissue patents. (*Id.*) MFV is a Maryland limited liability company which holds the patent rights of Michel Mirowski, M.D., inventor of the implantable cardiac defibrillator ("ICD"), and is the assignee of the reissue patents. (D.I. 86 at 2; D.I. 114 at 1)

2. There is a long history of litigation involving the parties in the case at bar. (*See* D.I. 86 at 1-8) Ely Lilly & Co. ("Lilly"), Guidant's predecessor-in-interest to the reissue patents, entered into a sublicense agreement ("Lilly agreement") with Medtronic in 1991 covering, inter alia, the '119 patent. (DTX-87 at 1) The Lilly agreement gave Medtronic the right to challenge allegations of infringement of the '119 patent as well as

the validity and enforceability of the '119 patent through one or more declaratory judgment actions. (*Id.*)

3. In 2003, by agreement of the parties, Medtronic began paying royalties into escrow on sales of certain products, while at the same time challenging the validity of the '119 patent ("2003 litigation").[1] (*Id.*) In 2004, the validity and enforceability of the '119 patent was also placed at issue in litigation between Guidant and St. Jude Medical, Inc. ("St. Jude litigation").[2] (*Id.*)

4. In 2006, Medtronic, Guidant, and MFV entered into a "Litigation Tolling Agreement" ("LTA"). (DTX-87) The LTA recognized that "an actual controversy exists . . . as to the scope, validity and enforceability of the '119 patent, and whether or not any valid and enforceable claims thereof cover Medtronic products, and consequently the proper distribution of substantial monies residing in or to be paid into various escrow accounts." (*Id.* at 2) The LTA tolled and suspended various litigation and defenses thereto pending the conclusion of the "DJ Suspension Period" and for ninety (90) days after receipt by Medtronic of a notice of infringement from Guidant or MFV. (*Id.* at 5) The "DJ Suspension Period" was defined to be "the later of: (a) final resolution of the St. Jude Litigation (including settlement thereof), or (b) October 1, 2007." (*Id.* at 2) The LTA provided that, within 60 days after the DJ Suspension Period, defendants could provide written notice to Medtronic of infringement of the '119 patent or subsequent reissue patents claiming priority to the '119 patent. (*Id.* at 5) The LTA further provided

---

[1] *Medtronic, Inc. v. Guidant Corp.*, No. 03-848-SLR (D. Del.)

[2] *St. Jude Medical, Inc. v. Guidant Corp.*, No. 04-0067-SLR (D. Del.)

that, within 90 days after such notice, Medtronic could initiate a final declaratory judgment, in this court, challenging infringement, unenforceability and/or validity of the asserted claims of the '119 patent and any asserted claims of any subsequent reissue patent(s). (*Id.* at 6) The declaratory judgment complaint in the present action was filed pursuant to the LTA. (D.I. 1)

2. The heart, its maladies and treatment

5. The human heart is divided into four chambers. (D.I. 154, ex. 1 at ¶ 22; D.I.146 at 3) The two upper chambers of the heart are called the left and right atria and receive blood from the body or lungs. (D.I. 154, ex. 1 at ¶¶ 22, 23; D.I. 146 at 3) "One upper chamber is called an 'atrium,' while both upper chambers together are called the 'atria.'" (D.I. 154, ex. 1 at ¶ 22) The two lower chambers in the heart are called the left and right ventricles and are the pumping chambers of the heart. (*Id.*; D.I. 146 at 3) When the ventricles contract, blood is pumped out of the heart with enough force to push blood through the lungs and entire body. (*Id.*)

6. The left and right sides of the heart are separated by a wall, called the septum. (D.I. 154, ex. 1 at ¶ 23; D.I. 146 at 3) Deoxygenated blood (blood with no oxygen) returning to the heart from the body moves through the right side of the heart. (*Id.*) Oxygenated blood (blood with oxygen) returning from the lungs moves through the left side of the heart. (*Id.*)

7. The right atrium receives deoxygenated blood from the body. (D.I. 154, ex. 1 at ¶ 22; D.I. 146 at 3) When the right atrium contracts, blood is pushed into the right ventricle. (*Id.*) Once the right ventricle has filled, it contracts and pumps blood to both

lungs. (*Id.*) Blood is circulated through the lungs where carbon dioxide is removed and oxygen is absorbed. (D.I. 146 at 3)

8. Oxygenated blood returns to the heart into the left atrium. (*Id.*) When the left atrium contracts, blood is pushed into the left ventricle. (*Id.*) When the left ventricle contracts, blood is pushed on to the rest of the body. (*Id.*) The circulatory cycle then begins again. (*Id.*)

9. A variety of problems can cause the heart to behave abnormally. (D.I. 148, ex. 1 at 5-6) One problem involves the heart's electrical system, which can affect the timing of the heart, resulting in arrhythmias (rhythm disorders). (*Id.*) One such disorder is bradycardia, a condition in which the heart beats too slowly. (*Id.*) Tachycardia, on the other hand, is a condition in which the heart beats too rapidly. (*Id. at* 7) Fibrillation is a condition in which the heartbeat is chaotic, or irregular, and the heart may skip beats. (*Id.*)

10. Treatment of these electrical disorders usually involves an implantable electronic device for stimulating the heart. (*Id.*) Bradycardia is treated using a pacemaker, a device that sends electrical impulses to the heart through electrical leads (wires) in the right atrium and right ventricle to maintain a suitable heart rate. (*Id.* at 6-7) Tachycardia and fibrillation are usually treated using an implantable cardioverter defibrillator ("ICD"). (*Id.* at 7) Compared to pacemakers, ICDs deliver a massive high-energy pulse (shock) to the heart through electrical leads to stop the arrhythmias. (*Id.*)

11. Separate from the timing problem of arrhythmias, a heart may also suffer from structural problems that affect its pumping ability, such as heart failure. (*Id.* at 8)

Heart failure is a disease in which the heart progressively loses its ability to effectively pump blood. (*Id.*)

12. Pacing of the heart, using a pacemaker, is performed in various modes described by a shorthand positional notation according to at least the following three parameters: (1) the chamber(s) where pacing occurs; (2) the chamber(s) where sensing occurs; and (3) the response to sensing. (D.I. 188 at 80:23-86:10) In this notation, the chambers paced and sensed are designated by characters, where "O" represents zero or none, "A" represents atrium, "V" represents ventricle, and "D" represents dual (A+V). (*Id.*) The response to sensing is designated by the characters "O" representing zero or none, "T" representing triggered output in response to a sensed event, "I" representing inhibited output in response to a sensed event, and "D" representing dual (T+I). (*Id.*)

13. The modes relevant to the reissue patents are: VOO, VVI, VDI, VVT, VAT, and VDD. VOO mode, also known as "Fixed-rate Ventricular pacing," describes ventricular pacing with no sensing. (D.I. 188 at 82:6-21; D.I. 193 at 42) VVI mode indicates activity is sensed in the ventricle, and stimulation of one ventricle is inhibited if intrinsic electrical activity is sensed. (D.I. 188 at 83:2-24; D.I. 193 at 42) VDI mode indicates activity is sensed in the ventricle and/or atrial chambers, and stimulation of one ventricle is inhibited if intrinsic electrical activity is sensed. (D.I. 188 at 83:2-24; D.I. 193 at 42) VVT mode, or "Triggered pacing," indicates stimulation of one ventricle is triggered upon the sensing of an electrical signal in another ventricle. (D.I. 188 at 83:25-84:3; D.I. 193 at 42) VAT mode, or "atrial-triggered, ventricular pacing," indicates

that the ventricle is paced if electrical activity is sensed in an upper (atrial) chamber of the heart. (D.I. 188 at 84:19-85:4; D.I. 193 at 42) Finally, in VDD mode, stimulation of the ventricle can be inhibited or triggered if intrinsic activity in the atrial or ventricular chambers is sensed. (D.I.188 at 85:23-86:9; D.I. 193 at 42)

3. Dr. Mower's invention

14. Dr. Mower is a renowned researcher in the cardiology field, having been inducted into the National Inventors Hall of Fame for his invention, in the 1970s with Dr. Mirowski, of the first ICD. (D.I. 189 at 479:7-481:10) As a practicing cardiologist in the 1980s, Dr. Mower concerned himself with the treatment of congestive heart failure, a condition more widespread than ventricular fibrillation for which the ICD was invented. (*Id.* at 481:20-482:8) At the time, Dr. Mower was practicing at Sinai Hospital in Baltimore, Maryland, where he "ran the heart station, which . . . did most of the EKG reading." (*Id.*) Dr. Mower noticed that "those patients who were diagnosed [with] congestive heart failure generally had widened QRSs," from which he inferred that "there was a slow conduction from one side of the heart to the other, and [] realized that there might be incoordinate contraction playing at least some role in the heart failure." (*Id.* at 488:7-22) This insight led to the invention that is the subject of the reissue patents. (*Id.* at 488:12-489:2)

15. Dr. Mower's invention is directed to a device to treat ventricular asynchrony. *Medtronic v. Guidant Corp.*, Civ No. 03-848-SLR, 2004 WL 5501181 at *3-4 (D. Del. July 19, 2005). Ventricular asynchrony is a condition in which the patient has a conduction defect in his ventricles causing the ventricles to contract at different times.

Id. Dr. Mower's invention addresses this defect by pacing the heart so as to cause substantially simultaneous ventricular contractions. *Id.* Unlike treating an arrhythmia (where the concern is the quantity of heartbeats), because the patient is suffering from heart failure, continuous bi-ventricular pacing improves the output of the heart and, therefore, the quality of the heartbeats. (D.I. 190 at 528:13-25) "Bi-ventricular pacing (or pacer/pacemaker)," a term used in the reissue patents, is now referred to as cardiac resynchronization therapy. ('119 patent at col. 3:56-57, col. 6:3-14, col. 7:17-20, and claims 9-13, 22-26; '897 patent, claims 132-133; D.I. 146, ex. 2 at 17)

4. The reissue patents

16. The reissue patents are both reissues of U.S. Patent No. 4,928,688 ("the '688 patent"). (Reissue patents at [64]) The '688, '119 and '897 patents are directed to a method and apparatus for treating hemodynamic dysfunction by using electrodes to simultaneously stimulate the ventricles of the heart. ('688, '119 and '897 patents, Abstract) The reissue patents share the specification and priority date of the '688 patent. (D.I. 147 at 2 n.2) The '688 patent issued on May 29,1990 from application No. 07/299,895 ("the '895 application"), filed on January 23, 1989. ('688 patent at [21, 22, 45])

17. The '119 patent issued on May 20, 2003 from application No. 08/547,691 ("the '691 application"), filed on October 19, 1995. ('119 patent at [21, 22, 45]) The '691 application was a continuation of application No. 10/214,474, ("the '474 application") filed Aug. 8, 2002, which in turn was a continuation of application No. 07/890,280, ("the '280 application") filed May 29, 1992, which was later abandoned. ('119 patent at [63])

18. The '897 patent issued on October 23, 2007 from application No. 10/214,474, filed on August 8, 2002. ('897 patent at [21, 22, 45]) The '897 patent is a continuation of the '119 patent. ('897 patent at [63])

19. The named inventor of the reissue patents is Morton M. Mower. (Reissue patents at [75]) Since a reissued patent is valid only for the "unexpired term of the original patent," the reissue patents each expired on January 23, 2009. *See* 35 U.S.C. 251.

20. Defendants allege that plaintiff infringed one or more of claims 15, 19, 20, 25 and 26 of the '119 patent and claims 15, 54, 84, 86, 120, 144, 172, 201, 217, 233, 248, 273, 288, 303, 308, 311, 315 and 324-328 of the '897 patent. (D.I. 188 at 4:22-25, 137:22-138:13; PTX-515[3])

5. Accused devices

21. Defendants accuse plaintiff's InSync, InSync ICD, InSync II Marquis, InSync Maximo, InSync II Protect, InSync Sentry, Concerto, Maximo II and Consulta devices (collectively "accused devices") of infringing the reissue patents. (D.I. 192 at 868:8-17; PTX-567) The accused devices are all cardiac resynchronization therapy devices. (D.I. 189 at 334:11-335:4) Although similar, slight differences exist among the accused products. (*Id.*) The InSync device does not provide defibrillation therapy, whereas the remaining accused devices are all CRT devices coupled with defibrillators. (*Id.*) Additionally, the InSync pacemaker does not have separate sensing and pacing circuitry

[3]Claims 184 and 309 of the '897 patent were originally asserted and are shown in PTX-515, but were later withdrawn. (D.I. 188 at 4:22-24)

for the two ventricular leads; instead, the leads are coupled together. (*Id.*) Some modes available in the other devices are not found in the InSync ICD. (*Id.*)

B. Claim Construction

22. The parties dispute construction of ten different terms of the asserted claims of the '119 patent. For the reasons discussed below, the court finds that only two terms, involving claim preambles, are dispositive of the issues at bar.

1. Legal standard

23. Claim construction is a question of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The words of a claim "are generally given their ordinary and customary meaning," as understood by a person of ordinary skill in the art in question, read in the context of the particular claim and that of the entire patent, at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citations omitted). The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (*quoting Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). It is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1317 "[A] court 'should also consider the patent's prosecution history, if it is in evidence.'" *Id.* (*quoting Markman*, 52 F.3d at 980).

24. "[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not

some other, is the one the patent protects." *Bell Commc'ns Research, Inc. v. VitaLink Commc'ns Corp.*, 55 F.3d 615 (Fed. Cir. 1995) (citations omitted). "[T]erms appearing in a preamble may be deemed limitations of a claim when they give meaning to the claim and properly define the invention." *In re Paulsen*, 30 F.3d 1475, 1479 (Fed. Cir. 1994).

25. "Although no 'litmus test' exists as to what effect should be accorded to words contained in a preamble, review of a patent in its entirety should be made to determine whether the inventors intended such language to represent an additional structural limitation or mere introductory language." *Id.* "The effect preamble language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) (holding that a preamble reciting "an optical waveguide" was limiting as to the specific type of waveguide taught by the specification, and not to any type, as would be the case without construing the preamble as a limitation). "Whether a preamble of intended purpose constitutes a limitation to the claim is, as has long been established, a matter to be determined on the facts of each case in view of the claimed invention as a whole." *In re Stencel*, 828 F.2d 751, 754 (Fed. Cir. 1987).

26. "'In considering whether a preamble limits a claim, the preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to the general field of the claim.'" *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1375 (Fed. Cir. 2008) (*quoting On Demand Mach.*

Corp. v. Ingram Indus., 442 F.3d 1331, 1343 (Fed. Cir. 2006)). "[W]hen reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d at 808. Conversely, "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention," the preamble is not limiting. *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997).

27. Having heard oral argument on, and having reviewed the papers submitted in connection with, the parties' proposed claim construction, the court construes the disputed claim language consistent with the tenets of claim construction set forth by the Unites States Court of Appeals for the Federal Circuit in *Phillips*, as follows:

2. Improving the hemodynamic efficiency of a heart

28. The parties dispute whether the preambles of independent claims 15 and 19 of the '119 patent constitute limitations and, if so, their proper construction. The preambles of claims 15 and 19 are identical and recite: "A method for improving the hemodynamic efficiency of a heart comprising the steps of: . . . ." At the very outset, the specification of the '119 patent defines an objective of the invention as "a method for increasing the cardiac output of a patient suffering from congestive heart failure," and points to this objective to distinguish over the prior art.[4] ('119 patent at col. 1:18-22) It

[4]"Although Funke does teach the concept of simultaneous stimulation of a plurality of spaced electrodes, he **does not disclose** its specific use as a method of **improving the cardiac output of patients suffering from congestive heart failure**." ('119 patent at col. 2:28-33) (emphasis added)

is evident from the specification that the invention exists in the context of improving the pumping ability of a heart that is in a state of (congestive) heart failure[5] and, thus, the preambles give meaning to the claims and properly define the invention. The court concludes that the preambles of claims 15 and 19 are limiting, and mean improving the heart's pumping ability for treatment of congestive heart failure. This construction is consistent with the specification: col. 1:18-22; col. 2:28-33; col. 3:12-15, 32-51; col. 4:23-27.

3. Bi-ventricular pacemaker

29. The preambles of independent claim 25 and of dependent claim 26 of the '119 patent recite, "[a] bi-ventricular pacemaker . . . ." Plaintiff argues that this phrase

---

[5]The specification teaches:

> The method of the present invention involves a procedure for pacing of the heart in a particular way so as to improve its contraction pattern, and thereby **augment the movement of blood through the heart**. Patients suffering from severe congestive **heart failure**, which is found not to respond well to conventional drug therapy and to have a conduction defect in the ventricle resulting in a widen [sic] Q-R-S complex have been aided by a pacing regimen in which stimulating pulses are simultaneously applied to both ventricles by way of a demand pacemaker or asynchronous pacemaker.
>
> It is theorized that a considerable part of the **hemodynamic impairment** in refractory congestive **heart failure** with conduction defects is due to an incoordinate contraction of the heart, so that a part of the heart muscle contracts and balloons out the part that is not contracting. When the latter area of the heart muscle does finally contract, the former has relaxed, so that a large part of the blood volume is merely shunted back and forth within the heart rather than being ejected as would happen with a more coordinate contraction pattern.

('119 patent at col. 3:32-51) (emphasis added)

"merely describes the purpose of claims 25 and 26." (D.I. 147 at 10) Although admitting that these claims require the capability to stimulate two ventricles, plaintiff argues that the language of the claim body alone, without consideration of the preamble, expressly creates this limitation.[6] Claim 25 recites:

> A bi-ventricular pacemaker comprising:
> **detecting means for detecting** a cardiac signal resulting from a **contraction of a first ventricle**;
> **stimulating means for effecting** immediate and unconditional **contraction of a second ventricle** in response to the detected cardiac signal, thereby effecting simultaneous contraction of both ventricles.

('119 patent at 11:1-7) (emphasis added)

30. Excluding the preamble, claim 25 discloses stimulating means for only one ventricle, the second. It is the preamble, with its term "bi-ventricular pacemaker," that describes structure capable of stimulating two ventricles. ('119 patent at col. 3:39-55, 6:13-22) Therefore, the court finds that the preamble of claim 25 contains a structural limitation that is not present in the body of the claim and concludes that the preamble of claim 25 constitutes a limitation. A bi-ventricular pacemaker, as used in the preamble of claim 25, means a device capable of providing stimulation to either one or both ventricles to effect a coordinated contraction thereof for the treatment of congestive heart failure. This construction is consistent with the specification: col. 3:32-4:26, col. 6:3-14, col. 7:17-20. Due to its dependency on claim 25, the preamble to claim 26 is similarly construed.

[6]"[T]he express language of the claims (without consideration of the preamble) calls for an apparatus for stimulating or pacing the two ventricles." (D.I. 147 at 10)

C. Infringement

1. Legal standard

31. To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents. *See Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336 (Fed. Cir. 2001). To establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). Significant to the case at bar, if an accused product does not infringe an independent claim, it also does not infringe any claim depending thereon. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989).

32. To prove infringement by the doctrine of equivalents, a patentee must provide "particularized testimony and linking argument" as to the "insubstantiality of the differences" between the claimed invention and the accused product, or with respect to the function/way/result test. *See Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996).

33. Establishing the literal infringement of a means-plus-function limitation "requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir.

1999). A patentee may show structural equivalence "if the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification." *Id.* The *Odetics* court differentiated between the "similar analysis" of equivalents under the doctrine of equivalents and 35 U.S.C. § 112, ¶ 6, noting that a component by component analysis is not required to establish structural equivalence in the latter. *Id.* Indeed, such an analysis would be improper to the extent that

> [t]he individual components, if any, of an overall structure that corresponds to the claimed function are not claim limitations. Rather, the claim limitation is the overall structure corresponding to the claimed function. . . . The appropriate degree of specificity is provided by the statute itself; the relevant structure is that which "corresponds" to the claimed function. Further deconstruction or parsing is incorrect.

Id. at 1268 (internal citations omitted). Conversely, the relevant structure does not include "structure 'unrelated to the recited function' disclosed in the patent . . . ." *Id.* (*citing Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus.*, 145 F.3d 1303, 1308 (Fed. Cir. 1998)).

2. Burden of proof

34. The parties dispute which side has the burden to prove infringement at trial. Plaintiff argues that the burden is always on the patentee (defendants). (D.I. 193 at 7-9) Defendants assert that the burden of proof was always on Medtronic as plaintiff, and argue three theories in support thereof. First, defendants argue that the Lilly agreement and the LTA provide that Medtronic must file a declaratory judgment action in order to challenge infringement, and that "the plaintiff usually has the burden of proof." (D.I. 247

at 38) Second, defendants argue that, due to these provisions, the case law cited by plaintiff is inapposite. (*Id.* at 38-39) Finally, defendants point to this court's guidelines as to post-trial briefing, establishing that the party having the burden of proof on an issue is usually permitted both an opening brief and a reply brief, whereas the opposing party is usually limited to an answering brief. (*Id.* at 39) Defendants allege that "Medtronic has taken the unusual position that it does not have the burden of proof but it is entitled to both open and reply on [the issue of infringement]." (*Id.*)

35. "The burden is always on the patentee to show infringement." *Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) (*citing Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir.1984)). "Neither [the patentee's] burden to prove infringement nor [the accused infringer's] burden to prove invalidity, both ultimate burdens of persuasion, ever shifts to the other party - the risk of decisional uncertainty stays on the proponent of the proposition." *Technology Licensing Corp. v. Videotek, Inc.,* 545 F.3d 1316, 1327 (Fed. Cir. 2008) (*citing Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986); *Ralston Purina Co. v. Far-Mar-Co, Inc.,* 772 F.2d 1570, 1574 (Fed. Cir. 1985); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)).

36. As the parties asserting infringement, defendants bear the burden of proof by a preponderance of the evidence. *See Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569 (Fed. Cir. 1991) (*citing Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361 (Fed. Cir. 1983)).

3. Sufficiency of evidence

37. Plaintiff asserts that defendants' evidence of infringement is insufficient. (D.I. 193 at 9-10) During pre-trial proceedings, plaintiff requested that the court preclude Dr. Berger, defendants' expert on infringement, from testifying because "he failed to map every element of each asserted claim against the accused Medtronic devices in his expert report." (D.I. 189 at 327:4-5; D.I. 193 at 9) (*citing* D.I. 177-2 at 25; D.I. 255 at 116:11-120:3) Pursuant to the court's order of January 22, 2010 (D.I. 185), plaintiff again raised this issue during trial. (D.I. 189 at 472:2-474:11) The court, at the behest of the parties, reserved judgment on this issue pending post-trial briefing, allowing supplementation of the record. (*Id.*) In essence, plaintiff has raised a *Daubert* challenge, claiming that, in opining on infringement, Dr. Berger failed to apply reliable principles and methods to the facts of the case. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

a. Legal standard

38. The Supreme Court in *Daubert* made clear that courts have to play a gatekeeping role with respect to experts. *Daubert*, 509 U.S. at 113. According to the Supreme Court, Rule 702 of the Federal Rules of Evidence[7] is the primary locus of the

[7] Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

gatekeeping role. Pursuant to Rule 702, a party can offer testimony of an expert witness at trial so long as the expert is qualified, the methodology the expert uses is reliable, and the opinion fits the facts of the case. *See Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000). A trial judge, then, is tasked with being a "'gatekeeper' to ensure that 'any and all expert testimony is not only relevant, but also reliable.'" *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008).

39. As recognized by the United States Court of Appeals for the Third Circuit, while an expert's methodology is required to pass muster under Rule 702, the data underlying the expert's opinion must pass muster under Rules 104[8] and 703.[9] More

---

Fed. R. Evid. § 702.

[8] Rule 104 provides:

> (a) **Questions of admissibility generally.** Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b)....
>
> (b) **Relevance conditioned on fact.** When the relevance of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

Fed. R. Evid. § 104.

[9] Rule 703 provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted[.]

Fed. R. Evid. § 703.

specifically, the Third Circuit in *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717 (3d Cir. 1994), made clear "that it is the judge who makes the determination of reasonable reliance, and that for the judge to make the factual determination under Rule 104(a) that an expert is basing his or her opinion on a type of data reasonably relied upon by experts, the judge must conduct an independent evaluation into reasonableness." *Id.* at 748. The Third Circuit concluded in *In re Paoli* that, because the policy considerations underlying the rules of evidence are the same, the "reliability requirement" for admission under Rules 104, 702 and 703 should be the same - "there must be good grounds on which to find the data reliable." *Id.*

b. Literal infringement

40. Having determined that defendants, as patentees, have the burden to prove infringement, the court recognizes at the outset of its discussion that there are litigation efficiencies in narrowing the issues to be resolved at trial. Therefore, if only certain limitations are in dispute, it makes sense to limit the presentation of evidence to such limitations. In this case, however, it is unclear from the record that there was an agreement among the parties to narrow the issues for trial. Aside from citing to an interrogatory response (DTX -71), it would appear that defendants relied primarily on their burden-shifting view of the case,[10] thus leaving the court between a rock (the way

[10]Defendants assert that they served an interrogatory on plaintiff, requiring plaintiff to identify each non-infringement assertion. (D.I. 247 at 35-36) Continuing their position that plaintiff had the burden of proof, defendants argue that,

> [s]ince Medtronic is the plaintiff in this action, Dr. Love's non-infringement expert report came before Dr. Berger's responsive infringement expert report. While Dr. Berger's expert report was primarily directed to each of

the parties chose to litigate this case) and a hard place (the court's responsibility to make an infringement determination based on appropriate evidence). Because plaintiff has asserted consistently that Dr. Berger failed to conduct an appropriate infringement analysis in his expert report, through his deposition and at trial, and because there is no affirmative evidence excusing Dr. Berger from this responsibility, the court will review the record to test the sufficiency of defendants' infringement analysis in this regard.

41. In its post-trial brief, plaintiff points to Dr. Berger's deposition testimony in support of its argument that "his expert report did not map every element of each asserted claim against each accused product."

> Q. Okay. And you understand that in undertaking an infringement analysis what you do is map each element of the asserted claim against the accused products; right?
> A. Correct.
> Q. Okay. In this case you did not do that for each limitation of the asserted claims; correct?
> A. I believe I did do that.
> Q. Okay. Well let's take a look at your report. As an example if we could turn to page 56, and section O of your report is dealing with the '897 patent, Claim 217. Do you see that?
> A. Yes.
> Q. Okay. And what follows is your analysis with respect to that claim; correct?
> A. I believe so, yes.

> Dr. Love's non-infringement assertions, Dr. Berger did cover all the elements of the asserted claims even though he did not repeatedly point out for each claim the undisputed presence of an element such as a pulse generator or a sense amplifier.
>
> Also, after Medtronic had identified its non-infringement assertions which formed the basis for its declaratory judgment complaint, there was no need for Dr. Berger to concentrate on claim elements that Medtronic did not dispute.

(*Id.* at 36).

Q. Okay. And in fact there are certain limitations in Claim 217 for which you did not map it to the accused products; correct, doctor?
A. Let me read the -
Q. Sure.
A. - section. (Witness reviewing exhibit.) Well in this section here in the - in the area of this report it does not list my opinions on each of the claims limitations, correct.
Q. And in fact what you did, doctor, was respond to certain limitations that were addressed in the report of Dr. Love; correct?
A. I believe that's -- I believe that was the philosophy that I took here, yes.
Q. Okay. So you didn't in fact independently map each asserted limitation onto the accused devices; correct, doctor?
A. In this - In this report that's correct.

(D.I. 193 at 910) (*citing* D.I. 193, ex. A at 7:11-8:21)

42. Plaintiff supplemented the record with a video clip on CD media (*id.*, ex. B) purporting to show that "Dr. Berger's admissions were not 'off the cuff' or made under time restraints. Dr. Berger carefully and deliberately reviewed his expert report for seven minutes before admitting that he failed to map the claims to the products." (D.I. 193 at 10) Plaintiff further asserts that, "[i]n addition, in their original pre-trial submission of Exhibit 5 to the Joint Pretrial Order to Medtronic, [d]efendants admitted that Dr. Berger did not address each claim limitation, stating that 'Dr. Berger was not required to map every element of each claim.'" (*Id.*) (*citing id.*, ex. C at 2)

43. Dr. Berger's expert report on infringement (D.I. 148, ex. 2, "Berger report") covers combinations of 27 claims of two patents asserted against nine accused products, and comprises 72 pages. The Berger report does not contain or reference a typical infringement analysis chart whereby each element of each asserted claim is individually compared with each accused product. Plaintiff does not assert that such a chart is required to prove infringement, although it would have certainly aided the

court's determination of whether Dr. Berger's analysis met the required standard. Instead, Dr. Berger provides only a narrative discussion of various claim limitations, organized to be responsive to Dr. Love's expert report on non-infringement. (D.I. 148, ex. 1)[11]

44. Dr. Berger's analysis of claim 15 of the '897 patent serves as an example of the issue at bar. That claim recites, as the first of three limitations after the preamble, "a sense amplifier to receive ventricular depolarization signals originating from a first ventricle." Dr. Berger's analysis of the entire claim is limited to a recitation of the full claim language, followed by:

> It is my opinion that each of Medtronic's cardiac resynchronization systems marketed under the names InSync, InSync II Marquis, InSync II Protect, InSync Sentry, InSync Maximo, Concerto, Consulta and Maximo II delivers a stimulating pulse to the ventricles in response to a ventricular sense for the reasons discussed above in Section V(A)(3) [sic], or does not operate substantially differently than a device that operates in this manner.

(D.I. 148, ex. 2 at 47-48, § VI(G)) Section VI(A)(3) (*id.* at 30-31), in turn, is a narrative analysis of claim 15 of the '119 patent relating to the limitation, "stimulating both ventricles . . . when a cardiac depolarization signal originating from a first ventricle is detected." The court is unable to locate any reference to the term "sense amplifier" in section VI(A)(3). Section VI(A)(3) has a further reference to unspecified preceding sections relating to the VVT mode and VSR feature. The court is also unable to locate any consideration of the "sense amplifier" limitation in preceding sections. Moreover, it is not incumbent on the court to do so.

[11]As can be observed by comparing the table of contents of each of the two reports.

45. Dr. Berger similarly performs his analysis of claims 54, 84, 86, 120, and 144 of the '897 patent and others. Only vague perfunctory language potentially covers the remaining elements of asserted claims. Defendants' argument that they need only address elements identified in plaintiff's response to its interrogatories or in Dr. Love's non-infringement report (collectively "non-infringement defense") is inapposite as it does not address the issue at bar, whether Dr. Berger's testimony lacks sufficient foundation.

46. The Berger report fails to demonstrate that Dr. Berger considered each limitation of each asserted claim in comparison to each accused product before rendering his infringement opinions.[12] Plaintiff's non-infringement defense, even if considered an admission, would not relieve Dr. Berger of this requirement absent affirmative evidence to this effect. There is no way to determine if "every limitation set forth in a claim is found in an accused product, exactly," without accounting for each limitation. Any such admission would merely render that task easier to accomplish. Defendants have failed to prove literal infringement by a preponderance of the evidence.

c. Doctrine of equivalents

47. Plaintiff contends that Dr. Berger's doctrine of equivalents analysis consists solely of conclusory statements, and fails to provide particularized testimony and linking arguments required to sufficiently prove infringement under this doctrine. (D.I. 193 at 27-28) (*citing id.*, ex. D at 19-23, 23-26, 31-33, 34-35, 36-39)

[12]The court notes in this regard that an expert cannot testify at trial beyond the opinions offered in his/her expert report. In this case, Dr. Berger's trial testimony is no more illuminating than his report and lacks a proper foundation.

48. Defendants' argument regarding doctrine of equivalents is subsumed in their term-by-term rebuttal to plaintiff's non-infringement defenses. (D.I. 247 at 34, ¶ 9) Defendants argue, for example, with respect to the term "contractions" and the doctrine of equivalents that

> Dr. Mower's invention is directed to resynchronization of the ventricles and not to any particular manner in which a contraction is sensed (by electrical or mechanical sensing). Therefore, the resynchronization would take place using either form of sensing. Accordingly, the difference would be "insubstantial." As explained by Dr. Berger, "[t]he difference would not be substantial at all. The purpose is the same, to detect when the atria are activated."

(D.I. 247 at 24) (*citing* D.I. 189 at 342:9-13; D.I. 192 at 983:7-18; D.I. 246, ex. D, D.I. 148, ex. 2, at 31-33)

49. The Federal Circuit has explained that its "prior cases stand for the proposition that mere generalized testimony as to equivalence is insufficient as a matter of law to support a [] verdict finding infringement under the doctrine of equivalents." *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182 (Fed. Cir. 1998). "'Generalized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice [to show infringement under the doctrine of equivalents].'" *Id.* (*quoting Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996)) (brackets retained) The Federal Circuit has also previously stated that "[t]he evidence and argument on the doctrine of equivalents cannot be merely subsumed in plaintiff's case of literal infringement. Rather, 'a patentee must prove substantial identity as to each of the function, way and result prongs of the doctrine of equivalents.'" *Id.* (*quoting Lear Siegler, Inc. v. Sealy Mattress Co.*, 873 F.2d 1422, 1425 (Fed. Cir. 1989); *Malta v. Schulmerich Carillons, Inc.*, 952

F.2d 1320, 1327 (Fed. Cir. 1991)) (brackets retained). "The thrust of these cases is to ensure that a [finder of fact] is provided with the proper evidentiary foundation from which it may permissibly conclude that a claim limitation has been met by an equivalent." *Id.*

50. "[W]hile infringement under the doctrine requires 'only' substantial identity, substantial identity must be proven with regard to all three elements of the doctrine specified in *Graver Tank*: function performed, means by which function is performed, and result achieved." *Lear Siegler*, 873 F.2d at 1425 (*citing Universal Gym Equip., Inc. v. ERWA Exercise Equip. Ltd.*, 827 F.2d 1542, 1548 (Fed. Cir. 1987)). "Absent the proper *Graver Tank* context, i.e., a showing of how plaintiff compares the function, means, and result of its claimed invention with those of the accused device, a [finder of fact] is more or less put to sea without guiding charts when called upon to determine infringement under the doctrine." *Id.* at 1425-26.

51. There are numerous instances in his testimony where Dr. Berger declares equivalent structure by simply stating "[t]he difference would not be substantial at all. The purpose is the same . . . ," or words of a very similar nature. (D.I. 189 at 342:9-13) (*see also id.* at 345:1-7, 348:3-5, 372:3-24, 373:13-17) Dr. Berger's testimony lacks sufficient foundation; his expert report reflects the same failure to execute a proper doctrine of equivalents analysis as his testimony. (*See, e.g.*, D.I. 148, ex. 2 at 19, 31, 33, 35, 48-50) Defendants have failed to show, by a preponderance of the evidence, that the accused products infringe the asserted claims of the reissue patents under the doctrine of equivalents.

D. Invalidity

52. Plaintiff frames its arguments regarding anticipation and obviousness by grouping claims according to pacemaker operational modes as follows: VOO - claim 308 of the '897 patent; VVI and VDI - claims 120, 217, 233, 288, 303, 315, 324-328 of the '897 patent; VVT - claims 15, 25, and 26 of the '119 patent and claims 15, 54, 84, 86, 144, 172, 201, and 311 of the '897 patent; VAT - claims 19 and 20 of the '119 patent; and VDD - claims 248 and 273 of the '897 patent.

1. Prior art

53. Plaintiff asserts that four alleged prior art references, either alone or in combination with each other or the state of the art, either anticipate or make obvious the asserted claims of the reissue patents: "Tyers"[13] (PTX-216); "Gibson"[14] (PTX-219); "Silva"[15] (PTX-269); and "Curtiss"[16] (PTX-217). Each of the four asserted prior art references ("asserted references") were before the examiner during prosecution of the '897 patent. (PTX-5 at MEDMIR0023011, 23017, 23018, 23148; '897 patent at [56]) Plaintiff argues that Silva renders VAT and VVT claims anticipated and/or obvious; that Gibson renders VVI and VDI claims anticipated and/or obvious; that Tyers renders

[13]Tyers, G. F. O., *Comparison of the effect on cardiac function of single-site and simultaneous multiple-site ventricular stimulation after A-V block*, The Journal of Thoracic and Cardiovascular Surgery, 59(2):211-217 (1970).
[14]Gibson, D. G., et al., *Effect of Changes in Ventricular Activation on Cardiac Haemodynamics in Man*, British Heart Journal 33:397-400 (1971).
[15]*Influence of the Location of Ventricular Electrical Stimulation on Cardiac Efficiency*, Experimental and Clinical Study, Doctoral Dissertation, Lorenzo Silva Melchor, Autonomous University of Madrid School of Medicine, Madrid (1987).
[16]Curtiss, E. I., et al., *Electrocardiographically Discrete Right and Left Ventricular QRS Complexes: A Case Report*, Journal of Electrocardiology, 20(2): 162-168 (1987)

VOO, VDD, and VAT claims obvious; and that Curtiss renders VVT claims obvious. (D.I. 193 at 42; D.I. 188 at 4:22-24; PTX-515)

a. The state of the art

54. Plaintiff argues that "the treatment of heart failure was not a 'new' use for biventricular pacing," and that "[p]acing for heart failure was known at least as early as the late 1950s." (D.I. 193 at 36) As proof of these statements, plaintiff proffers the testimony of its expert, Dr. Benditt, in this regard. In addition to the asserted references discussed below, Dr. Benditt recounts various disclosures of atrial-(uni-)ventricular pacing for complete heart block and for heart failure, permanent pacemaking for treatment of bradycardia, and uni-ventricular pacing to treat heart failure. (D.I. 188 at 87:5-109:6) One of Dr. Benditt's state of the art references did explore the use of bi-ventricular pacing to treat certain arrhthymias, not heart failure; even then the study concluded right atrial and right ventricular pacing was preferable to bi-ventricular pacing to correct the arrhythmias. (*Id.* at 109:24-110:4, 237:2-239:17) Dr. Benditt testified that persons of skill in the art were "aware of the difficulty of treating heart failure and that while single chamber ventricular pacing was helpful in some patients, it failed to be adequate in many other patients." (D.I. 188 at 107:5-9) Indeed, Dr. Benditt's testimony does establish that there was a long-felt need to better address heart failure, even with the then available single ventricle pacing. (D.I. 188 at 87:5-109:6) The court finds that, excluding the asserted references, which are discussed in more detail below, Dr. Benditt's testimony fails to establish that bi-ventricular pacing for heart failure was known, or even that uni-ventricular pacing was particularly successful in treating congestive heart failure.

b. Tyers

55. Tyers is a 1970 study of multi-site pacing in dogs with induced heart block (profound bradycardia) but normal ventricles. (D.I. 190 at 561:14-24, 563:9-10, 15-16) Tyers induced heart block by crushing the A-V node, eliminating intrinsic electrical stimulation of the ventricles, and making the dogs dependent on extrinsic stimulation to sustain life. (*Id.* at 561:16-19) Tyers experimented with using 1, 2, 3, and 4 simultaneous ventricular pacing sites. (PTX-216 at MEDMIR0007199) The results showed that "tri-site" stimulation, with one electrode on the left ventricle and two on the right ventricle, provided a highly significant increase over stimulation of the left ventricle alone. (*Id.*) In contrast, stimulation of two sites, with one electrode on each ventricle, provided "no significant alteration of cardiac function." (*Id.* at MEDMIR0007199-200)

c. Gibson

56. Gibson is a 1971 study of the impact of various pacing locations in postoperative patients having undergone valve replacement. (PTX-219 at MEDMIR0001055). Of the six patients included in the study, five were in sinus rhythm and one was in atrial fibrillation. (*Id.* at 398, table I) The particular device implanted was a Starr-Edwards prosthesis, an early valve that would allow one way flow of blood, comprising a birdcage-like container enclosing a ball. (D.I. 190 at 550:6-10) With the ball seated at the inlet end of the cage, the valve is sealed and back flow is prevented. (*Id.*) A characteristic property of the Starr-Edwards valve is that the ball makes a loud clicking sound as it contacts the end of the cage. (*Id.*) Gibson discloses a shortened ball travel time, based on timing of the clicks, when pacing is done to both ventricles as opposed to a single ventricle. (*Id.* at 550:20-23) Notwithstanding the shortened ball

travel time, Gibson concluded that "the change . . . from single to bi-ventricular pacing was associated with no consistent alteration in either arterial pressure or cardiac output." (PTX-219 at MEDMIR0001058) Instead, Gibson suggests that "it is possible that more conspicuous changes could be obtained by variation in the numbers, position, or sequence of activation of ventricular electrodes" (*Id.*)

d. Silva

57. Silva is a 1987 doctoral dissertation written at the Autonomous University of Madrid. Medtronic and defendants dispute whether Silva meets the requirements of a "printed publication" under 35 U.S.C. § 102.

(1) Legal standard

58. Whether a reference is a "printed publication," under 35 U.S.C. § 102, is a "legal determination based on underlying issues of fact." *In re Hall*, 781 F.2d 897, 898 (Fed. Cir. 1986). "A reference is a 'printed publication' within the meaning of section 102(b) if it was 'available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, [could] locate it.'" *Am. Stock Exch., LLC v. Mopex, Inc.*, 250 F. Supp. 2d 323, 328 (S.D.N.Y. 2003) (*citing In re Wyer*, 655 F.2d 221, 226 (C.C.P.A. 1981); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1568 (Fed. Cir. 1988)) (brackets retained). '"Accessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to. If accessibility is proved, there is no requirement to show that particular members of the public actually received the information." *Id.* at 328-29. "[C]ompetent evidence of [] general library practice may be relied upon to establish an approximate time when a thesis became accessible." *In re Hall*, 781 F.2d at 897.

(2) Public access to Silva

59. To support their respective positions, both parties point to deposition testimony of the librarian who indexed, catalogued and shelved the thesis, Ms. Barredo-Sobrino ("librarian"). (D.I. 246, ex. I at 37:20-40:5) The librarian was originally deposed on June 30, 2007 ("2007 deposition"), during the St. Jude litigation, to which Medtronic was not a party. (D.I. 246, ex. J) She was again deposed on December 14, 2009 ("2009 deposition"). (D.I. 246, ex. I) Both depositions required the services of an interpreter.

60. Plaintiff argues that the librarian's testimony establishes that, based on the library's normal business procedures, Silva was submitted to the library, cataloged, and available to the public no later than April 1988. (D.I. 193 at 59) (*citing* 2007 deposition at 61, 64-78, 142-143)

61. Defendants assert that, while "[t]he reading room where the card catalogue was located was apparently open to the public . . . the thesis was located in the stacks, which were not open to the public, [that required one] to pass through a 'control point' to access doctoral theses." (D.I. 247 at 59) (*citing* 2007 deposition at 17:5-14) Defendants further assert that individuals permitted to pass through this control point were members of the university community, whereas other doctors could request access to a doctoral thesis only by first providing "accreditation" and a reason for consulting the thesis. (*Id.*) (*citing* 2007 deposition at 16:14-22, 39:16-40:11)

62. The librarian testified that a doctor not affiliated with the university who desired access to a doctoral thesis would have to "[first] identify himself with his official medical identification as a doctor of Spain [and then] fill out a form indicating the reason

for his consultation." (2007 deposition at 39:16-40:3) It was possible for a non-Spanish doctor to "consult" a doctoral thesis by showing a passport in addition to the other requirements. (*Id.* at 40:4-8) Such consultation was restricted to the confines of the public reading room; the thesis could not be loaned out. (*Id.* at 40:8-11) Under such circumstances, provision was made for appropriate time to review the thesis and take notes. (*Id.* at 40:8-15) Non-Spanish doctors had, in fact, consulted doctoral theses in the reading room in this manner. (*Id.* at 40:16-18) The librarian **did not testify** that any group or person was or would have been denied the opportunity to consult any doctoral thesis, including Silva.

63. Defendants argue that there is no clear and convincing evidence that "anyone not a member of the university family had access to the stacks where the doctoral theses were located." (D.I. 247 at 59) Defendants conflate access to the room where a doctoral thesis was kept with access to the thesis itself. Only access to the thesis is required. Moreover, it is not necessary to show that the thesis was actually accessed by anyone. *See Am. Stock Exch., LLC*, 250 F. Supp. 2d at 328. Although defendants argue there was no proof that either the reason for consultation or the accreditation of a Spanish or foreign doctor would be approved, there is no evidence of record that approval was required. (D.I. 247 at 59) Instead, the record shows that sufficient access was granted to Spanish and non-Spanish doctors, as well as to the university community. The court concludes that Silva qualifies as a printed publication under 35 U.S.C. § 102, and was publicly available no later than April 1988. The '688 patent issued from an application filed on January 23, 1989, and no earlier priority date is claimed. ('688 patent at [22]) Silva qualifies as prior art to the '688 patent and the

reissue patents.

(3) Silva as prior art

64. Silva disclosed a study of the impact of various pacing locations in the hearts of healthy dogs and postoperative patients. (D.I. 190 at 556:21-560:24; PTX-269 at MEDMIR0006892) The selection criteria for patients included in the study were: (1) a stable (normal) sinus rhythm; (2) no atrioventricular conduction disorders or bundle branch blocks on the 12-lead peripheral electrocardiogram; (3) an ejection fraction greater than 0.50 (normal left ventricular function), evaluated by angiogram; and (4) no akinetic, dyskinetic or hypokinetic areas after performance of the angiogram. (PTX 269 at MEDMIR0006953; D.I. 190 at 630:18-632:13) In the actual study populations, both the dogs and patients were in sinus rhythm. (PTX-269 at MEDMIR0006937, 6953) All ten patients were without bundle branch blocks or conduction abnormalities. (*Id.* at MEDMIR0006953) Of the ten patients, seven had "coronary artery disease and maintained ventricular function," and three "suffered from valve disease." *Id.* "Coronary patients with prior myocardial necrosis were rejected even if ventricular function had been maintained." *Id.* Silva concluded that "[b]i-ventricular electrical stimulation in post-operative patients (VAT mode) is hemodynamically more favorable than that obtained from univentricular stimulation." (*Id.* at MEDMIR000702)

e. Curtiss

65. Curtiss is a 1987 case report of a single patient that presented with the extraordinarily unique condition of having two separate QRS complexes resulting in separate mechanical contractions of the left and right ventricles. (PTX-217 at MEDMIR0008797, 8802) The patient in Curtiss was treated experimentally by pacing

the left ventricle, triggered by sensing the right ventricle, wherein "[a] sense to pace interval of 50 msec. was selected since a therapeutic alternative was implantation of a modified universal pacemaker and the shortest sense to pace interval in the available units was 50 msec." (*Id.* at MEDMIR0008801) Curtiss reported that, hemodynamically, triggered left ventricular pacing was associated with a 24% rise in cardiac output. (*Id.*) In notational terms, triggered left ventricular pacing would be classified as VVT mode.

2. Anticipation

a. Legal standard

66. Under 35 U.S.C. § 102(a), "a person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."

67. A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

> [A]nticipation requires that each limitation of a claim must be found in a single reference. Although [the Federal Circuit has] permitted the use of additional references to confirm the contents of the allegedly anticipating reference, . . . we have made clear that anticipation does not permit an additional reference to supply a missing claim limitation.

Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1335 (Fed. Cir. 2002). That is, additional references may be used only to shed light on what a prior art reference would have meant to those skilled in the art at that time, not for a specific teaching, as this would be indicative of an attempt to improperly "combine the teachings

of the references to build an anticipation." *Studiengesellschaft Kohle, m.b.H. v. Dart Industries, Inc.*, 726 F.2d 724, 727 (Fed. Cir. 1984).

68. A single prior art reference may expressly anticipate a claim where the reference explicitly discloses each and every claim limitation. However, the prior art need not be *ipsissimis verbis* (i.e., use identical words as those recited in the claims) to be expressly anticipating. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984).

69. A single prior art reference also may anticipate a claim where one of ordinary skill in the art would have understood each and every claim limitation to have been disclosed inherently in the reference. *Continental Can Co. USA Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). The Federal Circuit has explained that an inherent limitation is one that is necessarily present and not one that may be established by probabilities or possibilities. *Id.* That is, "the mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* "[I]nherency operates to anticipate entire inventions as well as single limitations within an invention." *Schering Corp. v. Geneva Pharms. Inc.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). The recognition of an inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation. *Id.* at 1377.

70. An anticipation inquiry involves two steps. First, the court must construe the claims of the patent in suit as a matter of law. *Key Pharms. v. Hercon Lab. Corp.*, 161 F.3d 709, 714 (Fed. Cir. 1998). Second, the finder of fact must compare the construed claims against the prior art to determine whether the prior art discloses the claimed invention. *Id.*

b. Silva and the VAT and VVT claims[9]

71. Each of the VAT and VVT claims[10] require either: (1) "improving the pumping ability of a heart that is in a state of congestive heart failure," by "effecting a coordinated contraction of both ventricles;"[11] (2) "a device capable of providing stimulation to both ventricles to effect a coordinated contraction thereof for the treatment of congestive heart failure;"[12] or (3) are directed to devices for treating heart failure and methods for improving the pumping ability of a heart suffering from heart failure.[13]

72. Plaintiff argues that Silva anticipates the VAT and VVT claims of the reissue patents, both triggered modes, by disclosing triggered, bi-ventricular pacing. (D.I. 193 at 51; PTX-515) Plaintiff further argues that Silva "clearly teaches that pacing both ventricles would be beneficial to patients in heart failure." (D.I. 193 at 40) (*citing* D.I. 188 at 146:22-147:6; PTX-269 at 126; PTX-529 at 10; D.I. 188 at 145:4-14; PTX-269 at 120; PTX-529 at 8)

73. The parties disagree as to the nature of the patients included in the Silva study and as to the results. Plaintiff, relying on the testimony of its expert, Dr. Benditt, asserts "in 1988, Silva reported that bi-ventricular pacing was a better way to treat postoperative patients" and that the patients included those with "class II heart failure symptoms." (D.I. 193 at 39; D.I. 188 at 123:17-19). Defendants argue that Silva did not

---

[9]Claims 15, 19, 20, 25 and 26 of the '119 patent and claims 15, 54, 84, 86, 144, 172, 201 and 311 of the '897 patent.

[10]As construed by the court with respect to asserted claims of the '119 patent.

[11]Claims 15, 19, and 20 of the '119 patent.

[12]Claims 25 and 26 of the '119 patent.

[13]Claims 15, 54, 84, 86, 144, 172, 201 and 311 of the '897 patent.

address any subjects that were in heart failure or had uncoordinated contraction of the ventricles. (D.I. 247 at 50) Instead, defendants assert that Silva was an attempt "to see which [pacing] site might be best and most closely approach that during sinus rhythm." (D.I. 190 at 557:8-9) Defendants further argue that "Silva determined that the patients would have been better off, hemodynamically, with no pacing at all." (D.I. 247 at 50) (*citing* D.I. 190 at 559:16-560:9; DTX-203 at DDX-115, DDX-11)

74. To anticipate the VAT and VVT claims, each and every limitation must be expressly or inherently described in a single prior art reference. Plaintiff argues that treatment of heart failure is an inherent property of bi-ventricular pacing. (D.I. 193 at 35) Inherency may not be established by probabilities or possibilities. *See Continental Can*, 948 F.2d at 1268. In its non-infringement argument, plaintiff argued that "approximately 30% of patients with CRT devices are 'non-responders,' meaning their hearts do not respond to the devices, and their hemodynamic efficiency is not improved." (D.I. 193 at 12 n.8) Plaintiff proffers no evidence that treatment of heart failure using bi-ventricular pacing, as construed by the court, is inherently disclosed in the prior art. Silva itself distinguishes the apparatus and method used in the study from implantable devices which are more highly constrained as to ventricular pacing sites, and further identifies these constraints as the probable reason that earlier studies did not focus on bi-ventricular stimulation. The court finds that Silva did not address patients who were in (congestive) heart failure, a limitation shared by all of the VAT and VVT claims; therefore, the court concludes that Silva does not anticipate the VAT and VVT claims.

c. Gibson and the VVI and VDI claims[14]

75. Each of the VVI and VDI claims include one of three forms of preamble: a "heart stimulating device for treating heart failure;" a "method for improving the pumping ability of a heart suffering from heart failure;" a "heart failure treatment device for improving the pumping ability of a heart suffering from heart failure." The record shows that the examiner considered these preambles to be limitations and a means for distinguishing the claims over the prior art. (PTX-5 at MEDMIR0023137, "Notice of Allowance") ("[T]he prior art does not show a heart stimulating device for treating heart failure, or improving hemodynamics, as set forth in the claims.")

76. Plaintiff does not dispute that these preambles constitute limitations. Instead, plaintiff argues that Gibson renders VVI and VDI claims of the '897 patent anticipated by disclosing a commercial pacemaker capable of bi-ventricular pacing in a demand or inhibited mode; a lead placed in the atrium; a Y adapter used to allow electrodes to be placed in the left and right ventricles; and a predetermined A-V delay period. (D.I. 193 at 46) Plaintiff admits that "the experimental conditions in Gibson did not require atrial sensing," and instead argues that "one skilled in the art knew that the pacemaker Gibson used had the capability for atrial sensing and for an A-V delay period." (*Id.*) Presumably, this is in regard to VDI mode, which requires atrial sensing in addition to ventricular sensing. Finally, plaintiff asserts that Gibson further taught that bi-ventricular pacing effected a coordinated contraction, and that defendants' expert, Dr. Platia, "admitted that the improvement Gibson observed was due to a more synchronous contraction because of bi-ventricular pacing." (D.I. 193 at 47) The

[14]Claims 120, 217 233, 288, 303, 315, and 324-28 of the '897 patent.

improvement admitted to by Dr. Platia, however, was with reference to shortened ball travel time of the valve, at the onset of systole, and not to improvement in hemodynamic efficiency over the entire cardiac cycle. (D.I. 190 at 599:19-25; 600:16-601:9)

77. Relying on the testimony of its expert, Dr. Benditt, plaintiff further asserts that the patients in the Gibson study were suffering from heart failure. (D.I. 193, ex. E at ¶ 120) (citing D.I. 188 at 97:1-14, 99:2-100:9, 184:16-187:5). The referenced portions of Dr. Benditt's testimony show that his assertions of heart failure in the Gibson study were often tentative: "[Gibson] was dealing with abnormal hearts. These had all had aortic valve surgery, and their cardiac outputs were all low. . . . So these are not just normal hearts that he's playing around with. These were sick hearts who got aortic valve replacements for **presumably** failing to thrive." (D.I. 188 at 99:9-15) (emphasis added) "That's **typically** a heart failure scenario, and **he's implying** that this new pacing mode, biventricular pacing that he observed, **may be of value** there. But he's also appropriately saying that **more study is needed**." (D.I. 188 at 100:2-6) (emphasis added)

78. Defendants argue that Gibson does not address patients in heart failure, but rather valve disease. (D.I. 247 at 44-45) Defendants further argue that, while Gibson may disclose shortened ball travel time resulting from bi-ventricular pacing, it also discloses that there was no associated gain in hemodynamic efficiency. (D.I. 190 at 552:7-13; D.I. 247 at 45)

79. The court finds defendants' characterization of Gibson to be the more credible. Plaintiff has failed to prove, by clear and convincing evidence, that each and every limitation as set forth in the VVI and VDI claims is found, either expressly or

inherently described, in Gibson. Gibson does not disclose a "heart stimulating device for treating heart failure;" a "method for improving the pumping ability of a heart suffering from heart failure;" or a "heart failure treatment device for improving the pumping ability of a heart suffering from heart failure." Therefore, the court concludes that Gibson does not anticipate the VVI and VDI claims of the '897 patent.

3. Obviousness

a. Legal standard

80. "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). Obviousness is a question of law, which depends on several underlying factual inquiries.

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)).

81. "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. Likewise, a defendant asserting obviousness in view of a combination of references has the burden to show that a person of ordinary skill in the

relevant field had a reason to combine the elements in the manner claimed. *Id.* at 418-19. The Supreme Court has emphasized the need for courts to value "common sense" over "rigid preventative rules" in determining whether a motivation to combine existed. *Id.* at 419-20. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. In addition to showing that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, a defendant must also demonstrate that "such a person would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007). "Because patents are presumed to be valid, *see* 35 U.S.C. § 282, an alleged infringer seeking to invalidate a patent on obviousness grounds must establish its obviousness by facts supported by clear and convincing evidence." *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 968 (Fed. Cir. 2006) (citation omitted).

b. Tyers and the VAT[15], VOO[16] and VDD[17] claims

82. Plaintiff argues that the VAT claims are rendered obvious by Tyers, asserting that "Tyers disclosed all of the limitations of claim 19—including sensing the atrium and stimulating both ventricles for effecting a coordinated contraction of the ventricles following an A-V delay period." (D.I. 193 at 53) To complete the argument, plaintiff points to Dr. Benditt's testimony that, "this is all standard pacemaker stuff even in 1989."

[15]Claims 19 and 20 of the '119 patent.

[16]Claim 308 of the '897 patent.

[17]Claims 248 and 273 of the '897 patent.

(*Id.*) Plaintiff further asserts that "it was well known that a coronary sinus pacing lead could be placed to pace the left ventricle, as required by claim 20." (*Id.*) Plaintiff concludes by arguing that "[f]or all of these reasons, Tyers also anticipates and/or renders obvious claims 19 and 20 of the '119 patent." (*Id.*)

83. Defendants respond that "the dogs in the Tyers study did not have heart failure or weak contractions, they had complete heart block." Plaintiff's expert, Dr. Benditt, agrees:

> Q. And A-V block, is that a form of heart failure?
> A. A-V block is actually just interruption of the depolarization sequence between the atria and the ventricle, also previously talked of as heart block.

(D.I. 188 at 92:19-22)

84. The '119 patent, as discussed earlier, involved pacing of "both the right and left [ventricles] to thereby increase the hemodynamic efficiency of a patient experiencing congestive heart failure or weak contractions." The court construed claims 15 and 19 to include the limitation, "improving the heart's pumping ability for treatment of congestive heart failure." Claim 20 depends from claim 19 and, therefore, must include the same limitation. The dogs in Tyers did not have congestive heart failure or ventricles that were contracting in an incoordinate manner. Instead, the dogs had an induced total heart block. The court finds that Tyers lacks the above stated limitations, and concludes that Tyers does not anticipate the VAT claims.

85. Plaintiff argues that "Tyers taught that pacing both ventricles simultaneously resulted in a significant increase in blood pressure and cardiac output." In fact, Tyers did not find an improvement with bi-ventricular pacing when using only two leads.

Improvement was not shown except with the addition of a third lead. Bi-ventricular pacing, in and of itself, did not result in an improvement.

86. The VOO and VDD claims each require pacing the left and right ventricles for "effecting of a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure." Plaintiff argues that Tyers, in combination with the knowledge of one of ordinary skill in the art, renders the VOO and VDD claims obvious. Here, plaintiff goes into more detail, identifying background references that contribute to the comparison of the limitations with the claims. Most of these references are to known pacing modes. Plaintiff also asserts that coronary sinus electrodes, for pacing the left ventricle, were well known. Plaintiff fails to address the limitations directed to heart failure, coordinated contraction of ventricles, and the reason to combine the references.

c. Gibson and the VVI[18] and VDI[19] claims

87. Plaintiff argues that Gibson, "along with the knowledge of one of skill in the art," renders the VVI and VDI claims obvious. (D.I. 193 at 47-48) Plaintiff points to the availability of the various pacing modes as proof of obviousness. (*Id.*) The court's discussion above, with respect to anticipation by Gibson, informs its analysis of obviousness in light of Gibson. Gibson is not directed toward treating patients with heart failure or discoordinate ventricles. Bi-ventricular stimulation, as tested by Gibson, did not result in improved hemodynamic efficiency, thus teaching away from bi-ventricular pacing to improve hemodynamic efficiency.

---

[18]Claims 217, 233, 288, 303, 325, and 328 of the '897

[19]Claims 120, 315, 324, 326, and 327 of the '897 patent.

d. Curtiss and the VVT claims[20]

88. All of the asserted claims of the '119 patent, as construed by the court, require both ventricles to be paced to effect coordinated or simultaneous contraction of both ventricles.[21] The specification of the '119 patent teaches that "ventricular contractions which occur with [sic] 5-10 milliseconds of each other result in sufficient hemodynamic efficiency so as to not require treatment. Hence, the delay window may be of this order of magnitude." ('119 patent at 6:23-26)

89. Plaintiff argues that "Curtiss disclosed detecting a depolarization of the right ventricle and immediately stimulating the left ventricle." In its non-infringement argument, plaintiff asserts that a delay of 1.25 msec. is not immediate as used within the context of the reissue patents. (D.I. 193 at 17) Plaintiff admits that Curtiss discloses only single ventricle pacing, but argues that "pacing both ventricles was well known and standard in the art, as described, for example, in Tyers." (D.I. 193 at 54) Plaintiff further argues that "Curtiss provides the motivation for one skilled in the art to use bi-ventricular pacing in conjunction with the teachings of Curtiss." (D.I. 193 at 54) Dr. Benditt testified that "[Curtiss] could have stimulated both ventricles, but it's kind of a waste of energy to stimulate both," thereby suggesting that Curtiss teaches away from bi-ventricular pacing. (D.I. 188 at 172:5-8)

---

[20]Claims 15, 25 and 26 of the '119 patent.

[21]Claims 15 and 19 require "stimulating both ventricles for effecting a coordinated contraction of both ventricles." Claim 20 depends from claim 19. Claim 25 requires a "bi-ventricular pacemaker" for "effecting simultaneous contraction of both ventricles." Claim 26 depends from claim 25.

90. Plaintiff also argues that Curtiss in light of Tyers renders claims 25 and 26 obvious. (*Id.* at 54) That two or more prior art references disclose, in combination, all limitations of a claim does not, by itself, establish obviousness. Plaintiff fails to show any reason why a person of skill in the art would combine Curtiss, an extraordinary case involving one patient with dual QRS complexes, and Tyers, a study in dogs with complete heart block.

91. Defendants argue that the patient in Curtiss did not exhibit the "broadened QRS complex associated with heart failure" but, rather, "two distinct QRS complexes" that had never been seen before, nor since. (D.I. 190 at 541:16-24) Defendants' validity expert, Dr. Platia, opined that "[i]t certainly wouldn't occur to me that pacing in such a heart would give us any useful information to be interpreted broadly," and that this unique case was unrelated to the reissue patents. (D.I. 190 at 541:25-542:4)

92. Plaintiff again fails to provide motivation to combine Curtiss with any other reference or the knowledge of one of ordinary skill in the art. Curtiss involved single ventricle pacing of a single unique case, with a sense to pace interval of 50 msec. The reissue patents are directed to stimulating both ventricles effecting a coordinated contraction of the ventricles (within 5-10 msec.) for treating heart failure. The court finds that plaintiff has failed to show Curtiss, in combination with any other reference, renders the VVT claims obvious.

e. Silva and the VAT and VVT claims

93. As previously discussed, Silva does not anticipate the asserted claims of the '119 patent as it did not address patients in heart failure. Plaintiff argues that, "in 1988, Silva reported that bi-ventricular pacing was a better way to treat postoperative

patients." (D.I. 193 at 39) Silva itself distinguished the post-operative context as being less restrictive than using an implantable device. (PTX-269 at MEDMIR0006936) ("[I]t is not possible to select the point(s) of ventricular stimulation due to the limitations imposed by the implantation technique.") Defendants argue that, "[a]s with the Tyers and Gibson studies, the Silva thesis was directed to determining the least bad place to pace the heart." (D.I. 247 at 50) (*citing* D.I. 190 at 557:1 0-13)

94. Under *KSR*, it is not necessary that the prior art be directed to solving the same problem. *KSR*, 550 U.S. at 402, 418. The case at bar is not one, however, where "one of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *Id.* at 419-20. There was unquestionably a problem, one of long-felt need. Plaintiff has failed, however, to demonstrate an obvious solution. The field of the reissue patents is a complex one, involving the highest level of skill, incremental experimentation, uncertainty, and concerns over efficacy and safety. Even plaintiff admits that the patented devices and methods have far less than a 100% chance of success in treating heart failure. Experimentation in this field is time consuming, difficult, expensive, and poses some level of risk.

95. While Silva disclosed that bi-ventricular stimulation was more favorable, hemodynamically, than single ventricle pacing, this does not necessarily suggest hemodynamic improvement in heart failure. The base ejection fraction of the patients in Silva was 0.555 ± 0.018 whereas, with bi-ventricular pacing, it decreased to 0.535 ± 0.018. (PTX-269 at MEDMIR000699) Although the ejection fraction was even lower for

single ventricle pacing, it supports defendants' conclusion that Silva demonstrated bi-ventricular pacing was the least bad solution under the circumstances. (*Id.*) Further supporting defendants' position, Silva also found that, with all three experimental positions, there was "a widening of the QRS" although it was less pronounced in bi-ventricular pacing. (*Id.* at MEDMIR0006987)

96. The court finds defendants' characterization of the results of Silva to be the more persuasive. Plaintiff has failed to show, by clear and convincing evidence, that Silva, in view of the knowledge of one of ordinary skill in the art or in combination with any other reference, renders the VAT and VVT claims obvious.

f. Secondary considerations

97. As discussed earlier, Dr. Benditt pointed to the long-felt unfulfilled need to treat heart failure. (D.I. 247 at 57) Plaintiff admits that Dr. Mower's invention is successful in treating heart failure in more than 60% of cases. (D.I. 189 at 301:10-11, 23-24, 302:2-4) While arguing that all of the components of a bi-ventricular pace maker were available prior to Dr. Mower's invention, and such combination was obvious, Plaintiff fails to adequately account for the lack of success in addressing this long-felt need. Based on the foregoing, the court finds that, taken as a whole, the secondary considerations favor defendants and do not change the obviousness determination discussed above.

g. Conclusion

98. Plaintiff's arguments regarding obviousness are less than compelling, attempting only to demonstrate that limitations of the asserted claims can be found as disparate pieces in various combinations of the prior art. Dr. Benditt, plaintiff's invalidity

expert, admitted that he failed to consider any apparent reason to combine references in forming his opinions.[22] Moreover, many of the asserted references teach away from bi-ventricular pacing. Plaintiff has not demonstrated, by clear and convincing evidence, that the asserted claims of the reissue patents are invalidated on obviousness grounds.

E. Prosecution Laches

1. Legal standard

99. The doctrine of prosecution laches is an equitable defense to a charge of patent infringement that "'may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution' that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances." *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., LP*, 422 F.3d 1378, 1384-85 (Fed. Cir. 2005) ("*Symbol Techs. II*") (citation omitted). "[T]here are no strict time limitations for determining whether continued refiling of patent applications is a legitimate utilization of statutory provisions or an abuse of those provisions. The matter is to be decided as a matter of equity, subject to the discretion of a district court before which the issue is raised." *Id.* at 1385. A finding of prosecution laches further requires "a finding of prejudice, as does any laches defense." *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 729 (Fed. Cir. 2010).

100. An applicant may attempt to obtain new claims directed to inventions that he or she believes are fully disclosed and supported in an earlier application. *See In re*

---

[22]Dr. Benditt in his deposition stated, "it would be obvious to somebody who was working in the field who was familiar with the literature that this would not be a particular stretch of the imagination. . . . what would lead me to . . . say, 'Oh, I'm going to combine X and Y,' I don't think we can give you an answer here." (D.I. 188 at 225:17-226:9)

Bogese, 303 F.3d 1362, 1369 (Fed Cir. 2002). This is distinguished from an applicant failing to further the prosecution of his or her application toward the issuance of any claims. *Id.* The Federal Circuit has made clear that

> there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application.

Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988).

2. Discussion

101. The original '688 patent, on which the reissue patents are based, was filed on January 23, 1989 and issued on May 29, 1990. The '119 patent resulted from a series of three continuation applications, the first of which was filed on May 29, 1992, and issued May 20, 2003. The '897 patent was filed on August 8, 2002 and issued on October 23, 2007.

102. Plaintiff argues that the claims of the '897 patent are unenforceable for prosecution laches. (D.I. 193 at 2) In support of this argument, plaintiff asserts that the application for the '119 patent "lingered in the patent office until 2003, over 14 years after the filing of [the] original '688 patent application." (*Id.* at 3) Plaintiff further asserts that during those 14 years, the market developed for CRT devices. (*Id.*) Plaintiff introduced its first CRT product in 2001. (*Id.*)

103. The evidence of record demonstrates that the delays in prosecution of the '119 patent were reasonable. (D.I. 247 at 10-11; PTX-7; PTX-8) The delays are documented in the file history as being caused by a withdrawal of allowability by the

PTO and the PTO's twice losing the file. (*Id.*) Meanwhile, defendants diligently prosecuted the '119 patent seeking repeated status updates. (*Id.*)

104. Plaintiff further argues that, since the '119 patent did not cover commercially available devices, defendants filed a new reissue application a year after plaintiff's InSync product was released in 2001, in an attempt to obtain new claims to assert against their competitors. (*Id.*) This new reissue application resulted in issuance of the '897 patent. (*Id.*) Finally, plaintiff asserts that "Dr. Mower did nothing for over a decade after he first noticed the alleged errors in the '688 patent to ensure that these additional 300 claims [of the '897 patent] were prosecuted."

105. Defendants counter that the '897 application was filed on August 8, 2002 after the PTO stated that the '119 claims were allowable. (D.I. 247 at 12; PTX-5) Prosecution consisted of three rejections and three responses, all within the statutory period. *Id.*

106. Plaintiff, relying on *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., LP*, 301 F. Supp. 2d 1147, 1157 (D. Nev. 2004) ("*Symbol Techs. I*") argues that the failure to prosecute all claims of a patent (or reissue patent) as soon as they are known constitutes prosecution laches. *In Symbol Techs. I*, the patentee had "effectively extended his patent monopoly by maintaining co-pendency for nearly forty years through continuation practice, and added new claims to cover commercial inventions in the market place years after his original patents had expired." *Id.* The court finds no such unreasonable or unexplained delay with respect to the reissue patents.

III. CONCLUSION

For the reasons discussed above, the court concludes that defendants have not proven, by a preponderance of the evidence, that plaintiff Medtronic infringes claims 15, 19, 20, 25, or 26 of the '119 patent, or claims 15, 54, 84, 86, 120, 144, 172, 201, 217, 233, 248, 273, 288, 303, 308, 311, 315, or 324-328 of the '897 patent. Plaintiff has failed to prove, by clear and convincing evidence, that the aforesaid claims are invalid as anticipated. Plaintiff has not demonstrated, by clear and convincing evidence, that the aforesaid claims are invalid as obvious. Plaintiff likewise has failed to establish, by clear and convincing evidence, that the reissue patents are unenforceable by reason of prosecution laches. An appropriate order shall issue.