IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS, INC. and EVALVE, INC.,	
Plaintiffs,	REDACTED - PUBLIC VERSION
v.	C. A. No. 1:19-cv-00149
EDWARDS LIFESCIENCES CORP., and EDWARDS LIFESCIENCES LLC,	[redacted]
Defendants.	

PLAINTIFFS' OPENING BRIEF IN SUPPORT
OF THEIR MOTION FOR A PRELIMINARY INJUNCTION

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Dated: January 29, 2019

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Ex. 15	*Landmark Study Shows Treatment With Abbott's MitraClip is Superior to Medical Therapy for Advanced Heart Failure Patients with Significant Secondary Mitral Regurgitation* (Sept. 23, 2018)

[1] This table lists the exhibits that are cited in this brief. These exhibits, as well as the additional exhibits cited in the supporting declarations (Exs. 6–13), are filed with the accompanying Declaration of Aaron D. Resetarits.

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Ex. 174	*Abbott's Investigational Tendyne™ Device for Mitral Valve Replacement Demonstrates Positive Outcomes at 30 Days in Global Study* (May 23, 2018), *available at*: http://abbott.mediaroom.com/2018-05-23-Abbotts-Investigational-Tendyne-TM-Device-for-Mitral-Valve-Replacement-Demonstrates-Positive-Outcomes-at-30-Days-in-Global-Study
Ex. 279	Edwards Job Posting for Principal Engineer, Manufacturing, PASCAL -Transcatheter Mitral & Tricuspid Therapies, THE LADDERS (posted July 25, 2017), *available at:* https://www.theladders.com/job/principal-engineer-manufacturing-xfffd-pascal-transcatheter-mitral-tricuspid-therapies-edwards-lifesciences-irvine-ca_34832480

I. INTRODUCTION[2]

Edwards is about to infringe multiple Abbott patents covering its MitraClip®, a medical device that is revolutionizing the treatment of a life-threatening heart problem. Abbott spent years building a market from scratch for that patented product. To break into the market, Edwards tried to design around Abbott's patents. That effort failed due to "poor … results." (Ex. 52; *see also* Ex. 17.) [redacted] Now, as Abbott's efforts to build a market expected to reach billions of dollars are paying off, Edwards is attempting to launch an infringing, copycat product called PASCAL. The Court should preliminarily enjoin that infringing launch, which would undermine years of work and investment by Abbott.

Abbott's groundbreaking MitraClip treats mitral regurgitation ("MR"). MR is a life-threatening condition arising from the mitral valve failing to close properly, allowing blood to flow backwards in the heart. Before MitraClip, the standard of care for treating MR was highly-invasive open-heart surgery, requiring stopping a patient's heart. (Ex. 7 ¶¶ 42–46, 52; Ex. 13 ¶¶ 37–40, 74.) MitraClip avoided that high-risk surgery with an entirely new field of non-surgical treatment.

Abbott began developing MitraClip in the 1990s. (Ex. 12 ¶ 11.) Implanting a device into a beating heart presented enormous design, regulatory, doctor-training, and reimbursement challenges. (*Id.* ¶ 19; Ex. 13 ¶¶ 97–99.) Yet, Abbott persevered, overcoming all hurdles associated with this first-in-class device. After years of demonstrated outcomes and study, Abbott is changing how the medical community thinks about its new non-surgical procedure known as "edge-to-edge repair."

MitraClip is so groundbreaking that the New York Times touted MitraClip in September 2018 *on its front page*, calling MitraClip a "huge advance" that "sharply reduced deaths among patients with

[2] In further support, Abbott submits the declarations of Ajit Yoganathan, Ph.D. (Ex. 6); Stephen Little, M.D. (Ex. 7), Allan Will (Ex. 8), Christopher Vellturo, Ph.D. (Ex. 9), Troy Thornton (Ex. 10), Hugues Gervais (Ex. 11), Michael Meadors (Ex. 12), and Paul Sorajja, M.D. (Ex. 13). Emphasis and annotations on figures added unless otherwise noted.

a grim prognosis." (Ex. 14.) Doctors describe MitraClip as "a game changer," permitting them to treat MR "in a way we never thought we could." (*Id.*)

Because MitraClip is so pioneering—in the FDA's words, "a first-in-class device representing a breakthrough technology" (Ex. 58 at 7–8)—Abbott has [redacted] and devoted nearly two decades to developing MitraClip, obtaining regulatory approvals, and training doctors throughout the world. Abbott's investments are bearing fruit. In September 2018, for instance, a large clinical trial established MitraClip as the "first therapy" to treat certain "high-risk patients" (Ex. 15) with "difficult-to-treat" MR (Ex. 14). The clinical results were so "profound" that when announced at a major medical conference, the audience reacted with "spontaneous, rare, mid-presentation applause" and "cheering," reflecting a "once-in-a-lifetime" medical "revelation." (Ex. 13 ¶¶ 85–86.) MitraClip "knocked it out of the park." (Ex. 16.)

PASCAL's launch would transform a highly complex market in numerous ways, all impossible to quantify. Edwards is already targeting MitraClip customers, and has told investors PASCAL is an "alternative" to MitraClip. (Ex. 44 at 13–14.) MitraClip is purchased in bulk, and a PASCAL sale could convert an entire MitraClip hospital to PASCAL. (Ex. 11 ¶ 25.) PASCAL also would interfere with the customer relationships Abbott has been building to expand the MitraClip market, as well as the market for Abbott's future structural heart products. (Ex. 9 ¶¶ 116–19; Ex. 11 ¶¶ 25, 34, 39(c), 40(c), 53–54; Ex. 12 ¶ 22–26.) Abbott stands to lose an unquantifiable number of customers and sales, even beyond MitraClip. (Ex. 9 ¶¶ 61–76, 86–93.) The timing could not be worse. Edwards is manufacturing PASCAL in the U.S. and plans a European launch by mid-2019. That follows on the heels of Abbott's "seminal" clinical trial, called "COAPT," that showed MitraClip can treat patients who have little other option, and that is expected to "expand … MitraClip['s] market into the multibillion-dollar range." (Exs. 280, 281.) Abbott would lose the benefit of years of investment.

This is a classic case warranting an injunction. Infringement of just *one* valid claim is sufficient

for an injunction. Yet PASCAL infringes *dozens* of valid claims in *five* patents. And irreparable harm is established in multiple ways, including that PASCAL's launch would unjustifiably create a "two-player market," "the existence" of which alone "may well serve as a substantial ground for granting an injunction." *Robert Bosch LLC v. Pylon Mfg.*, 659 F.3d 1142, 1151 (Fed. Cir. 2011). The public interest also would be served by protecting patent rights and the innovation they encourage, particularly here, where MitraClip can serve the market on its own. The Court should issue a preliminary injunction (PI) to preserve the status quo pending a full trial.

II. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs Abbott Cardiovascular Systems, Inc. and Evalve Inc. (collectively, "Abbott") filed this action on January 28, 2019, asserting U.S. Patent Nos. 7,288,097, 6,752,813, 7,563,267, 7,736,388, and 8,057,493 (Exs. 1–5). Abbott seeks a PI against Edwards pending final judgment.

III. SUMMARY OF THE ARGUMENT

1. A PI is warranted because Abbott easily satisfies the four-element legal standard. *See Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 865 (Fed. Cir. 2017).
2. *First*, Abbott is likely to succeed on the merits. PASCAL meets all limitations of *multiple* valid claims of *multiple* Abbott patents.
3. *Second*, PASCAL's launch would irreparably harm Abbott. Edwards is already targeting Abbott's customers in a market Abbott created for edge-to-edge transcatheter mitral valve repair ("TMVr"). If PASCAL launches, Abbott would lose an irreversible and unquantifiable market share, even beyond MitraClip, and suffer reputational damage. These harms are irreparable. *See, e.g.*, *Bio–Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1565–66 (Fed. Cir. 1996).
4. *Third*, the balance of hardships strongly favors Abbott. An injunction would preserve the status quo, and any alleged harm to Edwards arises from "its own calculated risk" to make an infringing product in the U.S. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006).

5. *Finally*, there is a strong public interest in enforcing patents, particularly to stop infringing competition. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1342, 1345, 1362 (Fed. Cir. 2008). The public interest also favors protecting medical innovation, especially here, where PASCAL seeks to treat the same patients as MitraClip in the same way, using the same fundamental technology. *See Celsis In Vitro v. CellzDirect*, 664 F.3d 922, 931-32 (Fed. Cir. 2012).

IV. STATEMENT OF FACTS

A. Mitral Regurgitation And The Old, Open-Heart Surgery Treatments

One-way valves with "leaflets" connect the heart's four chambers, two atria and two ventricles. The leaflets open and close to control blood flow. The "mitral valve" connects the left atrium and ventricle (Fig. 1). Problems arise if the valve does not close properly, resulting in backward blood flow called "mitral regurgitation" or MR. (Ex. 7 ¶¶ 34–38; Ex. 13 ¶¶ 29–36.) MR is a "debilitating, progressive and life-threatening disease." (Ex. 174.)

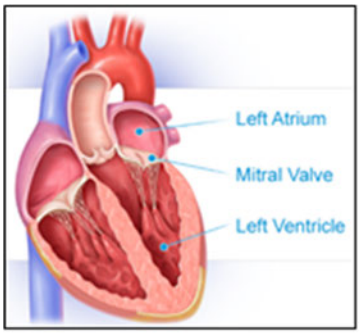

Figure 1

Traditionally, surgeons treated MR—afflicting one in ten over the age of 75—through open-heart surgery to repair or replace the faulty mitral valve in cases where patients were healthy enough to survive the surgery. (Ex. 7 ¶¶ 42–48; Ex. 13 ¶¶ 37–41; Ex. 174.) For the rest, drug therapy was the last resort, now shown to be not as effective as MitraClip. (Ex. 7, ¶¶ 39–41, 80–81.) In the early 1990s, Dr. Ottavio Alfieri developed a new edge-to-edge technique to *repair* the valve. He sutured the leaflets' edges to pull them together to create a "double orifice," which closed more completely during ventricular contraction (Fig. 2). (Ex. 7 ¶¶ 49–51; Ex. 13 ¶ 42.) His technique helped, but still required the trauma, risk, and long recovery of open-heart surgery. (Ex. 7, ¶¶ 49–51; Ex. 13 ¶ 42.)

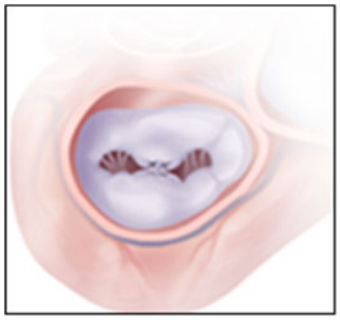
Figure 2

B. Abbott's Revolutionary Solution: The MitraClip

Evalve, now owned by Abbott, worked for years to develop the first-approved *non*-surgical

edge-to-edge device for MR treatment, the MitraClip. (Fig. 3). (Ex. 10 ¶¶ 8–26.) After many clinical trials, MitraClip received European approval in March 2008. (*Id.* ¶¶ 29–36). Abbott then acquired Evalve, sponsored additional clinical trials, and obtained FDA approval in October 2013. (*Id.* ¶¶ 37–40.) These trials were difficult because the novel MitraClip was being compared to established surgery, requiring years to convince enough doctors and patients to try MitraClip. (*Id.* ¶¶ 30–34.)

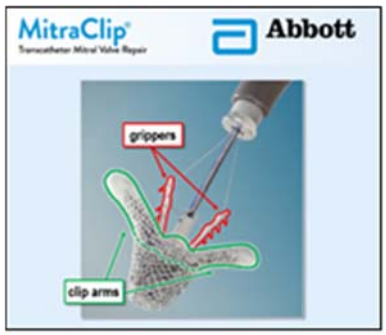

Figure 3

Even upon regulatory approval, MitraClip's success remained in jeopardy unless Abbott could convince physicians to broadly adopt the new procedure. Abbott thus invested enormous resources to demonstrate the benefits of MitraClip, which had no precedent. (Ex. 11 ¶¶ 27–36; Ex. 12 ¶¶ 12, 32–35.) Intensive education and training is required to acclimate doctors to a brand-new technique with a "first-in-class" device. (Ex. 21.) Abbott spent over a decade doing so, including providing specially-trained proctors to assist nearly every procedure. (Ex. 11 ¶¶ 27–36; Ex. 12 ¶¶ 16–21.)

MitraClip's true benefit to patients is now being recognized after the enormous success of Abbott's years-long COAPT clinical trial. MitraClip "offers significant clinical and quality-of-life benefit to patients, with an excellent safety profile compared with surgical intervention" (Ex. 22 at 52.) MitraClip is gaining "wide acceptance" and has "significantly advanced" MR therapy. (Ex. 23; Ex. 51 at 280; *see also* Ex. 7 ¶¶ 82–85; Ex. 13 ¶¶ 80–82, 89–91.)

The market is now poised to grow rapidly. As reported in September 23, 2018 on the New York Times' front page, MitraClip proved itself through COAPT to "drastically improve[] quality of life" and "sharply reduce[] death rates in patients with severe heart failure." (Ex. 14.) Physicians called MitraClip "a huge advance" that "will change how we treat these patients." (*Id.*)

MitraClip is thus poised to be the standard of care for MR patients. Indeed, to get FDA approval, Edwards is testing PASCAL against MitraClip in a "noninferiority" trial, designed to show

PASCAL is not inferior to MitraClip (as opposed to a superiority trial). (Ex. 25 at 11.) Edwards concedes Abbott's COAPT will serve "as the benchmark" for expanding the market. (Ex. 24 at 34.)

Abbott has continued investing in MitraClip. Based on physician feedback, Abbott has developed next-generation versions of MitraClip to improve performance. (Ex. 11 ¶ 31; Ex. 12 ¶ 13.) Abbott also has invested heavily in developing and maintaining its patent portfolio, including acquiring foundational patents such as the '097 patent covering MitraClip's fundamental "clipping system" approach. (Ex. 1; Ex. 10 ¶ 41.) And Evalve patented other MitraClip features in its "Goldfarb family," including the '813, '267, '388 and '493 patents that also are fundamental to edge-to-edge MR therapy with a clip. (Exs. 2–5; Ex. 10 ¶ 41.)

C. Edwards' Initial Edge-to-Edge TMVr Efforts And The Infringing PASCAL

Edwards has been trying to break into the edge-to-edge TMVr market since the 1990s. Its primary effort was "Mobius," a product which relied on a "stitch" approach that would have avoided Abbott's "clip" patents. (*See* Ex. 17 at 238; Ex. 26 at 3.) Edwards spent years developing Mobius, but abandoned it in 2007 due to "poor" results. (Ex. 52 at 1840.) "[F]ewer than one-half" of patients kept a "successful stitch in place" for even 30 days. (*Id.*) As Mobius was on its way to failure, [redacted]

[redacted]

Edwards then took a different tack: using MitraClip's patented features. Edwards designed PASCAL to treat MR in the same way as MitraClip, using a "clipping system" with elements that capture the mitral valve leaflets from the atrial and ventricular sides (Fig. 4).

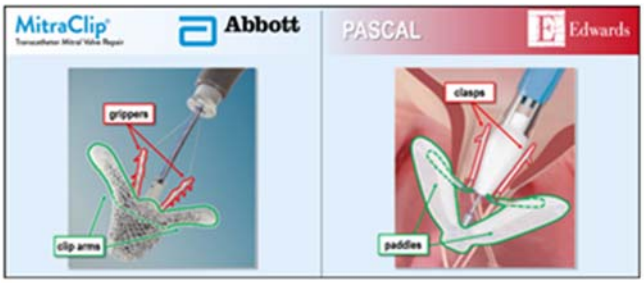

Figure 4

(Ex. 6 ¶¶ 88–118.) PASCAL also adopts other features essential to clip-based edge-to-edge repair, as with MitraClip, claimed in the other asserted patents. (*Id.* ¶¶ 119–496.)

Like MitraClip, PASCAL is designed to be introduced to a patient's heart through the patient's vasculature to effect edge-to-edge repair for MR. (Ex. 6 ¶¶ 62, 65; Ex. 30 at 775.) Also like MitraClip, PASCAL consists of a first pair of elements ("paddles") that engage the mitral valve leaflets on the ventricular side, and a second pair of elements ("clasps") that engage the mitral valve leaflets on the atrial side. (Ex. 6 ¶¶ 63–64; Ex. 31 at 9.)

An Edwards depiction (Fig. 5) shows both sets of clasps (highlighted in red) and paddles with inner and outer portions (highlighted in green) (Fig. 5) (Ex. 31 at 9). These paddles and clasps may be moved between various positions to grasp the valve leaflets. (Ex. 6 ¶¶ 67–72.) PASCAL then closes to bringing the edges of the leaflets together, which results in a double-orifice edge-to-edge repair just like MitraClip (Fig. 6). (Ex. 6 ¶ 65; Ex. 30 at Fig. 1(G).)

Figure 5

Figure 6

Despite its clear infringement, Edwards plans to bring PASCAL to market imminently. Edwards is manufacturing its infringing PASCAL in the U.S. (Ex. 28 at 7; Ex. 279.) And it has announced it plans to launch PASCAL in Europe by "mid-year 2019." (Ex. 29 at 2.)

V. ARGUMENT

The Court may grant a PI "to prevent the violation of any right secured by patent" and to "preserve the relative positions of the parties" during litigation. 35 U.S.C. § 283; *Abbott*, 544 F.3d at 1344–45. Absent such relief, "infringers could become compulsory licensees for as long as the litigation lasts." *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230, 1233 (Fed. Cir. 1985). Abbott meets the four-part test for a PI: (1) a reasonable likelihood of success; (2) irreparable harm; (3) a balance of hardships in its favor; and (4) that the public interest favors the injunction. *Mylan*, 857 F.3d at 865.

A. Abbott Is Likely To Succeed On Its Patent Infringement Claims

Abbott is likely to succeed on the merits. PASCAL infringes not just one, but *dozens* of claims

of *five* asserted patents, as fully explained in Dr. Ajit Yoganathan's accompanying declaration (Ex. 6).

1. The '097 Patent (Séguin)

The '097 patent is a foundational patent for MitraClip's "clipping system" and edge-to-edge clipping systems generally. It covers a device having pairs of elements to grasp each of the mitral valve leaflets from *both* the atrial *and* ventricular sides, in a way that attaches the free edges of the leaflets together for edge-to-edge repair. (Ex. 1, claim 1.) This clipping system is "vital" to the operation of and demand for MitraClip. (Ex. 6 ¶¶ 500–09, 770–71; Ex. 7 ¶ 88; Ex. 13 ¶ 93.)

PASCAL meets every limitation of claim 1 of the '097 patent. Claim 1 covers a "system for performing cardiac valve repair" (Ex. 1, claim 1), and PASCAL, of course, is a "mitral valve repair system." (Ex. 30; Ex. 6 ¶¶ 90–94.) Claim 1 also requires "a tube suitable for introducing through a patient's vasculature and into a chamber of a heart." (Ex. 1, claim 1.) PASCAL includes such a "tube," which is delivered through a vein and "consists of a 22 French steerable guide sheath, a steerable catheter, and an implant catheter." (Ex. 30 at 775; Ex. 31 at 9; Ex. 6 ¶¶ 95–101.)

PASCAL includes the claimed "clipping system," which claim 1 describes as "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." (Ex. 1, claim 1; Ex. 6 ¶¶ 102–118.) As described in peer-reviewed literature, PASCAL includes "paddles" for the ventricular side corresponding to the "first pair of elements," and "clasps" for the atrial side corresponding to the "second pair of elements." (Ex. 30 at 775.) As in the '097 patent, the leaflets are "grasped between" the clasps and paddles. (*Id.*; *see also* Ex. 32 at 57; Ex. 6 ¶¶ 102–06.)

Finally, claim 1 requires that the first and second pairs of elements "may be left to attach the free edges of the leaflets together." (Ex. 1, claim 1.) PASCAL meets this requirement too. (Ex. 6 ¶¶ 105–18.) Once the "implant [is] fully deployed and released from the catheter" (Ex. 30 at 775), PASCAL is, as Edwards' CEO has explained, "effective" in "leaflet attachment" (*i.e.*, left to attach the

leaflets together) (Ex. 57 at 7; *see also* Ex. 34 ("together" includes "proximity" of "two" "things")).

2. The "Goldfarb" patent family

Abbott's Goldfarb family of patents describes and claims additional features fundamental to the demand for MitraClip. (Ex. 6 ¶¶ 510–768, 772–85; Ex. 7 ¶¶ 89–94; Ex. 13 ¶¶ 94–101.) PASCAL blatantly adopts these patented design features.

a. PASCAL infringes the '493 patent

As required by claim 1, PASCAL is a "fixation device for engaging the tissue"—mitral valve leaflets. (Ex. 6 ¶¶ 290–93.) And PASCAL includes "a pair of fixation elements" (PASCAL's "paddles") with "a first end, a free end opposite the first end, and an engagement surface therebetween for engaging the tissue" (Fig. 7). (*Id.* ¶¶ 294–310.) PASCAL's paddle tips are "free ends." (Ex. 6 ¶¶ 296–97.) As in the '493 patent, the paddle tips move in different directions, such that the tips move away from and toward the axis of the device. (Ex. 2 at 4:12–17; Ex. 6 ¶¶ 299, 307–09.) Tracking the claims, the "free ends" on the tips of PASCAL's paddles are opposite other ends (the "first ends").

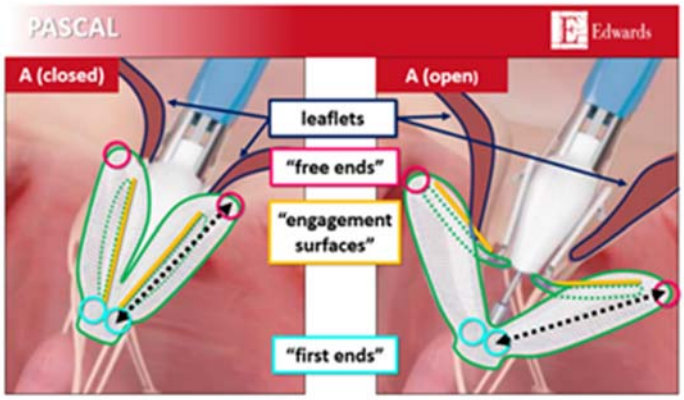

Figure 7-A

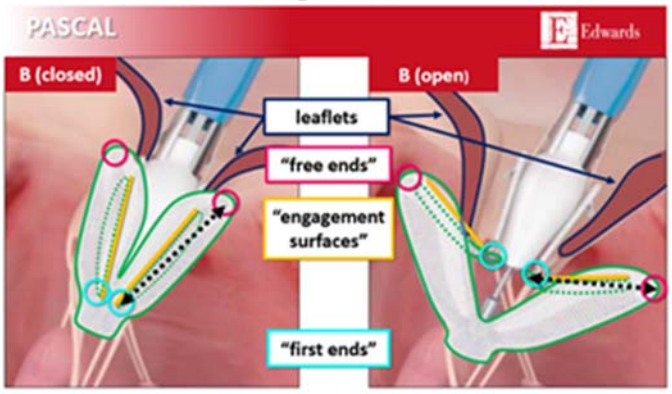

Figure 7-B

In fact, PASCAL meets this limitation in *two ways*. In this regard, PASCAL's paddles are divided into two parts, an inner and outer paddle. (Ex. 6 ¶ 66.) As shown in Figure 7-A, the inner paddle has an "engagement surface," which is between the "free end" on the one hand, and the "first end" at the bottom of the outer paddle on the other, "for engaging the tissue" (*see* black arrows in Fig.

7-A). (Ex. 6 ¶¶ 301–02.) This satisfies the claims. (*Id.*) As shown in Figure 7-B, the inner paddle "engagement surface" also lies between the "free end" on the one hand, and the "first end" on the *inner* paddle on the other (*see* black arrows in Fig. 7-B). (*Id.*) This also meets the claims. (*Id.*)

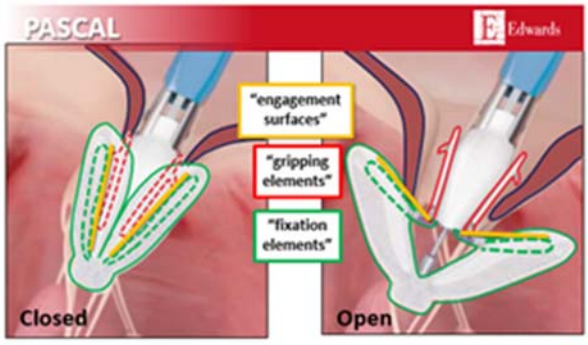

Figure 8

Just as required by the claims, PASCAL's "fixation elements" are movable from a "closed position" where the engagement surfaces "face each other" to a "first open position" where the engagement surfaces are "positioned away from each other" (Fig. 8, depicting the "engagement surfaces"). (Ex. 6 ¶¶ 311–315).) PASCAL's clasps are the required "pair of gripping elements" and are movable so they can be separated from or brought closer to the paddle engagement surfaces. (*Id.* ¶¶ 319–22, 327–30.) Published literature confirms this, describing PASCAL's "spring-loaded paddles" and "clasps" that "facilitate leaflet capture." (Ex. 30 at 775; *see also* Ex. 30a at 11 (the "mitral valve leaflet[s] [are] grasped between the [] Clasps and Paddles" of PASCAL).) PASCAL also includes the claimed "actuation mechanism": paddle actuation is accomplished with the rod extending from PASCAL's catheter to the bottom of the clip (Fig. 9). (Ex. 6 ¶¶ 316–18.)

Figure 9

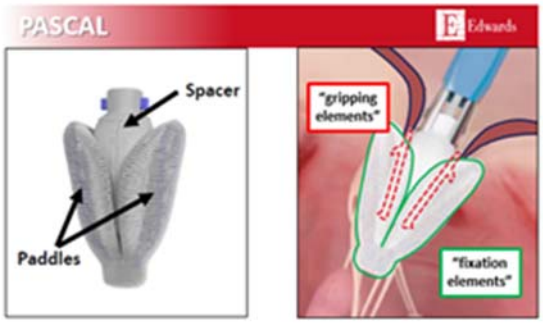

Figure 10

Finally, as shown in Figure 10, PASCAL's paddles are "at least partially concave," and the clasps are "at least partially recessed" within them "in the deployed configuration." (Ex. 6 ¶¶ 323–26.)

Thus, PASCAL meets all of the requirements of claim 1 of the '493 patent, and also those of claims 5–7, 10–12, 20–26, 29–31 and 34. (*Id.* ¶¶ 331–436.)

b. PASCAL infringes the '267 patent

PASCAL also meets each limitation of many claims of the '267 patent, most of which are addressed above for the '493 patent. Claim 1 of the '267 patent also requires the "fixation elements" to be moveable to "an *inverted* position wherein the engagement surfaces *face away* from each other." (Ex. 3, claim 1.) PASCAL's paddles move from a closed position, where the inner paddle's engagement surfaces face each other, to an inverted position (*i.e.*, "unfolded" position), where they face away from each other. (*See* Ex. 30 at 775, Fig. 1 (B) (showing PASCAL fully unfolded with engagement surfaces in an inverted position); Ex. 6 ¶¶ 144–52.) Thus, PASCAL meets all of the requirements of claim 1 of the '267 patent. (Ex. 6 ¶ 165.) It meets claims 2–7, 9 and 12 as well. (*Id.* ¶¶ 166–205.)

c. PASCAL infringes the '388 patent

PASCAL also meets each limitation of numerous claims of the '388 patent. As required by claim 1, PASCAL is a "fixation device for engaging" mitral valve leaflets (Ex. 6 ¶¶ 208–11) that includes a "coupling member," because PASCAL's central element, which Edwards calls a "spacer," and the mechanism at the bottom of the clip, together couple the clip to the delivery catheter (Fig. 11). (*Id.* ¶ 212–15.) The '388 patent also requires "engagement surfaces" that include 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 [the] profile of the device." (Ex. 4, claim 1.) PASCAL's outer paddles have precisely this type of engagement surface. (Ex. 6 ¶¶ 218, 239–41.)

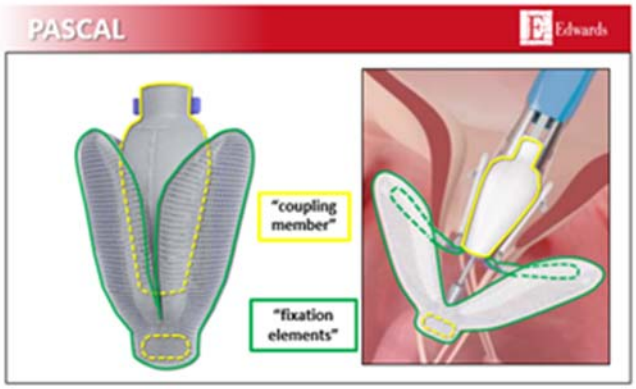

Figure 11

As the claim requires, PASCAL's outer paddles also have engagement surfaces that are "between" "a first end," and "a free end opposite the first end," as shown in Figure 12. (*Id.* ¶¶ 216–

Figure 12

227.) 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°" (Fig. 13). (*Id.* ¶¶ 228–31.) As the claim also requires, PASCAL's paddles are "adapted to atraumatically grasp and release the heart valve tissue," with the free ends "adapted to minimize trauma to the … tissue." (Ex. 4, claim 1; Ex. 6 ¶¶ 232–38.) As the literature explains, the open "convex curvature" of the outer paddles "aims to reduce tension on the valve leaflets." (Ex. 30 at 775.)

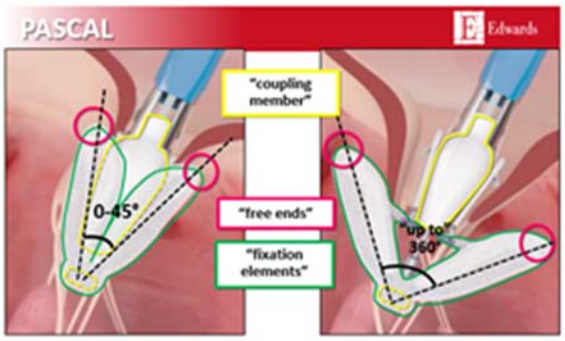

Figure 13

PASCAL's paddles are "at least partially covered with a covering material adapted to permit ingrowth of tissue thereto," as the claim requires. (Ex. 4, claim 1; Ex. 6 ¶¶ 242–44.) This is shown as a porous mesh covering at least the outer paddles (Fig. 11). (Ex. 6 ¶¶ 242–44.) As explained by Dr. Yoganathan, such a mesh allows tissue ingrowth just like the similar cover on MitraClip. (*Id.* ¶ 243; *see also* Ex. 55, Fig. 1(C) (showing tissue growth into MitraClip cover).)

Finally, PASCAL includes, as the '388 patent requires, a "pair of proximal elements" (PASCAL's clasps) which themselves have a "first end and a free end opposite the first end," with "the first ends being coupled to the coupling member" (central element) and the "free ends" being "movable relative to the coupling member" (Fig. 14). (Ex. 6 ¶¶ 245–49.) "[E]ach proximal element is at least partially recessed in the concave region" of the paddles, including "when the heart valve tissue is not disposed therebetween" (*e.g.*, when closed during at least part of the delivery procedure) (Fig. 10). (*Id.* ¶¶ 250–52.) Thus, PASCAL

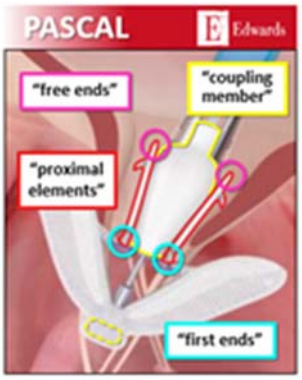

Figure 14

meets all elements of claim 1 of the '388 patent, as well as claims 2–6, 10 and 15–16. (*Id.* ¶¶ 253–87.)

d. PASCAL infringes the '813 patent

PASCAL also meets each limitation of numerous claims of the '813 patent. For example, as required by independent claim 113 and as detailed above, PASCAL has "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." (Ex. 6 ¶¶ 444–53; *see also* Ex. 30 at 775 (PASCAL catheter system).) PASCAL also includes a "capture device"—the clip itself—attached to the "interventional catheter" for delivery with paddles that are the "at least one distal element," which are "protrudable radially outward." (Ex. 6 ¶¶ 454–56.)

Claim 113 requires paddles having a "loop shape"—compared to other claims requiring an actual loop—"configured for pressing against a downstream surface of at least one leaflet." (Compare Ex. 5, claim 113 with claim 18.) A loop *shape* refers to the outline of a loop, as opposed to an actual loop. (Ex. 5 at 6:40–45 (stating "loops" may have "a petal shape"); Ex. 34 ("shape" means "[t]he outward form of an object defined by an outline.").) PASCAL not only has a loop shape, but one similar to the '813 patent's figures. (Ex. 5 at Fig. 3; Ex. 6 ¶¶ 457–67.) Thus, PASCAL meets every element of claim 113, as well as claims 114, 118–120, 123 and 129. (Ex. 6 ¶¶ 468–96.)

3. Abbott is likely to overcome any validity challenge by Edwards

Abbott's patents are presumed valid. *Microsoft Corp. v. i4i Ltd. P'ship,* 564 U.S. 91, 95 (2011). That presumption is particularly strong here, where the PTO thoroughly investigated the asserted patents for *years* while considering large volumes of prior art listed on the patents' covers. (Ex. 1 at 1–4; Ex. 2 at 1–7; Ex. 3 at 1–5; Ex. 4 at 1–7; Ex. 5 at 1–2.)

If it opts to assert invalidity, Edwards will bear the burden of showing invalidity by clear and convincing evidence, which it surely cannot do. *See Microsoft*, 564 U.S. at 95. Edwards' own failed efforts to develop an edge-to-edge TMVr solution emphasize the point, because such failures are

"particularly probative" of validity. *In re Cyclobenzabrine Hydrochloride Extended-Release Capsule Pat. Litig.*, 676 F.3d 1063, 1082-83 (Fed. Cir. 2012). Edwards' CEO admitted "[t]he minimally invasive transcatheter route for mitral valve repair 'has been a tough one' for the company to break into." (Ex. 18.) Edwards also [redacted], forcing it to develop a competing product only by adopting MitraClip's patented technology. This is "evidence that the invention is not an obvious one … particularly [ ] where [Edwards] had itself attempted for a substantial length of time" to find a solution but "failed." *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984).

B. Abbott Will Suffer Imminent Irreparable Harm Unless Edwards Is Enjoined

Absent an injunction stopping PASCAL's imminent launch in mid-2019, Abbott would suffer imminent irreparable harm in multiple ways, as detailed below.

1. PASCAL would result in irreparable losses of access to physicians, market share, and sales.

Launching PASCAL would irreparably harm Abbott by artificially creating a "two-player market," "the existence" of which alone "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 for the patentee." *Robert Bosch*, 659 F.3d at 1151; Ex. 9 ¶¶ 63–76. If launched, PASCAL would be only the second player and in "direct competition in [MitraClip's] primary market." *Liqwd, Inc. v. L'Oréal USA, Inc.*, 720 F. App'x 623, 633 (Fed. Cir. 2018); *see also* Ex. 9 ¶¶ 63–76. Edwards told investors that PASCAL's "***going to be*** a[n] … alternative for a market … with … ***only one competitor***," MitraClip, and serve "a patient population that's already being served" by MitraClip. (Ex. 39 at 5–6; Ex. 44 at 13.) Abbott cannot be made whole merely by awarding lost profits in the future, particularly 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. (Ex. 11 ¶ 25.) The "market [is] particularly sensitive because customers buy in bulk and at irregular times." *Celsis*, 664 F.3d at 930; Ex. 11 ¶ 25.

Additionally, based on a host of complex, dynamic market factors, including Edwards' own

training efforts or lack thereof, just one sale of PASCAL to a MitraClip-using doctor could transform that doctor into a PASCAL user for an extended time. (Ex. 11 ¶ 25; Ex. 12 ¶¶ 22–25.) To paraphrase Edwards as the patentee in an analogous case: "Not only [will Abbott lose] a substantial share of the market because of [Edwards'] willful infringement, [Abbott will lose] the opportunity to establish relationships and train medical centers that it otherwise could have had [PASCAL] not been on the market." (Ex. 45, *Edwards Lifesciences AG v. CoreValve, Inc.*, No. 1:08-cv-91, D.I. 359 at 8–9 (D. Del. Jun. 3, 2010); Ex. 9 ¶¶ 116–19; Ex. 11 ¶¶ 39(c), 54–55.) These lost sales will have a "far-reaching, long-term impact on [Abbott's] future revenues," and are difficult to quantify due to "'ecosystem' effects, where one company's customers will continue to buy that company's products and recommend them to others." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 640–41, 645 (Fed. Cir. 2015); Ex. 9 ¶¶ 86–92. This is quintessential irreparable harm. *Celsis*, 664 F.3d at 930; *see Apple*, 809 F.3d at 639 ("damage to … reputation as an innovator, lost market share, and lost downstream sales" were irreparable harm).[3]

The sales Abbott stands to lose are significant. (Ex. 9 ¶¶ 67–71.) Edwards is tasking its "PASCAL Launch Leader" with "ensuring fast uptake and strong market share position" (Ex. 40), and estimates its "[t]ranscatheter mitral / tricuspid global opportunity" "to reach $1B+ by 2021 and $3B+ by 2025" (Ex. 41 at 21; Ex. 42 at 2). All of those PASCAL sales would come at MitraClip's expense. (Ex. 9 ¶ 71.) This is further complicated because the market is poised to grow after Abbott's COAPT study in ways not yet completely understood, making the harm to Abbott further unpredictable and unquantifiable. (*Id.* ¶¶ 97–100; Ex. 11 ¶ 30; Ex. 12 ¶ 35.)

[3] That Edwards will first launch in Europe does not mean Abbott's harm is any less irreparable. *See, e.g.*, *Veeco Instruments, Inc. v. SGL Carbon, LLC*, 2017 WL 5054711, at *26–27 (E.D.N.Y. Nov. 2, 2017) (granting PI where foreign sales of U.S.-made product irreparably harmed patentee); *Howes v. Med. Components, Inc.*, 741 F. Supp. 528, 534 (E.D. Pa. 1990) ("[T]he sale of a product in a foreign country does not, in itself, avoid infringement, if the product is made in the United States.").

Preliminary injunctions are especially required in these circumstances. If the infringer creates a two-player market, "every sale to [the infringer] is essentially a lost sale to [the patentee]," which "also translates into a lost customer," irreparably injuring the patentee's market share. *Trebco Mfg. Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1170 (Fed. Cir. 2014); *see also TruePosition Inc. v. Andrew Corp.*, 568 F. Supp. 2d 500, 531 (D. Del. 2008); Ex. 9 ¶¶ 63–76. "Legal remedies are not adequate to compensate" the patentee for these injuries. *Novozymes A/S v. Genecor Int'l, Inc.*, 474 F. Supp. 2d 592, 612-13 (D. Del. 2007). Abbott's innovation, investments, and hard work created the market for treating patients with edge-to-edge TMVr. PASCAL's "interfere[nce] with …Abbott's key relationships" in "[t]he evolving and expanding …edge-to-edge TMVr market" will harm Abbott in "unquantifiable ways." (Ex. 9 ¶¶ 116–19.) Edwards itself has admitted in other litigation that "[plaintiff]'s harm in [a] two-player market cannot be completely undone." (Ex. 37, *Edwards Lifesciences AG v. CoreValve, Inc.*, No. 1:08-cv-91, D.I. 409 at 7 (D. Del. Aug. 18, 2010).) It argued that losing "the exclusivity" of its patent would mean that it "would lose its … market position as the top seller" of the device category. (Ex. 38, *Edwards Lifesciences AG v. CoreValve, Inc.*, No. 1:08-cv-91, D.I. 555 at 20 (D. Del. Nov. 27, 2013).)

2. PASCAL would undermine years of work and investment to build the market.

Abbott also would lose the return on its investments in building the market. (Ex. 11 ¶¶ 27–40(d); Ex. 9 ¶¶ 72–73, 103; Ex. 12 ¶¶ 22–26.) Unlike a new drug, where doctors already understand the concept of administering drugs as a pill or injection, MitraClip was completely unprecedented. MitraClip was such a foreign concept, Abbott had to [redacted] educating regulatory bodies and developing new ways to obtain regulatory approval. (Ex. 10 ¶¶ 6, 27.) Completing trials required truly herculean efforts, because "standard treatment at the time" was "open cardiac surgery," and "there were no comparable examples to follow for the clinical trial design," and no known ways of comparing open-heart surgery to MitraClip's "catheter-based paradigm." (*Id.* ¶ 27–36.)

Regulatory approvals were just the tip of the iceberg. Abbott also educated every MitraClip

doctor on MR and how to perform TMVr with the MitraClip. (Ex. 12 ¶¶ 16–21.) Each new MitraClip site involves a "multi-stage investment" by Abbott [redacted] before the first patient is treated. (*Id.* ¶¶ 17, 19.) Abbott also supplies extensively-trained representatives to be present at almost every MitraClip implantation. (*Id.* ¶ 21.) Abbott had to forge a new path to secure reimbursement too, opening access to MitraClip for thousands of patients who may not otherwise have benefitted from this life-saving device. (Ex. 11 ¶ 30.) [redacted]. (*Id.* ¶ 32.)

Through its infringing PASCAL device, Edwards will unjustly reap the rewards of Abbott's investments that are protected by its valid patents. Edwards already is using MitraClip's success in COAPT to propel PASCAL, telling investors that ***Abbott's*** "COAPT" trial "showed that ***we*** can alter the natural history of mitral regurgitation and … reduce mortality by intervening." (Ex. 24 at 30; Ex. 9 ¶ 38.) Edwards likewise touted the "built-in market that's already been developed over time" by Abbott, the "tailwind" for PASCAL that MitraClip's results created, and the fact that "there's already reimbursement and approval process [] in place." (Ex. 44 at 14; Ex. 24 at 33; Ex. 56 at 8.) Edwards is even recruiting doctors Abbott trained to use MitraClip. (Ex. 11 ¶ 62.) By free-riding on Abbott's investments in training and education, Edwards benefits by using that training in service of preparing physicians to use PASCAL. (*Id.* ¶ 39(d).) And Abbott loses its investment, market, reputation as a leader and consequently its relationships. (Ex. 12 ¶ 26.) Abbott's lost returns on its investments are irreparable. (Ex. 9 ¶¶ 101, 115, 119.)

3. Abbott will be irreparably harmed by Edwards' first-mover advantage for next-generation edge-to-edge TMVr products.

Absent a PI, Edwards also will acquire a first-mover advantage over Abbott's next-generation MitraClip, [redacted] (Ex. 9 ¶ 123; Ex. 11 ¶ 45.) Edwards' PASCAL [redacted] will destroy

Abbott's first-mover advantage. (Ex. 11 ¶ 45; Ex. 9 ¶¶ 120–28.) "Money damages alone cannot restore the technological lead-time that [Abbott] would … enjoy[ ] but for the infringement" of Edwards. *EyeTicket Corp. v. Unisys Corp.*, 155 F. Supp. 2d 527, 548 (E.D. Va. 2001). Thus, "loss of … 'first mover' advantage may lead to relief—especially where the movant demonstrates that it operates in a market with only one or several competitors." *Rimlinger v. Shenyang 245 Factory*, No. 2:13-CV-2051-JAD-NJK, 2014 WL 2527147, at *6 (D. Nev. June 4, 2014).

4. PASCAL will cause irreparable reputational harm.

PASCAL also will cause Abbott irreparable reputational harm. (Ex. 9 ¶ 127.) If PASCAL launches, Abbott's "reputation as the innovator in edge-to-edge TMVr" will be harmed. (*Id.*) Abbott has been known as the pioneer behind the extraordinary technological advancements in edge-to-edge TVMr. (Ex. 12 ¶¶ 27–30; Ex. 9 ¶ 108.) But if customers find Abbott's "'innovations' appearing in competitors' [products]," its "reputation as an innovator will certainly be damaged." *Douglas Dynamics, LLC v. Buyers Prod. Co.*, 717 F.3d 1336, 1344-45 (Fed. Cir. 2013); *see also* Ex. 12 ¶ 31; Ex. 9 ¶¶ 108, 127. Edwards already appears intent on implying PASCAL can treat patients MitraClip cannot, even though Edwards is only now beginning to test PASCAL head-to-head with MitraClip in a non-inferiority study. (Ex. 25 at 11.) Regardless of their truth, Edwards's suggestions will irreparably harm MitraClip's reputation. (Ex. 9 ¶¶ 108, 127; Ex. 12 ¶ 31.)

5. Abbott will suffer irreparable harm beyond MitraClip product line.

If PASCAL launches, Abbott would lose sales in its entire cardiovascular product line. (Ex. 9 ¶¶ 86–93.) Abbott is now the exclusive source for any customer seeking a device like MitraClip. Abbott thus relies on MitraClip "to attract customers with … access to an innovative product," and then try "to increase the sales of other products and services" too, such as Abbott's upcoming TriClip device. *Bendix Comm. Vehicle Sys., LLC v. Haldex Brake Prods. Corp.*, No. 1:09-cv-176, 2011 WL 14372, at *6 (N.D. Ohio Jan. 3, 2011); *see also* Ex. 9 ¶¶ 46, 91. If PASCAL launches, customers will have an

alternative to MitraClip, harming sales of Abbott's other products. (Ex. 9 ¶¶ 86, 90.) Such lost relationships and business opportunities cannot be quantified. *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996); *Apple Inc.*, 809 F.3d at 641, 645. Courts recognize that "lost sales of related … products" "may constitute irreparable harm." *Am. Cyanamid Co. v. U.S. Surgical Corp.*, 833 F. Supp. 92, 132 (D. Conn. 1992).

6. Abbott will suffer irreparable harm by being forced to divert resources.

Finally, Abbott would be irreparably harmed because it must divert resources from other projects, including the research and development of other innovative products. *See Vanda Pharm. Inc. v. Roxane Labs., Inc.*, 203 F. Supp. 3d 412, 436 (D. Del. 2016); Ex. 9 ¶¶ 102–115. For example, [redacted] (Ex. 11 ¶¶ 40–40(c); Ex. 9 ¶ 104.) This harm is ongoing and irreparable. *See Bio–Tech.*, 80 F.3d at 1566; *Vanda*, 203 F. Supp. 3d at 436; Ex. 9 ¶ 115.

C. The Balance Of Hardships Favors Abbott

The balance of hardships strongly favors Abbott. Without a PI, Abbott would be forced "to compete against its own patented invention," *Robert Bosch* 659 F.3d at 1156, and suffer enormous disruption and losses for Abbott's structural heart division, which earned almost all its hundreds of millions in sales in 2017 from MitraClip, [redacted]

By contrast, a PI would maintain the status quo for Edwards, which has "virtually no sales in this area today." (Ex. 57 at 6.) Any harm Edwards may allege would be "the result of its own calculated risk" to manufacture in the U.S. "with knowledge of [Abbott's] patent[s]." *Celsis*, 664 F.3d at 931.

MitraClip is marked with Abbott's patents, and Edwards listed them in its filings at the U.S. Patent Office. (*See* Ex. 46, Information Disclosure Statement at 4-8.) Yet Edwards has explicitly targeted MitraClip's established market, relying on manufacturing in the United States. (Ex. 11 ¶¶ 39(c), 50; Ex. 28 at 7; Ex. 279; section V.B.2, *supra*).

D. The Public Interest Favors Entry Of Injunctive Relief

A PI would also serve the public interest by preserving the status quo, where MitraClip is successfully treating MR patients, while also preserving Abbott's patent rights. Courts "have long acknowledged the importance of the patent system in encouraging innovation." *Sanofi-Synthelabo,* 470 F.3d at 1383. In particular, investment in the medical field "must be encouraged and protected by the exclusionary rights conveyed in valid patents," because otherwise the "incentive would be adversely affected by taking market benefits away from the patentee and giving them to the accused infringer." *Celsis*, 644 F.2d at 931–32. According to Edwards itself, if a patentee "cannot prevent its *only* competitor's continued infringement of its patent, the patent is of little value." (Ex. 45, D.I. 359 at 15). As Edwards' corporate representative testified:

> If someone could wait until you did all the heavy lifting and did all the design work and then they could just copy your design and bring it to market, they would come to market without any of that initial investment and could cut your price or do other things. If that happened, then you couldn't afford to make these investments in medical innovation and you couldn't run a business that way.

(*Id.* at 18.) Injunctive relief would not harm the public because "the public can obtain the product[ ]" from Abbott. *Celsis*, 644 F.3d at 932. Abbott has been supplying MitraClip in Europe since it received approval in 2008. (Ex. 12 ¶ 11). There is no public reliance because Edwards has not yet released PASCAL. Nor need there be: MitraClip can treat the same patients PASCAL allegedly can. (Ex. 11 ¶ 63). The public interest thus favors a PI. *Sanofi-Synthelabo*, 470 F.3d at 1383–84.

VI. CONCLUSION

For these reasons, the Court should grant Plaintiffs' Motion for a Preliminary Injunction.

Respectfully submitted,

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