IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS, INC. and EVALVE, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 19-149 (MN)
EDWARDS LIFESCIENCES CORP. and EDWARDS LIFESCIENCES, LLC,	)	REDACTED - PUBLIC VERSION
Defendants.	)	

MEMORANDUM OPINION

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June 6, 2019
Wilmington, Delaware

NOREIKA, U.S. DISTRICT JUDGE:

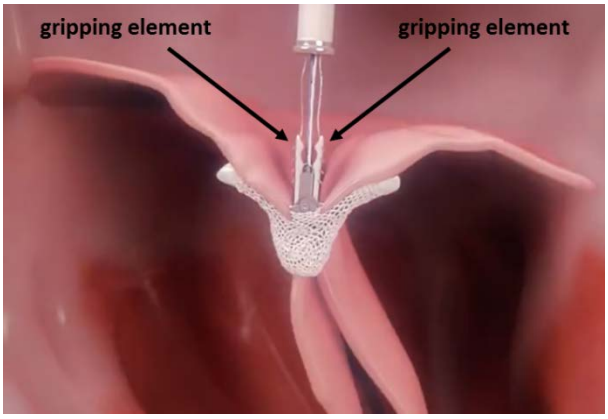
Presently before the Court is Plaintiffs Abbott Cardiovascular Systems, Inc.'s and Evalve, Inc.'s (collectively, "Plaintiffs" or "Abbott") motion for a preliminary injunction (D.I. 10), which seeks to enjoin Defendants Edwards Lifesciences Corp. and Edwards Lifesciences, LLC (collectively, "Defendants" or "Edwards") from manufacturing their PASCAL mitral valve repair system in the United States. In connection with this motion, the Court has reviewed thousands of pages of briefing, declarations and exhibits (*see* D.I. 10, 11, 12, 13, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 110, 111, 112, 113, 114, 115, 116, 117, 120, 134, 135, 138, 141, 142, 144, 145, 146, 148, 149, 151), and held a six-hour in-person hearing on April 15, 2019 (*see* D.I. 136). For the reasons set forth below, the Court DENIES Plaintiffs' motion. This opinion constitutes the Court's findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

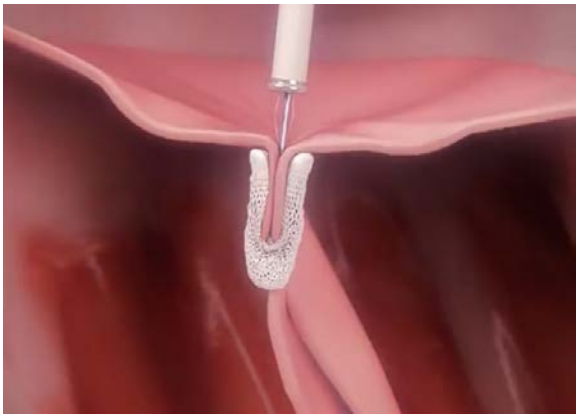
I. BACKGROUND

Plaintiffs market MitraClip in the United States and in Europe. (D.I. 12, Ex. 10 ¶ 6; *see also* D.I. 12, Ex. 6 ¶ 52). MitraClip is a medical device approved to treat mitral regurgitation, a condition that occurs when the mitral valve in the heart fails to close completely, thereby allowing blood to flow improperly from the left ventricle up into the left atrium. MitraClip is an implant system that is introduced into the heart through a patient's vasculature and is left behind in the heart after the procedure to hold portions of the mitral valve together and reduce backflow. (D.I. 12, Ex. 6 ¶¶ 53-57).

Below is an image of MitraClip before implantation:

(D.I. 12, Ex. 119 at 1:53 (image inverted for ease of viewing)). MitraClip has a pair of gripping elements to engage the valve leaflets from the atrial side and a pair of arms to engage the leaflets from the ventricular side. (*See* D.I. 12, Ex. 6 ¶ 52). Once MitraClip reaches the left atrium of the heart, it is passed through the mitral valve so that it may be pulled up from the ventricular side to engage the valve leaflets and draw them together:



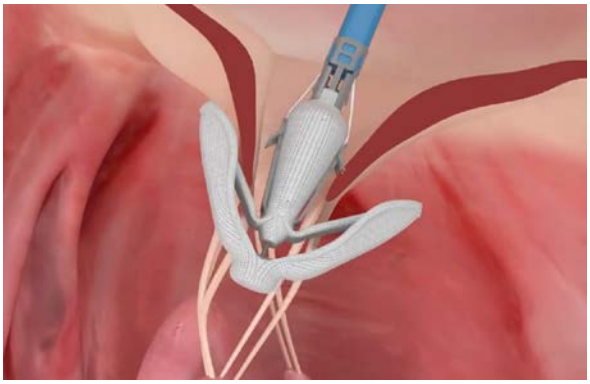


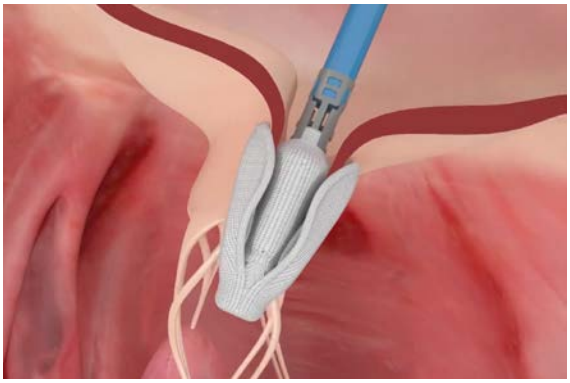
(D.I. 12, Ex. 119 at 3:05 (left with Court's annotation) and 3:10 (right); *see also* D.I. 12, Ex. 6 ¶¶ 53-55). The delivery system is then removed, and MitraClip is left in place holding the leaflets together, thereby reducing the backflow of blood from the left ventricle into the left atrium. (*See* D.I. 12, Ex. 6 ¶ 57; *see also* D.I. 12, Ex. 119 at 3:32-3:46). Thus far, there have been three versions of MitraClip commercialized: the original MitraClip, MitraClip NT and MitraClip NTR/XTR. (D.I. 12, Ex. 12 ¶ 13; *see also* D.I. 12, Ex. 6 ¶ 52; D.I. 91 ¶¶ 74-78). MitraClip NT,

which was introduced in 2015, uses a different material for the gripping elements. (D.I. 12, Ex. 12 ¶ 13; *see also* D.I. 91 ¶ 75). MitraClip NTR/XTR, which was introduced in early 2018, uses longer arms for grasping leaflets relative to the earlier versions. (*See, e.g.*, D.I. 87, Ex. 61; D.I. 12, Ex. 12 ¶ 13; *see also* D.I. 12, Ex. 6 ¶ 498). Plaintiffs are currently attempting to obtain approval for a fourth-generation MitraClip device. (*See* D.I. 12, Ex. 12 ¶ 13; D.I. 112, Ex. 293).

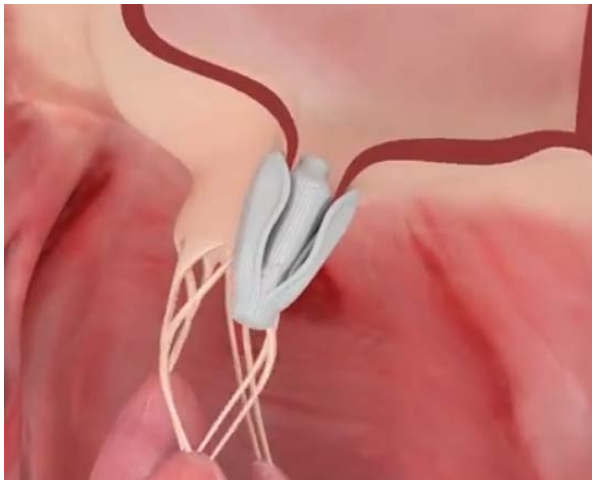
Defendants also developed a mitral valve repair system – PASCAL – which holds portions of the mitral valve together around a central spacer and is left behind as an implant in the heart. Below is an image of Defendants' PASCAL device before implantation:

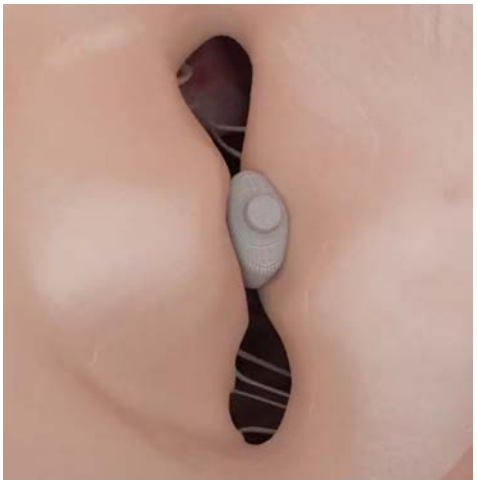
(D.I. 158, Ex. DX-173 at 1 (cited at preliminary injunction hearing)). Like MitraClip, PASCAL is introduced into the heart through a patient's vasculature and passes from the left atrium to the left ventricle through the mitral valve so that it may be pulled up from the ventricular side to engage the valve leaflets:





(D.I. 114, Ex. 355B at 1:16 (left) and 1:29 (right); *see also* D.I. 91 ¶¶ 53-54). Unlike MitraClip, the pair of paddles in PASCAL used to engage the valve leaflets from the ventricular side are comprised of two portions – an inner portion and an outer portion – which are joined at a flexible bend. Further, unlike MitraClip, the grasping clasps in PASCAL that engage the valve leaflets from the atrial side can move independently of one another. (D.I. 91 ¶ 67; *see also* D.I. 94 ¶¶ 14, 20). After placement, the delivery system is removed, and PASCAL is left in place to hold the mitral valve leaflets together about a central spacer, thereby reducing the improper backflow:





(D.I. 114, Ex. 355B at 1:34 (left) and 1:41 (right); *see also* D.I. 91 ¶¶ 53-54). As seen above, PASCAL has a central spacer, which is not present in MitraClip, and which is designed to reduce stress on the valve leaflets after implant. (*See, e.g.*, D.I. 91 ¶¶ 54, 104, 122; D.I. 94 ¶ 13).

On January 28, 2019, Plaintiffs filed the present action, alleging that Defendants' PASCAL mitral valve repair system infringes claims of U.S. Patent Nos. 7,288,097 ("the '097 Patent"), 6,752,813 ("the '813 Patent"), 7,563,267 ("the '267 Patent"), 7,736,388 ("the '388 Patent") and 8,057,493 ("the '493 Patent") (collectively, "the Patents-in-Suit"). (*See, e.g.*, D.I. 1 ¶¶ 109-64). The next day, on January 29, 2019, Plaintiffs filed a motion for a preliminary injunction, seeking an order enjoining Defendants from manufacturing their PASCAL system in the United States. (*See* D.I. 10, 11, 12). Shortly after that, on February 18, 2019, Plaintiffs filed a motion for a

temporary restraining order ("TRO"), seeking to enjoin Defendants from manufacturing PASCAL in the United States until the Court issued a decision on the preliminary injunction. (*See* D.I. 30). Although PASCAL was not approved for use in the United States or in Europe when Plaintiff moved for the TRO, Defendants received approval in Europe on February 19, 2019. (D.I. 86, Ex. 6). PASCAL launched in Germany shortly thereafter, and Defendants are planning to introduce PASCAL into select European markets next.[1] (D.I. 92 ¶ 6). On March 5, 2019, the Court denied Plaintiffs' request for a TRO, finding that Plaintiffs had not made a clear showing that they were likely to suffer irreparable harm prior to the Court reaching a decision on the preliminary injunction motion. (*See* D.I. 63). In the same order, the Court expedited the preliminary injunction hearing and associated briefing.[2]

Briefing on the preliminary injunction motion was completed on April 9, 2019 (*see* D.I. 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 110, 111, 112, 113, 114, 115, 116, 117, 120),[3] and the Court held a hearing on Plaintiffs' motion on April 15, 2019 (*see* D.I. 136). After the hearing, the parties were permitted to file supplemental letters regarding support for claim constructions that

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1 PASCAL remains unapproved in the United States, and Defendants do not anticipate a launch here before 2021. (*See* D.I. 136 at 113:8-114:2).

2 On March 8, 2019, Plaintiffs filed a First Amended Complaint to reflect the fact that PASCAL had launched in Europe and to add allegations of willful infringement. (*Compare, e.g.*, D.I. 1 ¶¶ 1, 3, 9, 12, *with* D.I. 64 ¶¶ 1, 3, 9, 12, 87, 89; *see also* D.I. 64 ¶¶ 16, 95-103, 117-122, 127, 137, 142, 147 (adding willfulness allegations)).

3 The original submissions were substantial. Plaintiffs' opening brief included eight declarations and hundreds of exhibits, totaling approximately 6,000 pages. Defendants' answering brief included six declarations and more than a hundred exhibits, totaling approximately 3,700 pages. And Plaintiffs' reply brief included nine declarations and about a hundred exhibits, totaling approximately 4,000 pages. In all, the Court had nearly 14,000 pages of material to consider, not including the submissions related to the TRO, which totaled another almost 3,000 pages. The Court denied Plaintiffs' request for a TRO (*see* D.I. 63), and the Court will not reconsider the TRO-related submissions in reaching its decision on Plaintiffs' motion for a preliminary injunction.

they contend are necessary for the Court to resolve in order to render its decision. (*See* D.I. 134, 135; *see also* D.I. 138).

Since the preliminary injunction hearing, the Court has received additional submissions. On April 26, 2019, at the Court's request (D.I. 137), Defendants filed a letter indicating the number of PASCAL devices that had been manufactured in the United States (all of which have been exported) and stating their estimate as to how long that inventory is projected to supply the relevant European markets (*see* D.I. 141). Defendants also provided arguments about how this information factored into the preliminary injunction analysis. (D.I. 141). Also on April 26, 2019, Defendants notified the Court that a patient in Israel had been successfully treated with PASCAL when MitraClip was apparently contraindicated, new facts that Defendants believe are relevant to the present motion. (*See* D.I. 142). Plaintiffs were permitted to respond to Defendants' submission regarding the number of PASCAL devices manufactured in the United States (*see* D.I. 144), and Plaintiffs also filed a response to Defendants' letter regarding the Israeli patient (*see* D.I. 145). Then, on May 3, 2019, Defendants informed the Court that Plaintiffs' request for a preliminary injunction was denied in related proceedings in the United Kingdom.[4] (D.I. 148). On May 5, 2019, Plaintiffs responded, pointing out that the preliminary injunction was denied only after Defendants formally agreed to limit themselves to no more than ten PASCAL procedures in no more than two centers in the United Kingdom prior to trial in December 2019. (D.I. 149). On May 8, 2019, Defendants provided the Court with a copy of the preliminary injunction decision

[4] "Various Abbott entities" have sued "various Edwards entities" in the United Kingdom, Switzerland, Italy and Germany, alleging PASCAL infringes foreign patents, and preliminary injunctions have been requested in at least the United Kingdom, Switzerland and Italy. (D.I. 86 ¶ 2; *see also* D.I. 85 at 19). To the Court's knowledge, Plaintiffs have not obtained injunctive relief in any of the European jurisdictions.

from the proceedings in the United Kingdom. (D.I. 151). The supplemental submissions finally came to an end with that last letter by Defendants.

II. LEGAL STANDARDS

Preliminary injunctive relief is an "extraordinary" remedy appropriate only in "limited circumstances." *Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004); *see also Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) ("[A] preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted."). A preliminary injunction may be granted only if the moving party shows (1) a likelihood of success on the merits, (2) irreparable harm is likely if an injunction is not granted, (3) the balance of equities tips in favor of the moving party and (4) an injunction is in the public interest. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also Osorio-Martinez v. Attorney Gen. United States of Am.*, 893 F.3d 153, 178 (3d Cir. 2018); *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009). The Court cannot grant a preliminary injunction unless the moving party establishes ***both*** a likelihood of success on the merits and the likely existence of irreparable harm without the injunctive relief. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). "[A]ll findings of fact and conclusions of law at the preliminary injunction stage are subject to change upon the ultimate trial on the merits." *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001).

III. DISCUSSION

Although Defendants' PASCAL system is not approved in the United States, Defendants manufacture PASCAL in the United States and export the completed systems for sale in the European markets where PASCAL is approved. (*See* D.I. 85 at 1, 7, 19; *see also* D.I. 92 ¶ 5). Plaintiffs seek a preliminary injunction that prevents Defendants from manufacturing PASCAL in

the United States, arguing that such manufacture infringes claims of the Patents-in-Suit under 35 U.S.C. § 271(a) and that Defendants' infringement is irreparably harming Plaintiffs. (*See* D.I. 10; *see also* D.I. 11 at 14-19; D.I. 110 at 7-13). For purposes of this motion, the parties agreed that Plaintiffs would elect no more than ten asserted claims from the Patents-in-Suit and Defendants would limit their defenses (*i.e.*, noninfringement and/or invalidity) to no more than four per claim. (*See* D.I. 65; D.I. 66; *see also* D.I. 85 at 20 (list of elected asserted claims)). The Court begins its analysis by addressing the first preliminary injunction factor – *i.e.*, likelihood of success on the merits – in the context of the asserted claims and defenses elected by the parties.

A. Likelihood of Success on the Merits

"With regard to the first factor – establishing a likelihood of success on the merits – the patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). In evaluating whether Plaintiffs are likely to succeed in proving infringement of the asserted claims, the Court employs the same two-step process used to determine infringement on summary judgment or at trial. *See Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed. Cir. 2003). First, the Court must determine the meaning and scope of the asserted claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Second, the Court must compare the accused PASCAL device to the claims as properly construed. *Id.* Similarly, in assessing whether Plaintiffs are likely to withstand the validity challenges made by Defendants, the Court compares the asserted claims as construed to the prior art. *See Oakley*, 316 F.3d at 1339. The Court should not grant a preliminary injunction if Defendants "raise[] a substantial question concerning either infringement or validity." *Amazon.com*, 239 F.3d at 1350; *see also Tate Access*

Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1365 (Fed. Cir. 2002) ("substantial question" means assertion of a defense that patentee cannot prove "lacks substantial merit").

1. Infringement

a. '097 Patent – Claim 1

The '097 Patent, titled "Surgical Device for Connecting Soft Tissue," is generally directed to a surgical device – a clipping system – that allows for the percutaneous connection of two areas of soft tissue that are ordinarily separate. ('097 Patent at 1:17-19). According to the specification, the claimed device is particularly suited for the reconstruction of heart valves, especially the mitral valve. (*Id.* at 1:19-20). The patent mentions some of the prior-art surgical procedures used to repair the mitral valve in cases of mitral insufficiency (*i.e.*, mitral regurgitation), including performance of a sternotomy and "suturing of the free edge of the anterior leaflet to the free edge of the back leaflet where the mitral insufficiency occurs." (*Id.* at 1:25-33). In contrast, the invention claimed in the '097 Patent allows for the repair procedure to be performed percutaneously, thereby diminishing some of the risks associated with the sternotomy. (*Id.* at 1:34-45). Plaintiffs allege that Defendants' PASCAL infringes claim 1 of the '097 Patent, which recites:

> 1. A system for performing cardiac valve repair, said system comprising:
>
> a tube suitable for introducing through a patient's vasculature and into a chamber of a heart; and
>
> a clipping system including a first pair of elements adapted to be brought up beneath a pair of valve leaflets from the ventricular side and a second pair of elements adapted to be brought down over the pair of valve leaflets from the atrial side, wherein the first pair of elements engages the ventricular side of both leaflets and the second pair of element engages the atrial side of both the leaflets to capture both leaflets and wherein the first and second elements may be left to attach the free edges of the leaflets together.

('097 Patent at Claim 1).

The dispute between the parties is whether PASCAL satisfies the "may be left to attach the free edges of the leaflets together" limitation of claim 1 of the '097 Patent.[5] (*See* D.I. 85 at 20-21; *see also* D.I. 136 at 30:13-16). Defendants argue that PASCAL does not meet this limitation because it is designed so that the free edges of the valve leaflets are each held against a central spacer once implanted. (D.I. 85 at 20). Defendants' expert, Dr. Morten Jensen, explains that when PASCAL is in place, the free edges are held against the spacer – instead of against each other – so as to reduce stress on the leaflets. (D.I. 91 ¶¶ 104, 122; *see also* D.I. 94 ¶ 13). In Plaintiffs' view, PASCAL satisfies the contested limitation because "attach the free edges of the leaflets together" does not require physical contact between the leaflet edges. (D.I. 11 at 8-9; *see also* D.I. 12, Ex. 6 ¶ 108). Rather, Plaintiffs argue that PASCAL brings the leaflet edges together in close proximity after implant and that is all that is required by the claim. (*See* D.I. 110 at 4). The dispute thus turns on the meaning of "attach the free edges of the leaflets together" as used claim 1 of the '097 Patent.

Defendants argue that the term "attach the free edges of the leaflets together" should be construed as "connect the free edge of one leaflet to the free edge of another leaflet." (D.I. 134 at 1). Plaintiffs argue that the term "may be left to attach the free edges of the leaflets together" should be construed as either: (1) "capable of being left to fasten the free edges of the leaflets together to the point where they are either in physical contact or close proximity" or (2) "capable of connecting the free edge of one leaflet to the free edge of another leaflet (connection may be direct or indirect)." (D.I. 135 at 1). Plaintiffs include the "may be left to" language in their

[5] The Court recognizes that there may be additional disputes regarding infringement for the '097 Patent (and the remaining Patents-in-Suit) as the case progresses. For purposes of the present motion, however, the Court focuses on the claim element(s) contested by Defendants in their opposition papers.

proposed term for construction, whereas Defendants contend that "attach the free edges of the leaflets together" is the term requiring construction to resolve the issue of infringement. (*Compare* D.I. 134 at 1, *with* D.I. 135 at 1). Although the parties dispute whether the "may be" language should be construed and whether the phrase is used to connote the capability of the claimed clipping system, the Court views the fundamental issue to be the meaning of "attach the free edges of the leaflets together" in the context of the claimed invention.[6]

The parties agree that this term should be given its plain and ordinary meaning to a person of ordinary skill in the art ("POSA"), but they dispute what that meaning is. Defendants argue that the term "requires that the free edges of the leaflets be attached together" and that "'proximity' is not attachment." (D.I. 85 at 20-21). Defendants rely heavily on their expert, Dr. Jensen, who opines that a POSA would understand "attach together" to require a direct physical connection between the valve leaflets and, in particular, the free edges of the leaflets. (*See, e.g.*, D.I. 91 ¶¶ 106, 108-19). In support, Dr. Jensen highlights portions of the specification that discuss "connection" of two areas of soft tissue as an important aspect of the '097 Patent invention. (*Id.* ¶ 109 (quoting '097 Patent at 1:17-19, 1:44-45, 2:13-16, 2:49-51, 3:27-29, 4:51-53)). Relying on Figures 7 and 8, which show different stages of a valve repair procedure where the leaflets are drawn together, Dr. Jensen opines that the procedure eventually results in "direct contact" of the leaflet free edges as shown in Figure 10. (D.I. 91 ¶¶ 110, 113-15). He also refers to statements made by the '097 Patent Applicants during prosecution to overcome a prior-art clipping system designed to join

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[6] The Court does not resolve whether the "may be left to" language requires that the claimed clipping system only be capable of being left in the heart to attach the leaflet free edges together. The issue here is what it means for the leaflet free edges to be attached together if the device is, in fact, left behind. Stated differently, even if a clipping system is capable of being left in the heart, it would not meet all elements of claim 1 if it could not "attach the free edges of the leaflets together" after being left behind. Thus, the Court focuses on the meaning of this latter term.

portions of separate blood vessels, asserting that a POSA would understand from these statements that the '097 Patent invention requires direct contact between the leaflet free edges. (*Id.* ¶ 118 (citing D.I. 88, Ex. 64)).

Plaintiffs, on the other hand, argue that "close proximity" between the leaflet free edges is all that is required by the term "attach the free edges of the leaflets together." (*See, e.g.*, D.I. 11 at 8-9; D.I. 110 at 4). Plaintiffs also rely heavily on their expert, Dr. Ajit Yoganathan, who opines that a POSA would not understand "attach together" to require direct contact.[7] (D.I. 12, Ex. 6 ¶ 108). He explains that his opinion is supported by dictionaries that define "together" as "proximity" and by Figure 7, which shows an embodiment where the leaflets have been drawn together but do not physically touch. (*Id.* ¶¶ 109-10; *see also* D.I. 112, Ex. 289 ¶ 15). In terms of the '097 Patent discussing the claimed invention as allowing for the "connection" of two areas of tissue, Dr. Yoganathan asserts that a POSA would understand that connection is a term that encompasses both direct and indirect connection. (D.I. 112, Ex. 289 ¶ 20; *see also id.* ¶¶ 21-22 (discussing items being connected without direct attachment)). And as to the '097 Patent Applicants' statements made during prosecution, Dr. Yoganathan opines that the prior art discussed during prosecution was fundamentally different in that it was intended to combine blood vessels, which required the clipping system to create and hold open a permanent space to allow blood flow. (*Id.* ¶¶ 32-40). In his opinion, any statements made by the '097 Patent Applicants regarding this prior art have no bearing on the meaning of the term in issue because that prior

[7] Both sides advance their claim construction arguments through experts – indeed, there is almost no mention of proposed constructions in the briefing. The role of experts in claim construction is limited, and their testimony on the proper construction of a term is only considered if the intrinsic evidence is ambiguous. *See, e.g.*, *Phillips*, 415 F.3d at 1318-19; *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1585 (Fed. Cir. 1996).

device was wholly unsuitable as a clipping system for cardiac repair as claimed in the ’097 Patent. (*Id.* ¶¶ 33, 38, 40).

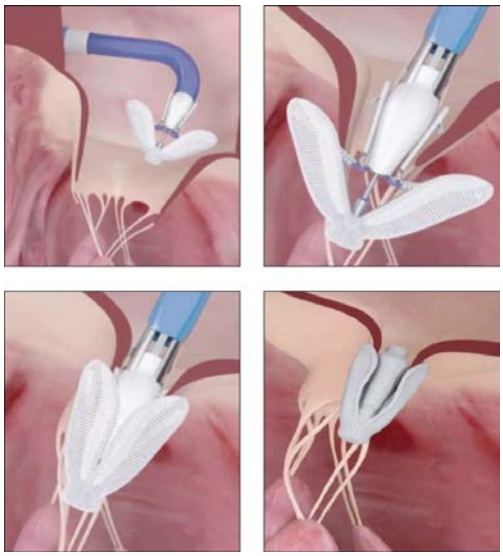
The Court finds that, in view of the intrinsic evidence, a POSA would not understand the term “attach the free edges of the leaflets together” to require direct contact between the leaflet free edges. *See Phillips*, 415 F.3d at 1312-14 & 1321 (plain and ordinary meaning for a claim term is the meaning as understood by a POSA in view of the intrinsic evidence). Beginning with the claim language itself, the term “attach the free edges of the leaflets together” does not use language indicating that direct contact is required – *e.g.*, “directly attach.” Likewise, there is no mention in the specification that physical contact between the free edges is necessary in the claimed invention. That the ’097 Patent describes the invention as permitting the “connection” of two areas of tissue does not compel the conclusion that the areas of tissue are connected because they are directly attached to each other. (*See, e.g.*, ’097 Patent at 1:17-20, 1:44-45, 2:13-16). Indeed, connection (and attachment) can be effectuated with indirect means. For example, the head and torso are connected, but only through the neck – *i.e.*, the indirect connection through the neck allows the head and torso to be attached together. As for the ’097 Patent figures, although Defendants are correct that the free edges of the leaflets appear to be touching in Figure 10, there is no suggestion that the figures are drawn to scale or that the invention is limited to the embodiment depicted in this figure. *See, e.g., Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1351 (Fed. Cir. 2013) (“Because the figures in the [asserted] patent do not evidence actual dimensions of the ‘stabilizer support’ and the ‘concha stabilizer,’ they cannot be relied upon to argue that the disputed terms should be limited to a particular structure.”); *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007) (“[P]atent coverage is not necessarily limited to inventions that look like the ones in the figures.”). Indeed, the specification states that the figures

are not limiting: "the invention is described again in reference to the enclosed Figures representing two ***unrestricted examples*** of the invention in its optimal capacity." ('097 Patent at 2:55-57 (emphasis added)).

As to the '097 Patent Applicants' statements in the prosecution history, the prior art at issue was different than the invention claimed in the '097 Patent. That prior art, U.S. Patent No. 5,695,504 ("Gifford"), was directed to a device for performing end-to-side anastomosis – *i.e.*, joining the end of one tubular organ to the side of another tubular organ, particularly blood vessels. (*See* D.I. 88, Ex. 64 at 4-5, *see also* Gifford at 1:5-19). As the '097 Patent Applicants explained, the purpose of the Gifford system was to ***create*** an opening in the side of a target vessel and ***maintain that opening*** to allow blood to flow from the target vessel to the graft vessel. (D.I. 88, Ex. 64 at 4; *see also* Gifford at 6:31-54). The '097 Patent Applicants pointed out that, if applied to a cardiac valve, the Gifford system would "force the free ends of the valve leaflet apart and provide a permanent port or aperture through the valve" (D.I. 88, Ex. 64 at 4), which would be unsuitable for repairing a cardiac valve that was not closing properly (*see, e.g.*, '097 Patent at 1:22-24, 2:58-60). Read in context, the statement that the Gifford system "would be unable to attach free edges of the valve leaflets together" (D.I. 88, Ex. 64 at 4) is not focused on the absence of direct contact between the leaflet free edges, but rather on the fact that Gifford would create and maintain an (undesired) opening in the context of a mitral valve. A POSA would not understand the '097 Patent Applicants' statements regarding Gifford to indicate or suggest that "attach the free edges of the leaflets together" requires direct contact of the leaflet edges.

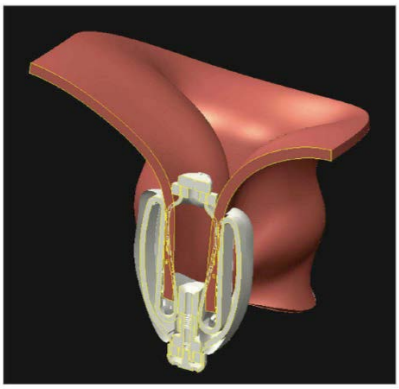
In sum, the intrinsic evidence does not support the conclusion that a POSA would understand the plain meaning of the term "attach the free edges of the leaflets together" to require

the leaflet edges to be directly attached to each other (*i.e.*, touching).[8] Under the proper construction, which does not require direct contact between the leaflet free edges, PASCAL appears to satisfy the "attach the free edges of the leaflets together" limitation of claim 1. Initially, the Court notes that Defendants do not contest infringement under a construction that does not require physical contact of the leaflet free edges. Moreover, the evidence presented demonstrates that PASCAL draws and holds the free edges of the leaflets together, and they are attached together in that way after PASCAL is left behind as an implant. Below is a depiction of PASCAL at various stages of the repair procedure, with the bottom right image showing that the valve leaflets have been attached together by the device, which has been left behind in the patient's heart:



(D.I. 12, Ex. 6 at Figure 27 (citing D.I. 12, Ex. 31)). Below is another image – a cut-away of PASCAL after implant – which shows the leaflet free edges attached together with the central spacer in between:

[8] The Court also rejects Plaintiffs' proposal to include "close proximity" in the construction of this term and their articulation of the meaning of "close proximity" – *i.e.*, that the free edges of the valve leaflets are "closer than where it was before." (D.I. 136 at 34:10-14). Importing that language injects unnecessary ambiguity into the claim, particularly given that the term in dispute is concerned with parts that move.



(D.I. 91 ¶ 120 (citing D.I. 88, Ex. 66)). Thus, the Court finds that Plaintiffs have demonstrated that they are likely to succeed in proving infringement of claim 1 of the '097 Patent.

b. '813 Patent – Claims 118 and 123

The '813 Patent, titled "Methods and Devices for Capturing and Fixing Leaflets in Valve Repair," is generally directed to methods and devices for repairing cardiac valves, particularly the mitral valve, using interventional tools introduced into the heart chambers from a patient's vasculature accessed away from the heart. ('813 Patent at 2:48-58). The specification provides that surgical interventions according to the claimed invention are performed with the general purpose of "modify[ing] the manner in which the valve leaflets coapt or close during systole so that back flow or regurgitation is minimized or prevented." (*Id.* at 3:50-54). The interventional tool according to the invention may be an interventional catheter that is passed through a patient's vasculature to reach the heart and can be used to introduce a fixation or capture device to capture valve leaflets. (*See, e.g.*, *id.* at 3:59-63, 4:2-5, 6:26-31). Plaintiffs allege that Defendants' PASCAL infringes claims 118 and 123 of the '813 Patent, both of which ultimately depend from independent claim 113:

> 113. A device for repairing a cardiac valve, said device comprising:
>
> an interventional catheter comprising at least one guide conduit, the interventional catheter configured to pass from the remote

> vasculature of a patient to a position within the heart adjacent to the cardiac valve; and
>
> a capture device on the interventional catheter comprising at least one distal element, wherein the distal element is protrudable radially outward and has a loop shape configured to pressing against a downstream surface of at least one leaflet.

('813 Patent at Claim 113). Claim 118 adds to claim 113 that the capture device "comprises two distal elements disposed on opposite sides of the shaft." (*Id.* at Claim 118). Claim 123 depends from claim 119, which in turn depends on claim 113. Claim 119 adds to claim 113 that "the capture device further comprises at least one proximal element disposed proximal to the distal element" (*id.* at Claim 119), and claim 123 further adds that "the capture device is detachable from the interventional tool" (*id.* at Claim 123).

The infringement dispute regarding the '813 Patent is whether PASCAL satisfies the "an interventional catheter comprising at least one guide conduit" limitation of claim 113, which is required by asserted claims 118 and 123 based on their ultimate dependency from claim 113. (*See* D.I. 85 at 21; *see also* D.I. 136 at 152:4-24). Defendants argue that the claimed interventional catheter and guide conduit are separate structures and, further, that the guide conduit serves to introduce "tools such as needles." (D.I. 85 at 21; *see also* D.I. 91 ¶ 137). According to Dr. Jensen, PASCAL does not have a separate guide conduit to introduce tools and, in his opinion, PASCAL uses no tools at all. (D.I. 91 ¶¶ 137, 143). Plaintiffs respond that, even if "guide conduit" means a separate structure to deliver "tools," PASCAL meets that requirement because it uses an implant catheter that contains multiple inner channels, including four that guide sutures to the implant site. (D.I. 110 at 5; *see also* D.I. 112, Ex. 289 ¶¶ 71-75).

At the preliminary injunction hearing, Defendants changed course and proposed to construe the disputed term to mean "an interventional catheter including at least one separate branching structure to guide other elements to a target location on the valve." (D.I. 134 at 1;

see also D.I. 136 at 148:13-22).[9] Defendants argue that the specification and figures show that the guide conduit is a separate structure positioned ***on*** the interventional catheter and that it extends angularly away from the catheter to guide "something" to a target location on the valve leaflet. (*See* D.I. 136 at 149:16-151:24; *see also* D.I. 91 ¶¶ 138-40 (Dr. Jensen relying on embodiments and figures in opining that "guide conduit" must deliver tools)). In Plaintiffs' view, the plain meaning of this term is simply "an interventional catheter including at least one channel to guide other elements to a target location on the valve." (D.I. 135 at 2).

Although Defendants' proposed construction has evolved over the course of these proceedings, the Court views the central dispute now to be whether the "guide conduit" must be a separate branching structure on the interventional catheter.[10] Such a limitation is not supported by the intrinsic evidence. The portions of the '813 Patent that Defendants rely on to support the position that the guide conduit must be a separate branched structure are specific embodiments. (*See, e.g.*, '813 Patent at 7:51-64, 19:51-65, 23:27-32, 23:66-24:22, 24:48-65, 25:19-23 & FIGs. 22, 34, 39). As to the disclosure of the guide conduits protruding radially outward from the interventional catheter (*id.* at 19:63-20:3), not only are these preferred embodiments, but the specification also states that the angle may be "around zero degrees, essentially parallel to the

---

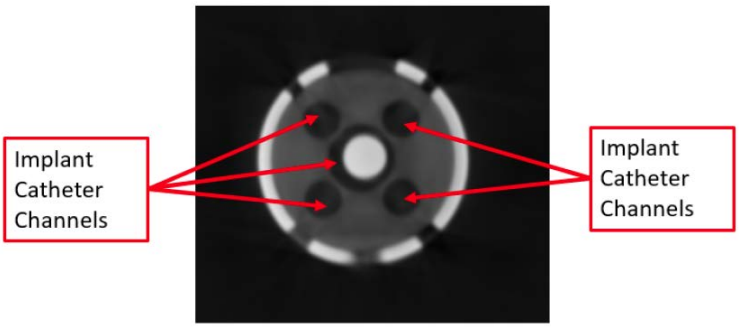
[9] Defendants' argument that the "guide conduit" must be a separate ***branching*** structure is different than what was presented in Defendants' papers. Dr. Jensen did not use a definition that assumed branching was required in rendering his noninfringement opinion, and Defendants never argued that PASCAL cannot infringe because it lacks a separate branching structure apart from an interventional catheter. (*See, e.g.*, D.I. 91 ¶¶ 137-38, 142-44; D.I. 85 at 21). The branching requirement was apparently added for the first time at the preliminary injunction hearing. (*See* D.I. 136 at 148:1-22, 222:7-17).

[10] Interestingly, both sides' experts appear to agree that the plain meaning of "conduit" is at least a "channel," with Defendants' expert further asserting that a POSA would understand it to mean a channel "that you can bring things towards and away from a location." (D.I. 112, Ex. 302 at 129:3-7 (Dr. Jensen deposition); *see also* D.I. 112, Ex. 289 ¶ 66 (Dr. Yoganathan asserting that the plain meaning of "conduit" is "channel")).

shaft" (*id.* at 20:3). Moreover, the language of claim 113 is broader than the disclosed embodiments, importing no structural relationship to the guide conduit as related to the interventional catheter. And the specification concludes with language indicating that preceding description of the invention is "by way of illustration and example" and that "alternatives, modifications and equivalents may be used." (*Id.* at 29:66-30:4). Although certainly not dispositive, such language supports a finding that the disclosed embodiments should not be considered limiting. *See, e.g.*, *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006); *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1345 (Fed. Cir. 2001).

Additionally, presently unasserted claim 127 provides further support for the conclusion that the "guide conduit" does not have to be a separate branching structure. Ultimately depending from claim 113, claim 127 adds "wherein each guide conduit is capable of extending angularly outward from the shaft." This means that claim 113 also encompasses guide conduits that cannot extend angularly away from the shaft of the interventional catheter – *i.e.*, they are not branching. *See, e.g.*, *Phillips*, 415 F.3d at 1315 ("[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim."); *Laitram Corp. v. NEC Corp.*, 62 F.3d 1388, 1392 (Fed. Cir. 1995) ("Although each claim is an independent invention, dependent claims can aid in interpreting the scope of claims from which they depend."). In view of the intrinsic evidence, a POSA would not understand the plain meaning of "an interventional catheter comprising a guide conduit" to require that the "guide conduit" be a separate branching structure extending away from the interventional catheter. Nor would a POSA understand that the "guide conduit" must be a separate structure external to the interventional catheter.

Applying the plain and ordinary meaning, PASCAL meets the "an interventional catheter comprising at least one guide conduit" limitation of claim 113 of the '813 Patent. PASCAL uses an implant catheter to deliver the device to the mitral valve (*see, e.g.*, D.I. 12, Ex. 6 ¶ 444; D.I. 112, Ex. 289 ¶ 64), and Defendants' expert agreed that PASCAL's implant catheter is an interventional catheter (*see* D.I. 112, Ex. 302 at 126:19-127:20). Plaintiffs have offered evidence that there are several channels within the implant catheter used to deliver PASCAL:



(D.I. 112, Ex. 289 ¶ 71 (annotated by Dr. Yoganathan); *see also* D.I. 114, Ex. 364 at 1). These inner channels guide sutures that are used to actuate the clasps on PASCAL – *i.e.*, the movable structures that engage the valve leaflets from the atrial side. (*See* D.I. 112, Ex. 289 ¶¶ 71-73; *see also* D.I. 91 ¶¶ 54-57, 67). These inner channels are therefore "guide conduits" for the PASCAL sutures.[11] Thus, the evidence presented shows that PASCAL employs an "interventional catheter comprising at least one guide conduit" as required by claim 113. Because this is the only contested limitation from dependent claims 118 and 123, the Court finds that Plaintiffs have

[11] To the extent there remains a dispute as to whether the "guide conduit" must guide "tools" or "fixation tools" in particular, the Court finds that PASCAL's suture lines are fixation tools given that they are attached to and move the clasps that engage the valve leaflets to ultimately be attached together. (*See, e.g.*, '813 Patent at 7:56-58 ("The guide conduits are used to guide the fixation tools to specific locations on the surfaces of the leaflets."); *id.* at 28:49-60 & FIG. 53).

demonstrated that they are likely to succeed in proving infringement of claims 118 and 123 of the ’813 Patent.

c. ’493 Patent – Claims 5, 7, 21 and 24

The ’493 Patent, titled “Fixation Devices, Systems and Methods for Engaging Tissue,” is generally directed to methods and devices for approximation and repair of tissue, particularly the fixation of tissue at treatment sites, including cardiac valves. (*See, e.g.*, ’493 Patent at 3:14-39). As to cardiac valves, the specification provides that the claimed invention “enables two or more valve leaflets to be coapted using an ‘edge-to-edge’ or ‘bow-tie’ technique.” (*Id.* at 3:40-43). In some embodiments, the claimed invention comprises a fixation device with fixation elements that can move between a first position that captures the valve tissue and a second position that fixes the tissue. (*Id.* at 3:61-66). Plaintiffs allege that Defendants’ PASCAL infringes claims 5 and 7 of the ’493 Patent, both of which depend from independent claim 1:

> 1. A fixation device for engaging tissue comprising:
>
> a pair of fixation elements each having a first end, a free end opposite the first end, and an engagement surface therebetween for engaging the tissue, the first ends being movably coupled together such that the fixation elements are moveable between a closed position wherein the engagement surfaces face each other to a first open position wherein the engagement surfaces are positioned away from each other; and
>
> an actuation mechanism coupled to the fixation elements adapted to move the fixation elements between the closed position and the first open position; and
>
> a pair of gripping elements, each gripping element moveable with respect to one of the fixation elements and being disposed in opposition to one of the engagement surfaces so as to capture tissue therebetween when the pair of fixing elements are in the first open position,
>
> wherein each fixation element is at least partially concave and each gripping element is at least partially recessed within the fixation element in the deployed configuration, and

> wherein the gripping elements are movable from an undeployed configuration in which each gripping element is separated from an opposing engagement surface, to a deployed configuration in which the gripping element is closer to the opposing engagement surface.

('493 Patent at Claim 1). Claim 5 adds that the gripping elements have "frictional features configured to enhance grip on tissue engaged thereby." (*Id.* at Claim 5). Claim 7 adds to claim 1 that the gripping elements "are biased toward the engagement surfaces." (*Id.* at Claim 7).

Plaintiffs also allege that PASCAL infringes claims 21 and 24 of the '493 Patent, both of which depend from independent claim 20:

> 20. A fixation device for engaging tissue comprising:
>
> a pair of fixation elements each having a first end, a free end opposite the first end, and an engagement surface therebetween for engaging the tissue, the first ends being movably coupled together such that the fixation elements are moveable between a closed position wherein the engagement surfaces face each other to an inverted position wherein the engagement surfaces face away from each other; and
>
> an actuation mechanism coupled to the fixation elements adapted to move the fixation elements between the closed position and the inverted position; and
>
> a pair of gripping elements, each gripping element moveable with respect to one of the fixation elements and being disposed in opposition to one of the engagement surfaces so as to capture tissue therebetween when the pair of fixation elements are in a position other than the closed position, and
>
> wherein each gripping element is at least partially positionable within the fixation element in the deployed configuration, and
>
> wherein the gripping elements are movable from an undeployed configuration in which each gripping element is separated from an opposing engagement surface, to a deployed configuration in which the gripping element is closer to the opposing engagement surface.

(*Id.* at Claim 20). Claim 21 adds that the fixation elements are "further moveable to an open position between the closed position and the inverted position." (*Id.* at Claim 21). And claim 24 adds to claim 20 that the gripping elements have "frictional features configured to enhance grip on tissue engaged thereby." (*Id.* at Claim 24).

Defendants argue that they do not infringe any of claims 5, 7, 21 and 24 of the '493 Patent because PASCAL does not contain "a pair of fixation elements each having a first end, a free end opposite the first end, and an engagement surface therebetween for engaging the tissue," which is a required element in each of the asserted claims (based on their ultimate dependency from either claim 1 or claim 20). (*See* D.I. 85 at 22-23; *see also* D.I. 91 ¶¶ 193-210, 223-37). In particular, Defendants argue that the purported "free end" of PASCAL's paddles (*i.e.*, the alleged fixation elements) is neither "free" nor an "end" – rather, the "free end" is actually a bend of continuous material that serves to connect the inner and outer portions of the paddle. (*See* D.I. 85 at 22; *see also* D.I. 91 ¶¶ 199-202). Further, as to claims 5 and 7, Defendants also contend that PASCAL does not meet the "first open position wherein the engagement surfaces are positioned away from each other" limitation incorporated from claim 1 because the alleged engagement surfaces continue to face each other in PASCAL's open position. (*See* D.I. 85 at 22; *see also* D.I. 91 ¶¶ 211-18). And finally, as to claims 21 and 24, Defendants argue that PASCAL does not have an "inverted position" but instead elongates when repositioning within the heart is necessary. (*See* D.I. 85 at 22-23; *see also* D.I. 91 ¶¶ 238-47).

The Court begins with Defendants' first noninfringement argument, which applies to all presently asserted claims and which involves a dispute over the meaning of "free end." Plaintiffs propose that the term should be construed as "free to move relative to the 'first ends' and the

longitudinal axis of the device."[12] (D.I. 135 at 2). Defendants contend that a "free end" is an end "not attached to any other portion of the implant." (D.I. 136 at 154:20-155:2).

Turning first to the claims, the Court finds the language of claims 1 and 20 edifying:

> A fixation device for engaging tissue comprising: a pair of fixation elements each having a first end, ***a free end opposite the first end***, and an engagement surface therebetween for engaging the tissue, ***the first ends being movably coupled together*** such that the fixation elements are moveable between a closed position . . . to a first open position . . . .

('493 Patent at Claim 1 (emphases added); *see also id.* at Claim 20 (same language)). Each of the claimed fixation elements has both a "free end" and a "first end," and the first ends are "movably coupled together." That is, the first ends are attached in such a way as to allow movement of the fixation elements between a closed position and an open position. The other end of each fixation element – the free end – stands in contrast to this requirement for the first ends. Although the '493 Patent Applicants could have simply chosen to recite "a pair of fixation elements each having a first end, a ***second*** end opposite the first end" in the disputed claim language, they did not. "Free end" must have meaning apart from simply being an end opposite the first end. A POSA would understand from the contrasting claim language between "free end" and "first ends" that a "free end" is free, at the very least, because it is not coupled or attached to the other free end.[13] But a POSA would also understand from the patent's overall disclosure that a "free end" is free because it is even less restrained – *i.e.*, it is an end not attached to another portion of the fixation device.

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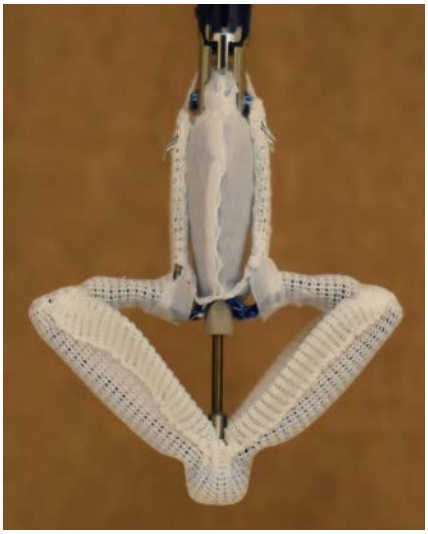
[12] It is unclear to the Court how the "free end" could be "free" to move relative to the "first end" when the "free end" and the "first end" are at opposite ends of the same continuous structure.

[13] Even if "free" only means uncoupled from the other "free end," PASCAL does not satisfy this limitation. The "free ends" that Plaintiffs point to – the connection between the inner and outer parts of the paddle – are arguably attached together (indirectly) through the central spacer. (*See, e.g.*, D.I. 91 ¶¶ 55, 197; D.I. 87, Ex. 48 at EDW-ABT00000310).

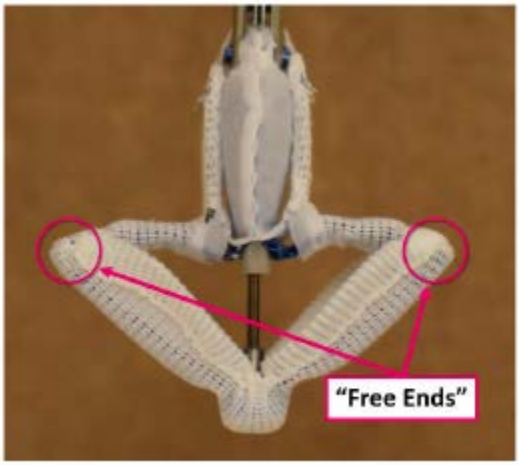
There is no disclosure in the '493 Patent of any fixation element "free end" attached to any other structure of the fixation device. The "free end" of the fixation element is only ever attached to the "first end" by virtue of the "free end" and the "first end" being disposed at opposite ends of the same structure. In arguing that the patent does, in fact, disclose a "free end" attached to something else, Plaintiffs point to certain embodiments where "proximal element lines" are attached to certain "free ends." (*See, e.g.*, D.I. 135 at 3 (citing '493 Patent at 22:14-18, FIGs. 12A & 18); *see also* D.I. 136 at 51:7-14, 224:18-25). In those examples, however, the "proximal element lines" are attached to and move the gripping elements between desired positions (*see, e.g.*, '493 Patent at 22:30-36), and the gripping elements are separate structures from the fixation elements (*compare, e.g.*, *id.* at 3:61-66 (fixation element), *with id.* at 4:63-5:4 (gripping element)). The claim language at issue here relates to a "free end" of the fixation element, not the gripping element. Moreover, the dispute is whether a "free end" must be free from attachment to other portions of the fixation device. Those "proximal element lines" are not part of the fixation device, and they are severed and removed when the fixation device has been placed in its final position and is left behind as an implant. (*See, e.g.*, *id.* at 23:4-12, 25:57-60). Although mindful that the claims are generally not limited to the disclosed embodiments, the Court finds that the use of "free end" instead of less structurally limiting claim language (*e.g.*, "second end") coupled with the specification's invariable depiction of those fixation element "free ends" as unattached demonstrates that a POSA would understand "free end" to mean an end not attached to another portion of the fixation device.

Applying the plain and ordinary meaning of "free end," which requires the end to be free from attachment to other portions of the fixation device, PASCAL does not meet this limitation.

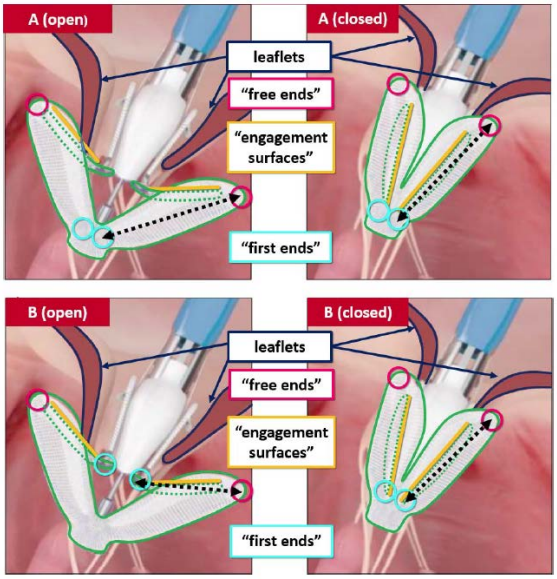
The evidence presented shows that the alleged fixation elements in PASCAL – *i.e.*, the paddles – are comprised of two connected paddle portions, an inner portion and an outer portion:



(D.I. 114, Ex. 363 at 2; *see also* D.I. 91 ¶ 197). Plaintiffs allege that the point of connection between the inner and outer parts of each paddle constitute the "free ends" of the fixation elements:



(D.I. 112, Ex. 289 ¶ 90 (annotated by Dr. Yoganathan); *see also* D.I. 12, Ex. 6 ¶ 297 & Figure 87). Dr. Yoganathan asserts that the inner and outer portions of each paddle each have their own "first end," and these "free ends" are opposite both sets of "first ends":



(D.I. 12, Ex. 6 ¶ 302 & Figure 89 (annotated by Dr. Yoganathan)). Although the alleged "free ends" may be opposite the "first ends" identified by Plaintiffs, neither is a "free end" within the meaning of the '493 Patent. As Dr. Jensen explains, the "free end" is a "bend between the inner part of the paddle and the outer part of the paddle." (D.I. 91 ¶ 202). Stated differently, the "free end" that Plaintiffs accuse is not an end free from attachment to another portion of the implant. In fact, it actually serves as a point of connection between the inner and outer portions of each paddle, which results in the alleged "free end" being attached to two separate parts of the fixation device. This is fundamentally different than the fixation element "free end" in the claims asserted from the '493 Patent, which is only attached to the "first end" and no other portion of the fixation device. Thus, PASCAL does not contain a "free end" as required by claims 5, 7, 21 and 24, and Plaintiffs have not shown a likelihood of success on infringement for the asserted claims of the '493 Patent.[14]

[14] Dr. Yoganathan also asserts that even if PASCAL does not literally meet the "free end" limitation, it nevertheless meets it under the doctrine of equivalents. (D.I. 12, Ex. 6 ¶¶ 304-09). Experts for both sides only cursorily address whether PASCAL uses an equivalent to the claimed "free end." (*See id.*; *see also* D.I. 91 ¶¶ 207-10; D.I. 112, Ex. 289 ¶¶ 99-100). Given the immensely factual nature of the doctrine of equivalents, and the sparse record

d. ’388 Patent – Claims 4, 10 and 16

The ’388 Patent, titled “Fixation Devices, Systems and Methods for Engaging Tissue,” issued from the parent application to the ’493 Patent. (*See* ’493 Patent at 1:7-8 (’493 Patent is continuation from ’388 Patent application)). As such, the two patents share the same specification, and both are generally directed to methods and devices for the fixation of tissue at treatment sites, including cardiac valves. Plaintiffs allege that Defendants’ PASCAL infringes claim 4, 10 and 16 of the ’388 Patent, all of which depend from independent claim 1:

> 1. A fixation device for engaging a heart valve tissue, said device comprising:
>
> a coupling member;
>
> a pair of fixation elements, each of the pair having a first end, a free end opposite the first end and an engagement surface therebetween for engaging the tissue, the first ends being pivotably coupled to the coupling member such that the fixation elements are movable from a closed position wherein the free ends are disposed at a separation angle of less than about 0° up to about 45° to a first open position wherein the free ends are disposed at a separation angle of up to about 360°, and wherein the fixation elements are adapted to atraumatically grasp and release the heart valve tissue, wherein the free ends are adapted to minimize trauma to the heart valve tissue, and wherein the engagement surfaces comprise a concave region in which the coupling member at least partially nests when the pair of fixation elements are in the closed position thereby reducing profile of the device, and wherein the fixation elements are at least partially covered with a covering material adapted to permit ingrowth of tissue thereto; and
>
> a pair of proximal elements, the pair of proximal elements each having a first end and a free end opposite the first end, the first

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on equivalents available at this preliminary stage, the Court cannot resolve this issue. *Cf. Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1384 (Fed. Cir. 2000) (affirming denial of preliminary injunction where no likelihood of success of literal infringement shown and declining to revisit district court’s equivalents analysis (or lack thereof), noting that “the issue of infringement under the doctrine of equivalents . . . rarely comes clear on a premature record”).

> ends being coupled to the coupling member such that the free ends of the proximal elements are movable relative to the coupling member, wherein each proximal element is at least partially recessed in the concave region of one of the pair of fixation elements when the heart valve tissue is not disposed therebetween.

('388 Patent at Claim 1). Claim 4 adds that at least one of the pair of proximal elements comprises a "frictional accessory." (*Id.* at Claim 4). Claim 10 adds to the fixation device of claim 1 "an actuation mechanism coupled to the fixation elements adapted to move the fixation elements between the closed position and the first open position." (*Id.* at Claim 10). And claim 16 adds to the fixation device of claim 1 "a proximal element line coupled to at least one of the proximal elements such that when the line is actuated, the at least one proximal element is retracted away from one of the fixation elements." (*Id.* at Claim 16).

Defendants raise at least three noninfringement defenses regarding claims 4, 10 and 16 of the '388 Patent. (*See* D.I. 85 at 21-22; *see also* D.I. 91 ¶¶ 152-67 (no "free end"); D.I. 91 ¶¶ 168-76 (no fixation element "first ends" are "pivotably coupled" to coupling member); D.I. 91 ¶¶ 177-82 (no pair of "proximal elements" coupled to "coupling member")). One of those defenses, however, is the same defense addressed above for the '493 Patent – *i.e.*, that PASCAL does not have a "free end" as required by the claims. (*See* D.I. 85 at 22; D.I. 91 ¶¶ 152-67; *see also* D.I. 91 ¶¶ 196-210 (no "free end" for '493 Patent)). Because "free end" appears in the same term in the '388 Patent as in the '493 Patent, and because the '493 Patent is a continuation of the application that issued as the '388 Patent, the term should be construed consistently across both patents. *See, e.g., Capital Mach. Co. v. Miller Veneers, Inc.*, 524 F. App'x 644, 647 (Fed. Cir. 2013) (claims should be construed consistently across all asserted patents when they share parent application and common terms); *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005) ("Because NTP's patents all derive from the same parent application and share many common

terms, we must interpret the claims consistently across all asserted patents. . . . We thus draw distinctions between the various patents only where necessary."). Both sides agree. (*See* D.I. 136 at 141:9-19).

Therefore, for the reasons stated above for the '493 Patent, the Court finds that Plaintiffs have not shown a likelihood of success on infringement of claims 4, 10 and 16 of the '388 Patent because PASCAL lacks the "free ends" required by the claims. As it is unnecessary to do so, the Court does not address the other two noninfringement defenses raised by Defendants.

2. Validity

Because the Court finds that Plaintiffs have demonstrated a likelihood of success on infringement for only the '097 and '813 Patents, the Court's analysis as to whether Plaintiffs are likely to withstand a validity challenge is limited to these patents.

a. '097 Patent – Claim 1

As a preliminary matter, the Court addresses Defendants' contention that the '097 Patent has expired because 35 U.S.C. § 156(e)(2) only permits interim term extensions for one patent and Plaintiffs obtained an interim extension for the '097 Patent after already receiving one on another patent (U.S. Patent No. 7,464,712) based on the same MitraClip clinical trials. (*See* D.I. 85 at 23). Defendants have not, however, identified any instance where a court has found that interim extensions under § 156(e)(2) for multiple patents based on the same regulatory review period are impermissible. Nor is this Court aware of any. Moreover, it is noteworthy that the statute itself provides that the ***ultimate*** patent term extension based on a product's regulatory review period (under § 156(e)(1)) may be granted for only one patent. *See* 35 U.S.C. § 156(c)(4) ("[I]n no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product."). There is, however, no such limiting language in connection with interim

extensions available under § 156(e)(2). Further, the Patent Office has previously granted interim term extensions under this provision for multiple patents based on the same regulatory review period. (*Compare, e.g.*, Prosecution History of U.S. Patent No. 5,616,608 (granting (e)(2) interim extensions based on regulatory review of ZILVER stent), *with* Prosecution History of U.S. Patent No. 7,820,193 (granting (e)(2) interim extensions based on regulatory review of ZILVER stent)). Thus, it seems interim term extensions for multiple patents based on the same regulatory review period are indeed permitted. As such, the '097 Patent is not expired.[15]

Turning to the validity challenge based on prior art, Defendants argue that claim 1 of the '097 Patent is invalid as anticipated by U.S. Patent No. 6,165,183 ("Kuehn") or, alternatively, as obvious over Kuehn alone or in combination with information known to a POSA at the time of invention.[16] (*See* D.I. 85 at 24; *see also* D.I. 91 ¶¶ 253-67). Kuehn, titled "Mitral and Tricuspid Valve Repair," issued on December 26, 2000 from an application filed on July 15, 1998. Because the '097 Patent claims priority to an application filed on September 14, 1998, and because Plaintiffs have not asserted an earlier priority date, Kuehn is § 102(e) prior art to the '097 Patent.

Kuehn discloses devices for the repair of mitral and tricuspid valves exhibiting regurgitation using less invasive techniques than previously available – *e.g.*, valvuloplasty or edge-to-edge suturing while patient is on cardiopulmonary bypass. (Kuehn at 1:4-8, 1:35-62; *see also*

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15 Defendants also argue that the '097 Patent is expired because it does not cover MitraClip as required to receive the patent term extension under § 156, but this argument is based on Defendants' construction of "attach . . . together" that requires direct contact between the free edges of the valve leaflets. (*See, e.g.*, D.I. 85 at 23; D.I. 91 ¶ 397). The Court rejected Defendants' proposed construction (*see supra* § III.A.1.a), and Defendants have no alternative argument for MitraClip not being covered by the '097 Patent.

16 As with infringement, the Court appreciates that there may be additional invalidity defenses (and responses) presented as the case progresses. Here, the Court focuses on the claim elements that Plaintiffs contend are missing from the prior art, as well as Plaintiffs' arguments regarding lack of motivation to combine and reasonable expectation of success.

id. at 5:3-10). Particularly relevant here, Kuehn discloses a valve leaflet gripping/fastener applicator that may be delivered to the target valves using a cardiac catheter. (*Id.* at 1:66-2:6). The cardiac catheter allows direct introduction of the device through a wall of the heart, which is accessed through the patient's chest. (*Id.* at 5:25-37). Once the cardiac catheter reaches a desired location, "the mitral leaflets are grabbed, and the edges of the leaflets are secured together." (*Id.* at 5:15-16). The leaflet fastener may be comprised of two pairs of arms that are capable of gripping and fastening the heart valve leaflets together (*id.* at 2:22-26), and in some embodiments the fastener is left behind as an implant (*id.* at 7:44-46). As an alternative to delivery using a cardiac catheter, Kuehn teaches that vascular approaches may be utilized to deliver the gripping/fastener device to the desired location within the heart. (*Id.* at 5:38-42; *see also id.* at 13:19-36).

As to anticipation, Defendants assert that Kuehn discloses each and every limitation of claim 1 of the '097 Patent, relying on Plaintiffs' proposed construction of "attach the free edges of the valve leaflets together," which does not require direct contact of the leaflet edges. (*See* D.I. 85 at 24, *see also* D.I. 91 ¶¶ 258-65). In response, Plaintiffs argue that Kuehn cannot anticipate claim 1 because it does not disclose the following elements: (1) "a tube suitable for introducing through a patient's vasculature and into a chamber of a heart" and (2) "a clipping system including a first pair of elements adapted to be brought up beneath a pair of valve leaflets from the ventricular side and a second pair of elements adapted to be brought down over the pair of leaflets from the atrial side." (*See* D.I. 110 at 7; *see also* D.I. 112, Ex. 289 ¶¶ 180-95). On the latter, the Court finds that Kuehn does disclose "a clipping system" as claimed in the '097 Patent. As Dr. Jensen points out – and Dr. Yoganathan apparently concedes – the gripper arms of Kuehn's gripping/fastening applicator extend on both sides of the leaflets (*i.e.*, brought up and down from

both ventricular and atrial sides) and therefore satisfy the "first pair of elements" and "second pair of elements" of the '097 Patent "clipping system." (*See* D.I. 91 ¶¶ 260-61; *see also* D.I. 112, Ex. 289 ¶ 193 (Dr. Yoganathan agreeing)). Dr. Yoganathan nevertheless disputes that the Kuehn gripping/fastener applicator would be considered a "clipping system" because the gripper arms engage the leaflets by being pushed and pulled along an inner core[17] and because Kuehn uses the term "clip" in another context elsewhere. (D.I. 112, Ex. 289 ¶ 194). Despite faulting Dr. Jensen for not explaining why the Kuehn system would be considered a "clipping system," Dr. Yoganathan fails to articulate why it would ***not*** be considered a "clipping system." Although neither party offers a construction for this term, or even suggests that there is a dispute over its meaning, the Court finds that a POSA would understand a "clipping system" to mean a system that clips (*i.e.*, secures) things together. The gripping/fastener applicator of Kuehn engages the valve leaflets and secures them together, and they remain that way after the gripping/fastener device is left behind as an implant. (*See* Kuehn at 5:15-16, 7:44-8:5, FIGs. 13A-E). Thus, Kuehn discloses "a clipping system" as required by claim 1 of the '097 Patent.

As to Plaintiffs' argument that Kuehn does not anticipate because it does not disclose "a tube suitable for introducing through a patient's vasculature and into a chamber of a heart," the Court agrees. (D.I. 110 at 7; *see also* D.I. 112, Ex. 289 ¶¶ 180-92). Defendants use the embodiment depicted in Figure 13 of Kuehn to argue that claim 1 is anticipated (*see, e.g.*, D.I. 91 ¶¶ 256-64), but that embodiment does not use vascular delivery of the gripping/fastener applicator. Rather, that system is delivered via a cardiac catheter, which is inserted through the chest. (Kuehn

[17] It is unclear why Dr. Yoganathan raises this as a potential basis for Kuehn not disclosing the "clipping system" claimed in the '097 Patent. The language of claim 1 of the '097 Patent imposes no such requirements for how the first and second pair of elements move to engage the leaflets in the claimed clipping system.

at 7:46-48; *see also id.* at 5:25-37). To anticipate claim 1 of the '097 Patent, Kuehn must disclose all elements ***as combined and arranged*** in the claim. *See SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1375 (Fed. Cir. 2013). Because the disclosure that Defendants use to argue anticipation does not include "a tube suitable for introducing through a patient's vasculature and into a chamber of a heart," but instead uses a cardiac catheter, Kuehn cannot anticipate claim 1 of the '097 Patent.

That being said, Kuehn ***explicitly teaches*** that the disclosed invention can also be delivered using several different vascular approaches. (*See* Kuehn at 5:38-42, 13:19-36; *see also* D.I. 91 ¶ 259). Dr. Jensen asserts that, given this disclosure, Kuehn "at a minimum renders this element obvious." (D.I. 91 ¶ 259). The Court finds that a POSA viewing the disclosure of Kuehn would likely find it obvious to combine the embodiment of Figure 13 with a vascular approach, particularly given that Kuehn explicitly recommends vascular approaches because they are less invasive than cardiac catheters. (Kuehn at 13:19-20 ("Alternatively, a less invasive, percutaneous vascular approach can be used.")). Such a combination would contain all elements from claim 1 of the '097 Patent. Although Kuehn was before the Patent Office during prosecution of the '097 Patent, it was not addressed substantively and, in any event, that is not a barrier to Kuehn serving as the basis for a substantial question of invalidity for claim 1. *See Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259-61 (Fed. Cir. 2012) (vacating grant of preliminary injunction because accused infringer raised substantial question of invalidity notwithstanding that the asserted prior art was considered by the Patent Office).

The Court is mindful that, even at the preliminary injunction stage, objective indicia of nonobviousness should be considered alongside the evidence of obviousness before reaching a conclusion about whether there is a substantial question as to validity. *See Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1379 (Fed. Cir. 2009). Here, however, there is no mention

of objective indicia (or secondary considerations) of nonobviousness in Plaintiffs' briefs. Although Plaintiffs hint in their Opening Brief at Defendants' prior failure to develop an "edge-to-edge" repair solution for mitral regurgitation (D.I. 11 at 13-14), refer to Defendants' "copycat" product (*id.* at 1), a long-felt need (*id.* at 1, 4-5) and praise (*id.* at 1, 5), there is no analysis or argument explaining how any purported objective indicia factor into the obviousness analysis at issue here (*see id.* at 13-14). And there is no mention of objective indicia in Plaintiffs' Reply Brief. (*See* D.I. 110 at 7). Similarly, at the hearing, there were only seventeen conclusory lines of argument in which Plaintiffs mentioned objective indicia. (*See* D.I. 136 at 67:24-68:16). The Court is doubtful that Plaintiffs' asserted objective indicia are properly before the Court given that they are not clearly addressed or argued in the relevant briefing. *Cf. SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) (issues only presented in footnotes are not preserved for appeal); *UCB, Inc. v. Accord Healthcare, Inc.*, 201 F. Supp. 3d 491, 542 n.33 (D. Del. 2016) ("Arguments that are presented in limited form in footnotes are entitled to little weight."), *aff'd*, 890 F.3d 1313 (Fed. Cir. 2018); *Robocast, Inc. v. Apple Inc.*, No. 11-235-RGA, 2014 WL 2622233, at *1 (D. Del. June 11, 2014) (arguments made in footnotes are disfavored). Moreover, Plaintiffs presenting their objective indicia only through the purported "opinions" of their expert does not suffice. The Court is not obligated to go digging for evidence and analysis in an effort to transform expert opinion into the legal arguments necessary to show Defendants' obviousness challenge lacks substantial merit. *See Hoffmann-La Roche Inc. v. Apotex Inc.*, 496 F. App'x 46, 52 (Fed. Cir. 2012) ("'District judges are not archaeologists,' and it was not the court's burden to 'excavate masses of papers in search of revealing tidbits' to help Roche satisfy its burden to obtain a preliminary injunction." (citation omitted)).

In any event, the Court has reviewed the objective indicia evidence and arguments presented through Plaintiffs' expert. (*See* D.I. 112, Ex. 289 ¶¶ 304-37). In view of the obviousness challenge presented by Defendants and the countervailing objective indicia presented, the Court finds that there are difficult questions relating to validity of the '097 Patent on both sides. That each side makes compelling arguments on validity renders this Court unable to find that Defendant's obviousness challenge lacks substantial merit, thus weighing against issuance of a preliminary injunction. *See, e.g.*, *Baxalta Inc. v. Genentech, Inc.*, No. 17-509-TBD, 2018 WL 3742610, at *8 (D. Del. Aug. 7, 2018) (Dyk, J., sitting by designation) ("With respect to both of the merits issues, the parties have presented challenging questions of law and sharply conflicting expert testimony. Both issues are best decided on the basis of a more developed record. But Genentech has at the very least established that there are difficult questions with respect to infringement and invalidity. These difficult merits questions weigh in favor of denying injunctive relief at this stage.").

b. '813 Patent – Claims 118 and 123

Defendants argue that claims 118 and 123 of the '813 Patent are invalid as obvious over Kuehn alone or in combination with information known to a POSA at the time of invention, relying on Plaintiffs' proposed construction of "guide conduit." (*See, e.g.*, D.I. 85 at 24; D.I. 91 ¶¶ 268-91). Because the '813 Patent claims priority to an application filed on April 9, 1999, and because Plaintiffs have not asserted an earlier priority date, Kuehn is § 102(e) prior art to the '813 Patent.

Plaintiffs respond that, as related to the asserted claims of the '813 Patent, Kuehn does not disclose or teach the following limitations: (1) "an interventional catheter configured to pass from the remote vasculature of a patient to a position within the heart adjacent to the cardiac valve" and (2) "wherein the distal element is protrudable radially outward and has a loop shape configured

for pressing against a downstream surface of at least one leaflet." (*See* D.I. 110 at 7; *see also* D.I. 112, Ex. 289 ¶¶ 197-214). The Court views the "interventional catheter" limitation to be in the same vein as the "a tube suitable for introducing through a patient's vasculature and into a chamber of a heart" limitation of the '097 Patent – *i.e.*, both elements require vascular approaches to reach and enter the patient's heart. As explained above for the '097 Patent, Kuehn explicitly teaches use of a vascular catheter to reach the heart and deliver the gripping/fastener applicator to the target valve. (*See supra* § III.A.2.a). Thus, contrary to Plaintiffs' assertion, Kuehn teaches "an interventional catheter configured to pass from the remote vasculature of a patient to a position within the heart adjacent to the cardiac valve" as required by claims 118 and 123 of the '813 Patent.

As to the second disputed limitation – "wherein the distal element is protrudable radially outward and has a loop shape configured for pressing against a downstream surface of at least one leaflet" – the Court agrees that Kuehn does not disclose the required "loop shape." As Dr. Yoganathan notes, the Kuehn embodiments that Defendants use to show such a shape appear different than the invention of the '813 Patent. (*See* D.I. 112, Ex. 289 ¶ 203; *see also* D.I. 91 ¶¶ 285-86 (Dr. Jensen relying on Kuehn Figure 14D and balloon plunger embodiment for required loop shape)). The Court agrees that the embodiment in Figure 14D does not appear to comprise a "loop shape configured for pressing against a downstream surface" of the valve leaflet. (D.I. 112, Ex. 289 ¶¶ 206-08). Rather, the curved arms of Kuehn would engage the valve leaflets from both the ventricular and atrial side, but there would be no "loop shape" pressing against the leaflet surface – on either side. (*Id.*; *see also* Kuehn at FIG. 14D). Similarly, the balloon plunger embodiment of Kuehn that can push the valve leaflets towards graspers (Kuehn at 9:52-67) does not appear to comprise a "loop shape" like the one of the '813 Patent because, *inter alia*, it is configured to press against the upstream valve leaflet surface approaching from the atrial side

(*see* D.I. 112, Ex. 289 ¶¶ 209, 211; *see also id.* ¶¶ 210, 212 (balloon plunger also not a distal element and it is removed with catheter after implant)).

Although Kuehn does not explicitly disclose the "loop shape" limitation, Dr. Jensen opines that a POSA would have been motivated to use such a shape so as to maximize the surface area for leaflet contact, to reduce stress on tissue from sharp points or edges and to minimize trauma to surrounding tissue. (D.I. 91 ¶ 287). Further, he asserts that a POSA would have reasonably expected success in combining a "loop shape" with the embodiment of Kuehn Figure 13 because it was well known in the art that rounded edges – which would accompany a loop – would avoid trauma and reduce stress. (*Id.*). These assertions are consistent with one of the purposes of Kuehn – *i.e.*, to use a minimally invasive technique and reduce trauma in performing edge-to-edge mitral valve repair with a leaflet fastener. (*See, e.g.*, Kuehn at 13:37-55). That there may not yet be fulsome evidence on motivation to combine and reasonable expectation of success does not mean that Defendants fail to raise a substantial question as to the '813 Patent's validity. "Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial." *Amazon.com*, 239 F.3d at 1359; *cf. also id.* at 1363 ("Whether the CompuServe Trend reference either anticipates and/or renders obvious the claimed invention in view of the knowledge of one of ordinary skill in the relevant art is a matter for decision at trial.").

As above with the '097 Patent, Plaintiffs' evidence on objective indicia of nonobviousness presents difficult questions as to the validity of the '813 Patent when viewed alongside Defendants' obviousness arguments regarding Kuehn. These competing arguments weigh against issuance of a preliminary injunction because the Court cannot conclude that Defendants' obviousness challenge to the '813 Patent lacks substantial merit. *See, e.g.*, *Baxalta*, 2018 WL 3742610, at *8.

Although the Court concludes that a preliminary injunction should not issue because there are substantial questions as to the validity of the '097 and '813 Patents, this conclusion is further confirmed by the fact that Plaintiffs will not suffer irreparable harm if an injunction is denied.

B. Irreparable Harm

"A party seeking a preliminary injunction must establish that it is likely to suffer irreparable harm if the preliminary injunction is not granted and there is a causal nexus between the alleged infringement and the alleged harm." *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017); *see also Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1375 (Fed. Cir. 2012) (causal nexus requires some connection between the alleged infringement and harm such "that the infringing feature drives consumer demand for the accused product"). The moving party must demonstrate that immediate irreparable harm is likely in the absence of injunctive relief – not merely that irreparable harm may possibly occur at some point in the future. *See Winter*, 555 U.S. at 22 (2008) ("Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy . . . ."). Further, the moving party must make a "clear showing" of the risk of irreparable harm to obtain the injunctive relief. *See Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012).

Plaintiffs argue that they will be irreparably harmed if the Court does not enjoin Defendants from manufacturing PASCAL in the United States (where PASCAL is not approved for sale) to be exported to Europe (where PASCAL is approved and sold). Plaintiffs concede that the Court cannot enjoin Defendants from exporting already manufactured PASCAL devices from the United States. (*See* D.I. 136 at 18:14-19:3). The Court must first address an important threshold issue – *i.e.*, whether injunctive relief is an available remedy to Plaintiffs under the facts of this case.

Relying on *WesternGeco LLC, v. ION Geophysical Corp.*, 138 S. Ct. 2129 (2018), Plaintiffs contend that irreparable harm from European sales is legally cognizable in the United States. (*See* D.I. 136 at 75:18-76:11). That is, Plaintiffs argue that the holding of *WesternGeco* may be extended to situations where, as here, alleged infringement in the United States has some possible connection to a purported irreparable harm in another country. But *WesternGeco* addressed infringement under § 271(f)(2), which explicitly recognizes limited activities that may occur outside of the United States as being actionable under this country's patent laws. *See* 35 U.S.C. § 271(f)(2) ("Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention . . . intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer."); *see also* 35 U.S.C. § 271(f)(1) (also delineating limited extraterritorial activities as actionable). Plaintiffs do not allege infringement under § 271(f), instead basing their infringement allegations only on § 271(a). This Court does not understand *WesternGeco* to stand for the proposition that a patentee in the United States may obtain damages (or injunctive relief) based on harm in another country independent of the theory of infringement liability at issue – *i.e.*, § 271(a) versus § 271(f).[18] Instead, the Court understands that an injunction (preliminary or otherwise) is not an available remedy when the sole purported irreparable harm caused by infringement occurs in another country and the patentee asserts infringement only under § 271(a). Thus, for these reasons alone, Plaintiffs' motion for a preliminary injunction should be denied.

[18] Indeed, § 271(f) would be superfluous if extraterritorial activities could give rise to liability under § 271(a), or more accurately under §§ 271(b) and (c), which are the domestic counterparts to §§ 271(f)(1) and (2).

For the sake of completeness, however, the Court will address the specific harms alleged by Plaintiffs. As a preliminary matter, the Court notes that Defendants do not dispute that MitraClip is covered by the Patents-in-Suit apart from the argument that MitraClip does not attach the leaflet free edges together as required by the '097 Patent. As noted above, however, this argument fails in light of the Court's claim construction. Additionally, the Court observes that PASCAL differs from the available versions of MitraClip in several ways: (1) PASCAL has bigger contoured paddles to engage the leaflets, (2) PASCAL's clasps that engage the leaflets from the atrial side can move independent of each other and (3) PASCAL has a central spacer that reduces stress on the leaflets after implant. (*See, e.g.*, D.I. 85 at 10; D.I. 86, Ex. 21 at 2; D.I. 86, Ex. 22 at 5; D.I. 91 ¶¶ 67, 73, 104, 122; D.I. 94 ¶¶ 8, 13-17, 20; D.I. 95 ¶¶ 14-21; D.I. 96 ¶¶ 15-18).

Turning to the specific irreparable harms alleged, the Court begins by remarking that Plaintiffs' presentation of the issues is often difficult to follow. For each purported irreparable harm, Plaintiffs include only one or two paragraphs in their briefs, instead relying on citations to hundreds of pages of expert opinions and fact declarations to present their arguments. Faced with the arduous task of piecing together Plaintiffs' assertions regarding irreparable harm, the Court finds that the confusing presentation of the issues presented militates against a finding that Plaintiffs have "clearly shown" they are likely to suffer irreparable harm in the absence of an injunction. In any event, the specific harms argued by Plaintiffs are addressed below.

1. Lost Market Share and Sales

"Evidence of potential lost sales alone does not demonstrate irreparable harm." *Metalcraft*, 848 F.3d at 1368. Loss of market share to the accused infringer, however, may constitute irreparable harm in cases where damages are insufficient to remedy the lost market share. That being said, speculative loss of market share cannot support issuance of a preliminary injunction.

See Nutrition 21 v. United States, 930 F.2d 867, 871 (Fed. Cir. 1991) ("[N]either the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial."). Indeed, as the Federal Circuit has made clear, "lost market share must be proven (or at least substantiated with some evidence)." *Automated Merch. Sys., Inc. v. Crane Co.*, 357 F. App'x 297, 301 (Fed. Cir. 2009).

Plaintiffs argue that they will lose sales and market share in Europe as a result of Defendants' sale of PASCAL, which will "artificially" create a two-player market because PASCAL will be the only other product to compete directly with MitraClip. (D.I. 11 at 14-16; *see also* D.I. 12, Ex. 9 ¶¶ 63-76; D.I. 110 at 7-9). Plaintiffs assert that any sale of PASCAL is a lost sale of MitraClip and, further, that a single sale of PASCAL to a particular doctor using MitraClip could convert that doctor into a PASCAL user for "an extended time." (D.I. 11 at 15). Recouping lost profits in the future are allegedly insufficient to remedy the harm because "doctors switching to PASCAL will likely stay with it[] because purchase contracts typically last at least a year and doctors do not like switching between devices." (D.I. 11 at 14; *see also* D.I. 12, Ex. 11 ¶ 25).

Further, according to Plaintiffs, Defendants are deliberately targeting MitraClip customers with the goal of taking control of the market and "vanquishing" MitraClip. (D.I. 110 at 8). Relying on Defendants' own aspirational estimates, Plaintiffs assert that PASCAL is likely to achieve [redacted] market share in 2019. (D.I. 110 at 8 (citing D.I. 93 ¶ 74 and D.I. 92 ¶ 12)). Projecting those estimates into 2021, when Plaintiffs assert that trial is likely to occur, PASCAL will

purportedly have roughly [redacted] market share by then.[19] (D.I. 110 at 8 (citing D.I. 93, Ex. D-2)). In support of their arguments on lost sales and market share, Plaintiffs offer expert testimony from Dr. Christopher Vellturo (*see, e.g.*, D.I. 12, Ex. 9 ¶¶ 63-76; D.I. 112, Ex. 287 ¶¶ 20-41), and they also rely on a number of fact declarations and documents purporting to evidence Defendants' plans and predictions for PASCAL sales (*see, e.g.*, D.I. 12, Ex. 11 ¶¶ 25, 41-63; D.I. 12, Ex. 12 ¶¶ 22-25; D.I. 115, Ex. 374; D.I. 114, Exs. 371-72; *see also* D.I. 93, Ex. D-2 (Defendants' market share predictions)).

Defendants deny that Plaintiffs have shown the requisite causal nexus between the sale of PASCAL and the alleged infringement – *i.e.*, that the infringing features drive the sale of PASCAL. (D.I. 85 at 18). Indeed, Defendants assert that there are a number of factors unrelated to the patented features that may lead to the sale of PASCAL instead of MitraClip. (*See, e.g.*, *id.* at 5-7, 18; D.I. 12, Ex. 30 at 779-80 ("[PASCAL's] novel features represent technical advancements because they translate into favourable results in patients considered difficult or impossible to treat using the existing MitraClip device."); D.I. 94 ¶¶ 8-18). Moreover, in Defendants' view, not all sales of PASCAL are lost sales for MitraClip, particularly because PASCAL can treat patients that MitraClip cannot. (D.I. 85 at 15; *see also* D.I. 12, Ex. 30; D.I. 93 ¶ 82; D.I. 92 ¶ 14; D.I. 96 ¶¶ 15-16). Although Defendants do acknowledge that there may be some sales of PASCAL at MitraClip's expense, they argue that any such sales can be compensated with money. (D.I. 85 at 14; *see also* D.I. 93 ¶¶ 153-64).

As to loss of market share, Defendants offer evidence that Plaintiffs expect PASCAL's impact on market share to be less than Plaintiffs claim in their papers. (D.I. 85 at 15; *see also*

[19] Relying on statistics from Docket Navigator, Plaintiffs argue that 2021 would be the estimated time for trial in this case (*see* D.I. 110 at 8), but Plaintiffs themselves have proposed a trial date in November 2020 (*see* D.I. 161 ¶ 21).

D.I. 93 ¶¶ 76-85; D.I. 12, Ex. 211 (Abbott document projecting maximum [redacted] market share loss to PASCAL by end of 2020 under worst case scenario)). Moreover, Defendants point out that at least one of Plaintiffs' corporate witnesses testified that it is "too early" to know the effects of PASCAL's presence on the market. (D.I. 86, Ex. 25 at 250:13-254:13). Further, according to Defendants, PASCAL is going to assist in growing the relevant market and, as a result, will lead to increased MitraClip sales in the future. (D.I. 85 at 15; *see also* D.I. 93 ¶¶ 73, 82; D.I. 92 ¶ 13). In support of this argument, Defendants offer evidence of significant growth in an analogous market – transcatheter aortic valve replacement – which occurred in the wake of competition. (*See* D.I. 92 ¶¶ 27-31; *see also* D.I. 136 at 168:8-171:15). Plaintiffs also appear to expect a market expansion because of PASCAL. (*See* D.I. 89, Ex. 78 at 6 (Abbott document noting that market development is likely with PASCAL entry)). And finally, Defendants emphasize that physicians and hospitals are unlikely to convert from MitraClip to PASCAL – instead, they are free to and will, in fact, use both systems, choosing which to use case-by-case based on the needs of the patient. (D.I. 85 at 15-16; *see also* D.I. 92 ¶¶ 14-18). At least one of Plaintiffs' witnesses apparently concedes that customers would likely not use either device exclusively. (*See* D.I. 12, Ex. 11 ¶¶ 13-14, 25).

The Court begins by rejecting Plaintiffs' contention that any sale of PASCAL is a lost sale of MitraClip. Plaintiffs have not clearly shown that this is the case here. In fact, the Court is doubtful given that there is evidence in the record that PASCAL can treat patients that MitraClip cannot, owing to a patient's particular anatomy and/or certain features that PASCAL offers over MitraClip. (*See, e.g.*, D.I. 12, Ex. 30 at 773 ("A considerable proportion of patients with mitral regurgitation are not eligible for treatment with the MitraClip for anatomical reasons."); *id.* at 779-90 ("These novel features represent technical advancements because they translate into favourable

results in patients considered difficult or impossible to treat using the existing MitraClip device."); D.I. 92 ¶¶ 14-17; D.I. 94 ¶¶ 8-17; D.I. 95 ¶¶ 16-22; D.I. 96 ¶¶ 15-19; D.I. 142 (submissions regarding treatment of patient with PASCAL after patient deemed untreatable with MitraClip)).[20] Similarly, the Court does not agree with Plaintiffs that a sale of PASCAL is likely to cause any physician or hospital to convert from using MitraClip to using only PASCAL. Instead, as the available evidence suggests, physicians and hospitals are likely to continue using both depending on the needs of the patient. (*See, e.g.*, D.I. 92 ¶¶ 14-18; D.I. 12, Ex. 11 ¶¶ 13-14, 25). Thus, the Court cannot conclude that any sale of PASCAL is a lost MitraClip sale or that any sale of PASCAL is likely to cause a customer to convert from MitraClip to PASCAL exclusively (before trial or even at all). This suggests that sales of PASCAL at MitraClip's expense are ones that could be compensated with money damages.

As to the purported loss of market share, the Court finds that the available evidence is too speculative to support the extraordinary remedy of a preliminary injunction. As shown above, both sides offer different models on how PASCAL's presence may affect the share of the European market that MitraClip currently holds. Notably, even Plaintiffs' own documents offer conflicting views: in one scenario, PASCAL is projected to potentially gain around [redacted] of the market share by the end of 2020, but in another more conservative scenario, PASCAL is project to only gain around [redacted] of the market. (*Compare* D.I. 12, Ex. 211 at 4 (PASCAL - Extreme in the PASCAL - 14 Acc/Q table), *with id.* (PASCAL - Conservative in the PASCAL - 7/Acc/Q table)). This

[20] The Court is aware that Plaintiffs dispute the import of the *Lancet* study (D.I. 12, Ex. 30) because it concerned an older version of MitraClip, but Plaintiffs do not yet have approval for a version of MitraClip that incorporates some of these desirable PASCAL features. (*See* D.I. 136 at 108:2-5 ("By the way, the independent clasping and larger wider paddles that Edwards is touting, June 19, that's when we expect regulatory approval.")). Thus, Plaintiffs' attempt to distinguish this study is not persuasive.

speculation is compounded by the evidence that Plaintiffs believe it is too early to understand PASCAL's effect on the market. (D.I. 86, Ex. 25 at 250:13-254:13).

Moreover, that Defendants have offered evidence that the market may grow at least in part because of PASCAL's presence further adds to the speculation as to what is likely to happen to MitraClip's market share in response to PASCAL. Indeed, this potential growth is something that Plaintiffs appear to anticipate as well. (*See, e.g.*, D.I. 89, Ex. 78 at 6). The speculative nature of the available evidence compels the conclusion that Plaintiffs have not clearly shown they are likely to lose a substantial share of the market from now until trial (whether in 2020 or 2021) without an injunction. *See Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006) (affirming district court's finding of no irreparable harm where "the parties' models of how the market will react to generic competition . . . remain highly speculative" (quotation marks and citation omitted)).[21]

Additionally, this case does not appear to be one where Defendants would be unable to satisfy a judgment awarding substantial money damages. *See Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1155 (Fed. Cir. 2011) ("A district court should assess whether a damage remedy is a meaningful one in light of the financial condition of the infringer before the alternative of money damages can be deemed adequate."). Indeed, Defendants assert that they are a

[21] Plaintiffs' reliance on *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142 (Fed. Cir. 2011), does not change the analysis. (D.I. 11 at 14). In *Bosch*, the Federal Circuit noted that "a two-player market may well serve as a substantial ground for *granting* an injunction – *e.g.*, because it creates an inference that an infringing sale amounts to a lost sale." 659 F.3d at 1151 (emphasis in original). The court did not, however, recognize a blanket rule to that effect. Indeed, such a rule would not be appropriate in cases such as this one where there is evidence that the products are not interchangeable and that PASCAL can treat patients that MitraClip cannot.

"financially healthy company that could satisfy any judgment." (D.I. 85 at 14). Plaintiffs have not disputed this. This is also a factor that weighs against a preliminary injunction.

In sum, PASCAL and MitraClip are not simply interchangeable copies, a sale of PASCAL is not necessarily a lost sale of MitraClip and a lost sale of MitraClip does not necessarily translate into a lost customer (thus significantly changing the market). These facts, coupled with the speculative nature of the evidence on loss of market share in the relevant European market, counsel against this Court issuing a preliminary injunction preventing Defendants from manufacturing PASCAL in the United States. Although Defendants have not shown that money damages will ultimately suffice to remedy any harm felt in Europe from lost sales or lost market share, Plaintiffs have not satisfied their burden of clearly showing that damages are inadequate. *See Abbott*, 452 F.3d at 1348 ("[W]here a patentee has not shown a likelihood of success on the merits, and where the patentee has not clearly established that monetary damages could not suffice but the defendant has not established that monetary damages do suffice, we cannot say that the irreparable harm prong of the analysis favors either party.").

2. Loss of "First Mover" Advantage

Plaintiffs also argue that they will suffer irreparable harm by losing their "first mover" advantage as related to their next-generation MitraClip device purportedly set to launch some time this year. (D.I. 11 at 17-18; *see also* D.I. 12, Ex. 9 ¶¶ 120-28; D.I. 12, Ex. 11 ¶ 45). That version of MitraClip, which is alleged to have improved features like independent leaflet grasping, will purportedly be at a disadvantage if PASCAL is on the market with "the same central features." (D.I. 11 at 17; *see also* D.I. 12, Ex. 9 ¶ 124; D.I. 12, Ex. 11 ¶¶ 42-45). But MitraClip was approved in Europe in 2008 (*see* D.I. 12, Ex. 6 ¶ 52), and Europe is the only relevant market at issue here as PASCAL is not approved in the United States. In that market, Plaintiffs had an eleven-year head

start over all other players seeking to market devices for edge-to-edge mitral valve repair. Plaintiffs' contention that they will lose their "first mover" advantage is overstated given the length of time that Plaintiffs were the only ones in the market. *See, e.g.*, *Integra Lifesciences Corp. v. Hyperbranch Med. Tech., Inc.*, No. 15-819-LPS-CJB, 2016 WL 4770244, at *15 (D. Del. Aug. 12, 2016) ("[I]n light of this 10-year head start over any other player in this market, it seems somewhat difficult for Plaintiffs to argue that 'DuraSeal is in . . . [imminent] danger of losing a first-mover advantage.'" (citation omitted)).

Moreover, Defendants presented evidence that the industry perceived a lack of progress with respect to MitraClip development in those ten years that Plaintiffs were alone in the market – and that Plaintiffs knew it. (*See, e.g.*, D.I. 93 ¶¶ 122-25; D.I. 89, Ex. 95 at ABT1060321 ("If these claims that [independent grippers actuation] IGA in PASCAL is leading to great MR results and 25 minute device times are correct, then we've been missing out on this opportunity [redacted]); D.I. 89, Ex. 92 at ABT0489465 ("The lack of visible investment in product development to improve MitraClip and delivery system performance during procedures, despite the significant knowledge gained by Abbott in transcatheter mi [sic] procedures over the past 7 years, is perceived negatively by customers.")). If Plaintiffs wanted to be "first mover" with respect to the upcoming features in the next-generation of MitraClip, ten years was sufficient time for Plaintiffs to do so. This factor does not weigh in favor of a finding of irreparable harm.

3. Reputational Harm / Loss of Return on Investment

Plaintiffs also argue that sales of PASCAL in competition with MitraClip are likely to cause reputational harm to Plaintiffs because Abbott has become known as "the innovator" in edge-to-edge mitral valve repair and the presence of PASCAL will damage that reputation.

(D.I. 11 at 18; *see also* D.I. 110 at 11). Specifically, Plaintiffs suggest that their innovations being incorporated into PASCAL will cast doubt on the perception that Plaintiffs are "behind the extraordinary technological advancements" in edge-to-edge repair. (D.I. 11 at 18). In support, Plaintiffs largely rely on their expert, Dr. Vellturo, who asserts that "new customers adopting edge-to-edge TMVr devices for the first time will no longer necessarily view Abbott as the pioneering edge-to-edge TMVr innovator." (D.I. 12, Ex. 9 ¶ 127; *see also id.* ¶ 108; D.I. 12, Ex. 11 ¶ 46 ("If PASCAL is allowed to enter the market before MitraClip Gen 4, Abbott's reputation would suffer because Edwards would suggest Abbott is not the market leader and innovator."); D.I. 12, Ex. 12 ¶¶ 27-31; D.I. 112, Ex. 287 ¶ 75). This purportedly will cause Plaintiffs to lose certain reputational advantages – ones that could otherwise be transferred to other products. (D.I. 12, Ex. 9 ¶ 127). Defendants respond that this argument is simply speculation, arguing that there is no evidence as to why physicians would come to believe that Plaintiffs (and MitraClip) are not innovative simply because PASCAL exists. (*See* D.I. 85 at 17). The Court agrees with Defendants.

As an initial matter, the Court does not understand relevant caselaw to stand for the broad proposition that Plaintiffs suggest – *i.e.*, that irreparable reputational harm exists where a patentee was the first to do something (hence the patent) and another comes along and markets a product allegedly incorporating the patented features to compete with the patented product. Indeed, if that were true, it is hard to imagine many patent cases where a preliminary injunction should not issue if likelihood of success on the merits is shown. Moreover, as Defendants point out, Plaintiffs have not offered any ***evidence*** showing that PASCAL is likely to cause the complained-of reputational harm. Dr. Vellturo and Plaintiffs' corporate witnesses simply assert – without support – that PASCAL will cause damage to Plaintiffs' innovator reputation. (*See* D.I. 12, Ex. 9 ¶ 127; D.I. 12, Ex. 11 ¶ 46; D.I. 12, Ex. 12 ¶¶ 27-31). But as Plaintiffs have repeatedly noted, MitraClip was

touted in the *New York Times* as a breakthrough treatment. (*See* D.I. 12, Ex. 14). It is unlikely that PASCAL could cast a shadow on Plaintiffs' or MitraClip's reputation in view of the profound industry reaction to MitraClip. And as to Defendants' statement that PASCAL can treat patients who cannot be treated with MitraClip (*see* D.I. 11 at 18), it is unclear how this is causing actionable reputational harm to Plaintiffs given that it appears to be true because of PASCAL's different features.[22] (*See, e.g.*, D.I. 142). Thus, Plaintiffs have not shown they are likely to suffer reputational harm in the absence of a preliminary injunction.

For similar reasons, the Court rejects Plaintiffs' contention that they are likely to be irreparably harmed from a loss of return on investment in MitraClip. (*See* D.I. 11 at 16-17; *see also* D.I. 110 at 10-11 ("Free-riding")). Plaintiffs assert that they spent "untold millions" in educating regulatory agencies and attempting to obtain regulatory approval, which included clinical trials that required "truly herculean efforts" because the benchmark of care was open-heart surgery. (D.I. 11 at 16; *see also* D.I. 12, Ex. 10 ¶¶ 6, 27-36 (Vice President of Research & Development at Evalve detailing efforts to develop MitraClip)). Plaintiffs also contend that they had to educate every physician on how to perform a repair procedure with MitraClip, provide trained representatives at "almost every MitraClip implantation" and spent millions of dollars in advocating for reimbursement in Europe. (D.I. 11 at 16-17; *see also* D.I. 12, Ex. 12 ¶¶ 16-21; D.I. 12, Ex. 11 ¶¶ 32-37). Plaintiffs argue that Defendants will unfairly benefit from this investment by, *inter alia*, working with physicians already trained with MitraClip and using the

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[22] In their Reply Brief, Plaintiffs now assert that Defendants are "badmouthing MitraClip." (D.I. 110 at 10). In support, Plaintiffs cite to an ***hour-and-a-half*** long video (D.I. 113, Ex. 342) without any indication where the complained-of statements are made within that video. Notwithstanding the unhelpful nature of this "citation," the Court does not find this sufficient evidence to show that irreparable harm to Plaintiffs' reputation is likely absent an injunction. Indeed, Plaintiffs are not requesting that this Court enjoin Defendants from talking about MitraClip.

reimbursement procedure already in place in Europe. (D.I. 11 at 16-17; *see also* D.I. 12, Ex. 9 ¶¶ 101, 115, 119).

The Court finds that, even if true, this purported "free-riding" does not suffice as irreparable harm necessary to support a preliminary injunction. As with the generic reputational harm argument, it is hard to imagine many patent cases where a preliminary injunction should not issue if Plaintiffs' asserted loss of investment return constitutes irreparable harm. Patentees that sell a product covered by their patent invest resources into developing and marketing that product and, if Plaintiffs' contention were correct, these patentees would only have to show a likelihood of success to obtain an injunction. Indeed, it would transform "the 'extraordinary' relief of a preliminary injunction into a standard remedy, available whenever the plaintiff has shown a likelihood of success on the merits." *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996). Moreover, Plaintiffs have not shown how any potential "free-riding" is likely to ***harm*** them in the future – as opposed to simply benefit Defendants – or that the "free-riding" has the requisite causal nexus to the infringement by PASCAL. Thus, the Court finds that the asserted "free-riding" does not suffice as irreparable harm.

4. Diversion of Resources / Harm to Product Lines Beyond MitraClip

Plaintiffs also contend that being forced to compete with PASCAL will necessitate a diversion of resources to "respond to PASCAL[]" when those resources could otherwise be applied to "the research and development of other innovative products." (D.I. 11 at 19). Dr. Vellturo asserts that Plaintiffs have made "large, sustained investments" in building the edge-to-edge repair market in Europe and that, if forced to compete with PASCAL, Plaintiffs would have to divert resources from their market-expansion efforts to defend MitraClip's current share of the market. (D.I. 12, Ex. 9 ¶¶ 102-04, 112-15). Dr. Vellturo, however, cites little evidence in support of his opinion that Plaintiffs would have to divert any such resources. (*See id.* ¶¶ 104, 112). In a few

instances, he relies on the declaration of Mr. Gervais, Abbott Vascular, Inc.'s Vice President of the Structural Heart business unit in Europe, the Middle East and Africa, and on the declaration of Mr. Meadors, Abbott Vascular, Inc.'s Director for Global Training and Commercial Excellence for the Structural Heart Division. (*See, e.g.*, D.I. 12, Ex. 9 ¶¶ 102, 112-13, 115; *see also* D.I. 12, Ex. 11 ¶ 1; D.I. 12, Ex. 12 ¶ 1). Both Mr. Gervais and Mr. Meadors generically state that Plaintiffs would have to divert resources but offer few concrete details. (*See* D.I. 12, Ex. 11 ¶¶ 39-40; D.I. 12, Ex. 12 ¶ 26). In their reply papers, Plaintiffs offer limited examples of diverting resources to purportedly combat PASCAL – *e.g.*, less focus on COAPT study, cancelling sponsorship of "Heart and Brain Summit." (*See* D.I. 112, Ex. 287 ¶¶ 58-64; *see also* D.I. 112, Ex. 288 ¶¶ 5-8).

Somewhat relatedly, Plaintiffs also contend that the presence of PASCAL in the market will cause Plaintiffs to lose sales on their "entire cardiovascular product line." (D.I. 11 at 18; *see also* D.I. 12, Ex. 9 ¶¶ 86-93). According to Plaintiffs, the very presence of PASCAL as an alternative to MitraClip will harm the sale of Plaintiffs' other products. (D.I. 11 at 18). In support, Dr. Vellturo asserts that if Defendants bundle PASCAL with other products (that Plaintiffs also sell), that bundling will cause Plaintiffs to also lose sales on non-MitraClip products. (D.I. 12, Ex. 9 ¶¶ 86-92; *see also* D.I. 12, Ex. 11 ¶¶ 51-53). In their Reply Brief, Plaintiffs add further nuance to this argument, explaining that a loss of sales on other products will also result from PASCAL disrupting Plaintiffs' customer relationships. (D.I. 110 at 10; *see also* D.I. 112, Ex. 287 ¶¶ 48-49, 72-74; D.I. 112, Ex. 288 ¶ 13). In Defendants' view, this argument is not supported by the available evidence, which suggests that Plaintiffs will continue to hold "the overwhelming majority of the market" for at least two years. (D.I. 85 at 17 (citing D.I. 93 ¶¶ 75-76, 79, 82-85)). Defendants do not specifically address Plaintiffs' claim of lost sales for non-MitraClip products,

but their expert Dr. Sullivan and corporate declarant Mr. Adelman assert that Defendants are unlikely to bundle PASCAL with other products. (*See, e.g.*, D.I. 93 ¶¶ 103-110; D.I. 92 ¶ 24).

Based on the available evidence, the Court cannot conclude that Plaintiffs are likely to suffer irreparable harm from the purported diversion of resources or loss of sales from non-MitraClip product lines. Plaintiffs provide only a few examples of having to divert resources in response to PASCAL's presence on the market, but they do not offer any explanation – let alone evidence – that suggests that this is likely to continue in the future or that it is likely to expand in such a way that could cause irreparable harm. Instead, the Court views Plaintiffs' argument on diversion of resources to be grounded in a select few examples projected forward based only on speculation. Likewise, as to loss of sales on non-MitraClip products, Defendants assert that they have no plans to bundle PASCAL with other products that compete with Plaintiffs. The present record does not establish that Defendants are going to use PASCAL to leverage sales of other products, through bundling, customer relationships or any other tactic. Thus, the Court cannot conclude that Plaintiffs are likely to suffer irreparable harm based on either the asserted diversion of resources or loss of non-MitraClip sales.

5. Price Erosion

Although omitted from their Opening Brief (*see* D.I. 11 at 14-19), Plaintiffs apparently assert through Dr. Vellturo that PASCAL will cause price erosion. (*See* D.I. 12, Ex. 9 ¶¶ 78-85). Defendants respond that any projected price erosion is based only on speculation and, further, that PASCAL is likely to be sold at a price premium. (*See* D.I. 85 at 18; *see also* D.I. 93 ¶¶ 93-96). Defendants offer evidence that Plaintiffs are aware that PASCAL is likely to be priced at a premium, that Plaintiffs are not aware of any instances where PASCAL was sold at a lower price than MitraClip and that Plaintiffs have no current plans to reduce the price of MitraClip in response

to PASCAL. (*See* D.I. 93 ¶¶ 91-93; *see also* D.I. 86, Ex. 25 at 146:10-23, 243:7-245:17 (Abbott Vice President of Structural Heart Business in non-US markets testimony on current and potential future pricing of MitraClip)). Plaintiffs respond that, even if PASCAL is currently priced at a premium, MitraClip prices will fall "quickly" if PASCAL performs well on the market. (D.I. 110 at 12). Moreover, according to Dr. Vellturo, there is already some evidence showing that PASCAL has, in fact, been sold at a price lower than MitraClip. (D.I. 112, Ex. 287 ¶¶ 43-44 (largely relying on D.I. 113, Ex. 324)). At the hearing, Defendants' expert addressed this new evidence, explaining that he believes it to be unreliable given the "exceptional variability" in pricing and its inconsistency with other evidence showing no such discounted pricing of PASCAL. (D.I. 136 at 189:16-9; *see also id.* at 235:7-236:5 (Plaintiffs' witness conceding variability); *id.* at 191:5-192:3; *id.* at 192:11-195:2). Moreover, Dr. Sullivan reiterated that evidence exists that PASCAL is being priced at a premium. (*Id.* at 192:4-10).

In the Court's view, Plaintiffs' argument on price erosion amounts only to speculation that PASCAL will – eventually – be priced lower than MitraClip. Although Plaintiffs offered some evidence that PASCAL has been priced lower than MitraClip, Defendants have called that evidence into doubt and offered countervailing evidence that PASCAL is being priced at a premium. Given the limited yet competing evidence on PASCAL's pricing relative to MitraClip, the Court cannot conclude that Plaintiffs have clearly shown that irreparable price erosion is likely in the absence of an injunction.

In sum, the Court finds that Plaintiffs have not clearly shown that they are likely to suffer any irreparable harm in the absence of a preliminary injunction.[23] Unable to conclude that

[23] As the Court has previously noted, the submissions in connection with the present motion are extensive and voluminous. The Court has carefully reviewed the submissions but cannot discuss every fact asserted in the papers. *See Metalcraft*, 848 F.3d at 1368 ("There

Plaintiffs are likely to suffer irreparable harm (or that Plaintiffs are likely to succeed on the merits), the Court need not reach the remaining factors in the four-part analysis. *See, e.g., Jack Guttman, Inc. v. Kopykake Enterprises, Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002) ("[A] trial court may . . . deny a motion based on a patentee's failure to show any one of the four factors – especially either of the first two – without analyzing the others."); *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 973-74 (Fed. Cir. 1996) ("[A] trial court need not make findings concerning the third and fourth factors if the moving party fails to establish either of the first two factors."). Nevertheless, for the sake of completeness and because Defendants have raised a compelling public interest argument, the Court will briefly address the two remaining factors in the injunction inquiry.

C. Balance of Hardships

In the third factor of the preliminary injunction inquiry, the Court looks at "the potential injury to the plaintiff if an injunction does not issue versus the potential injury to the defendant if the injunction is issued." *Novartis Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 596 (3d Cir. 2002). This factor "assesses the relative effect of granting or denying an injunction on the parties." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91 (2011). Here, this factor does not favor either party.

As discussed above, Plaintiffs have not shown that they are likely to be irreparably harmed by the sale of PASCAL in Europe. Moreover, Abbott is a large company.[24] The evidence presented suggests that Abbott has substantial experience and resources and is prepared to compete with PASCAL. (*See* D.I. 93 ¶¶ 26, 176). Abbott has anticipated Defendants' entry in the European

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is no requirement that the district court discuss every fact alleged by Toro."). To the extent that arguments offered in the papers are not explicitly addressed in this opinion, the Court has found them to be unpersuasive.

[24] Abbott is a company with approximately 103,000 employees and sales of approximately $30.6 billion in 2018. (D.I. 93 ¶ 26).

marketplace and has planned accordingly. (*Id.* ¶ 176; *see also* D.I. 12, Ex. 213 at 53-62 (Abbott document from 2018 anticipating effects of PASCAL launch)). Absent an injunction, Plaintiffs will continue to sell MitraClip and will continue to hold the lion's share of the market. (D.I. 93 ¶¶ 72-79).

Similarly, Defendants would not be substantially harmed if an injunction were to issue. PASCAL sales started only a short time ago, and Defendants have forecast limited sales in the upcoming year or two. Defendants claim that a preliminary injunction "would force" them to "wait to benefit from" PASCAL sales (D.I. 85 at 25), but that is a problem of their own making. As Plaintiffs point out, any alleged harm to Defendants would be the result of their "own calculated risk" to manufacture in the United States "with knowledge of [Plaintiffs'] patent[s]." (D.I. 11 at 19-20 (quoting *Celsis In Vitro v. CellzDirect*, 664 F.3d 922, 931 (Fed. Cir. 2012))).

D. Public Interest

Finally, the Court must ask whether granting "an injunction is in the public interest." *Winter*, 555 U.S. at 20; *see also Celgard, LLC v. LG Chem, Ltd.*, 624 F. App'x 748, 752 (Fed. Cir. 2015). "There is no question that the public has an interest in the enforcement of patent rights . . . ." *Baxalta*, 2018 WL 3742610, at *12. It is also clear, however, that "the public interest factor requires consideration of other aspects of the public interest." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1341 (Fed. Cir. 2012); *see also Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988) ("[The] focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief.").

In litigation such as this involving a medical product, the public has "two primary interests" – *i.e.*, the "protection of intellectual-property rights and access to necessary and effective medical

care." *Baxalta*, 2018 WL 3742610, at *12. "[F]or good reason, courts have refused to permanently enjoin activities that would injure the public health." *Cordis Corp. v. Bos. Sci. Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004). For example, courts have refused to grant an injunction when doing so would eliminate "an important alternative for patients." *Conceptus, Inc. v. Hologic, Inc.*, No. 09-02280 (WHA), 2012 WL 44064, at *3-4 (N.D. Cal. Jan. 9, 2012); *see also Hybritech*, 849 F.2d at 1458 (affirming district court's exclusion of certain cancer test kits and hepatitis test kits from the scope of an injunction because "the public interest is served best by the availability of these kits").

In *Conceptus*, the district court denied a request for a permanent injunction against the sale of a product found to be infringing at trial because, in part, an injunction "would leave only one product" and the "[p]ublic health has benefitted, and will continue to benefit, from having a choice of products." *Conceptus*, 2012 WL 44064, at *3. In finding that the availability of two products for patients "militates strongly against an injunction," the court noted that "[t]his is especially important because the products are different." *Id.* at *3-4.

Similarly, in *Cordis*, the Federal Circuit affirmed the denial of a motion for preliminary injunction, holding that "a strong public interest supports a broad choice of drug-eluting stents, even though no published study proves the superiority of either Cordis's [patented stent] or BSC's [accused] stent." *Cordis*, 99 F. App'x at 935. Specifically, the Federal Circuit noted that Cordis's stent "may have, for example, safety or efficacy concerns beyond those shared by" BSC's patented stent and that "the record contains evidence that some doctors prefer the [BSC] stent over the [Cordis] stent." *Id.* at 935-36 (citing *Datascope Corp. v. Kontron, Inc.*, 611 F. Supp. 889, 895 (D. Mass. 1985), *aff'd*, 786 F.2d 398 (Fed. Cir. 1986) (noting that the public would be harmed by an injunction because some physicians prefer the accused product)).

And in *Baxalta*, in denying a motion for preliminary injunction, Judge Dyk noted that "the parties' products, while competing with each other, differ in meaningful ways. These differences, taken together, explain why the public's interest in access to [the accused hemophilia product] weighs strongly against a preliminary injunction." *Baxalta*, 2018 WL 3742610, at *12. He concluded that, "given the ample evidence of medical need, the public interest weighs strongly against issuing a preliminary injunction since [the accused product] has unique medical benefits not available from Baxalta's competing products." *Id.*

Here, there is also a strong countervailing public interest in allowing Defendants' PASCAL device to remain available for medical treatment. Defendants presented evidence that there are at least three features of the PASCAL device that differentiate it from the MitraClip versions currently available: (1) availability of a central spacer, (2) independent leaflet capture and (3) contoured, potentially less traumatic paddles to capture the mitral valve leaflets.[25] (D.I. 142-1 at 1; *see also* D.I. 85 at 10; D.I. 86, Ex. 21 at 2; D.I. 86, Ex. 22 at 5; D.I. 91 ¶¶ 67, 104, 122; D.I. 94 ¶¶ 8, 13-17; D.I. 95 ¶ 14-21; D.I. 96 ¶¶ 15-18). Defendants have also offered evidence showing that at least some physicians consider PASCAL preferable to use in certain high-risk patients. (*See, e.g.*, D.I. 94 ¶ 8; D.I. 95 ¶ 16; D.I. 96 ¶¶ 14-19; D.I. 86, Ex. 22 at 3 ("key opinion leaders (KOLs) have noted that PASCAL is more maneuverable and is easier to use" and "[m]any KOLs have also stated that they are able to treat anatomies that the MitraClip therapy cannot"); *see also* D.I. 142-1). Plaintiffs dispute the truth of this assertion, pointing out that there is no controlled clinical study showing any advantage of PASCAL over MitraClip. (*See* D.I. 136 at 103:5-104:17).

[25] Plaintiffs acknowledge that PASCAL has certain features not available in the current versions of MitraClip but assert that they expect approval of yet another version with additional features. To the Court's knowledge, however, that version has not yet been approved.

And Plaintiffs further argue that the anecdotal evidence about the inability to use MitraClip in certain patients is based on a two-year old study that compared PASCAL to "older generations of MitraClip" and is not sufficient to raise an issue of patient safety currently." (D.I. 110 at 13-14). Yet Defendants have offered evidence indicating at least one patient in which the currently available MitraClip versions could not be used, but PASCAL was, in fact, used successfully. (*See* D.I. 142; *see also* D.I. 142-1 & D.I. 142-2 (referring to a critically-ill patient helped by PASCAL after doctor "had been ***advised by Abbott*** that he should not use MitraClip with [that] particular patient" and that "unlike the PASCAL, the MitraClip does not have a spacer" (emphasis added))).

The Court is convinced that, notwithstanding the lack of clinically proven superiority, at least some physicians – and more importantly patients – are likely to suffer negative consequences if PASCAL is no longer available (the consequence of an injunction issuing). *See Cordis*, 99 F. App'x at 935 ("In this case, a strong public interest supports a broad choice of drug-eluting stents, even though no published study proves the superiority of either Cordis's Cypher or BSC's Taxus stent."). As in the cases cited above, MitraClip and PASCAL are "not interchangeable products" and do not involve interchangeable procedures. Because different physicians may find one device more suitable for particular patients with challenging anatomies than the other, healthcare providers and patients benefit substantially from having both products available in the market. Here, the public benefits from having different products with different features available and, given the importance of this potentially life-saving device, the public interest weighs against granting a preliminary injunction.

IV. CONCLUSION

Although Plaintiffs have shown a likelihood of success as to infringement of the asserted claims of the ’097 and ’813 Patents, Plaintiffs have failed to show that the obviousness challenges raised by Defendants lack substantial merit. Moreover, Plaintiffs have not clearly shown that they are likely to suffer irreparable harm in the absence of an injunction, or that the public interest weighs in favor of enjoining the U.S. manufacture of Defendants’ PASCAL device for sale in Europe. In weighing the relevant factors, the Court thus concludes that preliminary injunctive relief is not appropriate here. Accordingly, Plaintiffs’ motion for a preliminary injunction (D.I. 10) is DENIED. An appropriate order will follow.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS, INC. and EVALVE, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 19-149 (MN)
EDWARDS LIFESCIENCES CORP. and EDWARDS LIFESCIENCES, LLC,	)	
Defendants.	)	

ORDER

At Wilmington this 6th day of June 2019:

For the reasons set forth in the SEALED Memorandum Opinion issued this date, IT IS HEREBY ORDERED that Plaintiffs' motion for a preliminary injunction (D.I. 10) is DENIED. The Court will separately docket a public version of this Memorandum Opinion on this date.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge