IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE LLC, Defendants.	)	C.A. No. 08-91 (GMS)

MEMORANDUM

I. INTRODUCTION

On February 12, 2008, plaintiffs Edwards Lifesciences AG and Edwards Lifesciences LLC ("Edwards") filed suit against CoreValve, Inc. and Medtronic CoreValve LLC ("Medtronic"). (D.I. 1.) In its complaint, Edwards alleged that Medtronic infringed U.S. Patent No. 5,411,552 ("the '552 patent"), U.S. Patent No. 6,168,614 ("the '614 patent"), and U.S. Patent No. 6,582,462 ("the '462 patent"). (*Id.*)[1] On March 23, 2010, trial commenced regarding the '552 patent. On April 1, 2010, a jury returned a judgment in favor of Edwards against Medtronic, finding that the CoreValve Generation 3 ReValving System ("CoreValve Generation 3"[2]) literally infringed claim

[1] On March 18, 2010, the court approved a stipulation among the parties dismissing with prejudice Edwards' cause of action based on the '614 patent and also dismissing Medtronic's responses, defenses and counterclaims relating to the '614 patent. (D.I. 284.) On March 22, 2010, the court granted Medtronic's motion for summary judgment of invalidity of the '462 patent and thereby ruled that the '462 patent could not be asserted against Medtronic for the conduct at issue in the case. (D.I. 293.) Thus, only the '552 patent remained.

[2] In some declarations and briefs, the parties refer to the device as the "CoreValve THV", the "CoreValve Generation 3", and the "ReValving". All three names are equivalent.

1 of the '552 patent and that the infringement was willful. (D.I. 313.) The jury awarded Edwards $72,645,555.00 in lost profits for infringement and $1,284,861.00 as a reasonable royalty.[3] (*Id.*)

On November 26, 2013, Edwards brought a motion for preliminary injunction seeking to enjoin Medtronic from continuing to infringe claim 1 of the '552 patent by selling the CoreValve Generation 3 as soon as Medtronic obtained FDA approval. (D.I. 548-49.) On March 4, 2014, the court ordered an evidentiary hearing "concerning the public interest considerations implicated by the plaintiffs' motion, as well as the response and reply thereto, and the carve-out proposal in the plaintiffs' motion". (D.I. 586 (order setting an evidentiary hearing for April 11, 2014).) At the full-day evidentiary hearing on April 11, 2014, each of the parties engaged in oral argument and examined and cross-examined witnesses regarding the public interest factor of the preliminary injunction motion. (D.I. 593 (official transcript of the April 11, 2014 evidentiary hearing).) At the conclusion of the evidentiary hearing, and after considering both the parties' briefs and the evidence introduced at the hearing, the court granted in part and denied in part Edwards' motion for preliminary injunction.[4] (D.I. 593 at 256:1-260:8.) The court's reasoning is provided in greater detail below.

II. BACKGROUND

Both Edwards and Medtronic are in the business of making and selling transcatheter heart valves ("THV" or "TAVI"). (D.I. 549 at 6; D.I. 560 at 3-4.) Edwards makes the SAPIEN line of THVs, (D.I. 549 at 2), while Medtronic makes the Medtronic CoreValve System for transcatheter aortic valve implantation, (D.I. 560 at 1). Medtronic is Edwards' only competitor in the United

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[3] Judgment was entered on May 4, 2010. (D.I. 324.) The Federal Circuit affirmed the jury's findings and the Supreme Court of the United States denied Medtronic's petition for writ of certiorari.

[4] The court also granted Medtronic's request for a stay of seven business days to "seek emergency relief in the Federal Circuit" and "give hospitals some notice of what ha[d] happened". (D.I. 593 at 260:9-265:12.)

States. (D.I. 549 at 1.) The '552 patent, of which Edwards AG is the assignee and Edwards LLC the exclusive licensee, (D.I. 1 at ¶ 10), is titled "Valve Prothesis [sic] for Implantation in the Body and a Catheter for Implanting such Valve Prothesis [*sic*]". The '552 patent discloses medical technology for implanting prosthetic valves into patients' aortic annuluses by means of a catheter. (D.I. 52 at 1.) In essence, this invention allows a prosthetic heart valve to be delivered through the skin to patients' aortic annuluses and thereby avoids traditional open heart surgery and its accompanying risks. (*Id.*)

On May 2, 2012, the term of the '552 patent expired. (D.I. 560 at 5.) Subsequently, the U.S. Patent Office ("PTO") granted two one-year extensions, extending the patent's term to May 2, 2014 pursuant to 35 U.S.C. § 156. (D.I. 560 at 5.) Edwards anticipates that the PTO will ultimately extend the term of the '552 patent to March 22, 2016. (D.I. 549 at 12.) Despite the April 2010 verdict in which the jury found that Medtronic was a literal and willful infringer of the '552 patent, Medtronic has continued to make the CoreValve Generation 3. (D.I. 549 at 10.) There is evidence that Medtronic may have sought to stockpile infringing devices in the United States after the verdict as part of a greater plan to overtake Edwards in the THV market. (D.I. 549 at 7, 10.)

Prior to FDA approval of the CoreValve Generation 3, Medtronic was able to make the CoreValve Generation 3 available to extreme risk patients through the FDA-sanctioned Continued Access clinical trial. (D.I. 560 at 9.) In their initial briefing, the parties reported that Medtronic planned to launch the CoreValve Generation 3 in the United States as soon as it received FDA approval for commercial sale of the CoreValve Generation 3 in extreme risk patients. (D.I. 549 at 2, 7; D.I. 560 at 9.) In the time that has elapsed since the parties submitted their briefs, the FDA has approved the CoreValve Generation 3. (D.I. 582-1 (FDA letter dated January 17, 2014 stating

that the CoreValve Generation 3 is approved.).) The FDA approved sale of the CoreValve Generation 3 in the United States without also approving extension of the continued access program through which Medtronic was providing the CoreValve Generation 3 to extreme risk patients.[5] (D.I. 582-1.) Thus, the continued access program must now end and Medtronic claims that the only way that extreme risk patients will be able to access the CoreValve Generation 3 will be if Medtronic makes the device commercially available as soon as possible. (D.I. 560 at 9.)

The parties agree that Edwards will almost certainly gain FDA approval to replace the SAPIEN with a next-generation product, the SAPIEN XT, at any time now. (D.I. 550 at ¶ 7 (explaining that Edwards expects to gain FDA approval in early 2014); D.I. 560 at 5.) As a result, Medtronic's CoreValve Generation 3 and Edwards' SAPIEN XT could be entering the market for commercial sales around the same time. (D.I. 550 at ¶ 7.)

III. LEGAL STANDARD

To secure a preliminary injunction under Section 283, the movant must establish four factors: "(1) the likelihood of success on the merits of the underlying litigation, (2) whether irreparable harm is likely if the injunction is not granted, (3) the balance of hardships as between the litigants, and (4) factors of the public interest." *Abbott v. Sandoz*, 544 F.3d 1341, 1344 (Fed. Cir. 2008); *see also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1049 (Fed. Cir. 2010) ("A plaintiff seeking a preliminary injunction must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest.") (Citations omitted).

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[5] The letter in which the FDA approved commercial sales of the CoreValve Generation 3 did not state explicitly whether the continued access program would be permitted to continue. (D.I. 582-1.) At the hearing on April 11, 2014, however, counsel for Medtronic represented to the court that the continued access program has been mandatorily discontinued as a result of FDA approval of the CoreValve Generation 3. (D.I. 593 at 25:5-21 (Stating, among other things, that "now that CoreValve has been approved for use in extreme-risk patients, the clinical trial on that phase is over, and you can only get the device commercially. It's not available for extreme-risk patients anymore now that it has been approved.").)

The court must balance all four factors, but the court may grant the preliminary injunction where "the weakness of the showing regarding one factor is overborne by the strength of the others." *Chrysler Motors Corp. v. Auto Body Panels of Ohio, Inc.*, 908 F.2d 951, 953 (Fed. Cir. 1990). Although the court has full discretion over the decision to grant a preliminary injunction, "a preliminary injunction is a drastic and extraordinary remedy that is not routinely granted." *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993).

IV. DISCUSSION

A. Likelihood of Success on the Merits

Edwards contends that it has already succeeded on the merits because of the jury verdict in its favor and the conclusion of the appellate process. (D.I. 549 at 12-13.) Medtronic, on the other hand, contends that Edwards has yet to succeed on the merits because the rights on which Edwards motion are based allegedly expired with the '552 patent. (D.I. 560 at 11.) According to Medtronic's reading of 35 U.S.C. § 156, since Edwards based its extension only on the SAPIEN, Edwards' rights are limited to copies of the SAPIEN and do not cover any devices, such as the CoreValve Generation 3, that are not copies of the SAPIEN. (D.I. 560 at 11-12.) In response, Edwards argues that Medtronic's contentions have no basis in the statutory language of Section 156. (D.I. 570 at 3.) The court concludes that Edwards is correct.

Section 156(b)(1)(A) provides that "the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended (1) in the case of a patent which claims a product, be limited to any *use* approved for the product (A) before the expiration of the term of the patent[.]" (Emphasis added.) Thus, the language of the statute makes clear that the rights secured by the extension of the '552 patent are limited by the approved *use* of the SAPIEN, not just copies of the SAPIEN. The case law also makes clear that Section 156 applies to uses of devices, not merely the actual devices and copies

thereof. *See, e.g.*, *Ortho-McNeil Pharm., Inc. v. Lupin Pharm.*, 603 F.3d 1377, 1382 (Fed. Cir. 2010) (Explaining that the rights secured by Section 156(b) apply to uses of the product.) (Citation omitted); *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1349 (Fed. Cir. 2010) (Explaining that the plaintiff "had the right to exclude the '*use* then under regulatory review"—namely the *use* of pramipexole for the treatment of the 'signs and symptoms of idiopathic Parkinson's disease....'") (Citation omitted).

Ultimately, in order to establish a likelihood of success on the merits, a patentee must show that "it will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer." *AstraZeneca LP v. Apotex*, 633 F.3d 1042, 1050 (Fed. Cir. 2010) (citations omitted). Since Edwards has outright prevailed in the litigation regarding the '552 patent and the appeals process is over, the court concludes that Edwards has more than demonstrated a likelihood of success on the merits.

B. Irreparable Harm

The purpose of the irreparable harm inquiry is to "measure harms that no damages payment, however great, could address." *Celsis in Vitro v. CellzDirect*, 664 F.3d 922, 930 (Fed. Cir. 2012) (citations omitted). Of the numerous forms of irreparable harm that Edwards lists in its briefs and declarations in support, the court finds Edwards' arguments regarding price erosion and loss of sales, market share and revenue to be most convincing. Thus, the court concludes that Edwards has sufficiently demonstrated that it will suffer irreparable harm should it not be granted an injunction.

1. Loss of Sales, Market Share, and Revenue

In its briefs and through multiple declarations, Edwards argues that it will lose sales, market share, and revenue if Medtronic is permitted to launch the CoreValve Generation 3 in the United

States. (*See, e.g.*, D.I. 549 at 14-15; D.I. 550.) As support for its contentions, Edwards points to the fact that Medtronic will be Edwards' only competitor in the United States and will compete directly against Edwards for the same patients. (D.I. 550 at ¶ 5.) Edwards also highlights the drop in its market value and the negative projections regarding Edwards's future that have accompanied Medtronic's announcement in October 2013 that its launch of the CoreValve Generation 3 in the United States would be accelerated.[6] (D.I. 549 at 9; D.I. 550 at ¶ 5.)

Relatedly, Edwards argues that Medtronic will target hospitals that have become TAVI-trained sites through significant expenditures of time and money by Edwards. (D.I. 550 at ¶ 5-6.) According to Edwards, this will have two ramifications that an injunction granted later will not be able to ameliorate. First, Medtronic will be able to build on Edwards' existing relationships and quickly gain accounts that Edwards has not yet secured. (*Id.*) Second, Edwards will lose "immeasurable market opportunities" once Medtronic gains this foothold because of the tendency of doctors and hospitals to remain faithful to a THV product once they begin using it. (D.I. 549 at 15; D.I. 550 at ¶ 6 (describing the THV market's "'sticky' characteristics").)

In response to Edwards' arguments about losses in market share and revenue, Medtronic contends that its entry into the market will not affect Edwards' sales and financial standing and that there is little reason to expect that hospitals will abandon the SAPIEN line of products. Medtronic observes that, in December 2013, after Medtronic had announced that it would likely receive FDA approval sooner than previously expected, Edwards predicted that its 2014 THV sales would be between $700 million and $820 million. (D.I. 560 at 14.) According to Medtronic, the fact that these numbers are very similar to Edwards' 2013 projections of between $710 million and

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[6] Specifically, Edwards claims that the very announcement on October 29, 2013 that Medtronic's U.S. launch of the CoreValve Generation 3 would be accelerated was sufficient to cause financial analysts to downgrade Edwards and Edwards' market value to drop by $760 million. (D.I. 549 at 9.)

$790 million suggests that Medtronic's earlier than expected entry on the market will not affect Edwards' sales. (*Id.*) Medtronic further contends that experts' increasingly negative projections for Edwards are due more to Edwards' failure to reach about 20-30% of qualified hospitals during its exclusivity period than to Medtronic's impending market entry. (D.I. 560 at 13.) Medtronic also points out that Edwards acknowledges that it has already secured 71-81% of the THV-qualified hospitals in the United States. (D.I. 560 at 13 (citing D.I. 553 at ¶ 12).) Thus, Medtronic reasons, if Edwards' claim that hospitals are prone to fidelity to whichever THV program they first begin is correct, then there is little reason to expect that the hospitals already using the SAPIEN will abandon the product. (D.I. 560 at 13; D.I. 566 at ¶ 10.)

Medtronic further denies that it will seek to "piggyback" off Edwards' investments in enabling hospitals to be TAVI sites. Indeed, Rhonda Robb, the Vice President and General Manager of Catheter-Based Therapies at Medtronic, Inc. claims that "the fact that a site is already trained in implantation of the SAPIEN...does not eliminate or reduce the need for compete training in implantation of the CoreValve THV." (D.I. 566 at ¶ 8.) The reason for this, Ms. Robb claims, is that "the balloon-expanding SAPIEN THV and the self-expanding CoreValve THV are inherently different devices with a different implantation procedure." (*Id.*)

Despite Medtronic's vigorous arguments to the contrary, the court is persuaded that Edwards will suffer a loss of sales and market share. The court is also convinced that Medtronic will indeed not only seek to convert to its own uses hospitals in which Edwards has invested, but also succeed to a degree that a later injunction will not be able to fully address. First, although reasonable minds can differ regarding why experts downgraded Edwards after Medtronic's announcement of earlier FDA approval, there is no dispute that Medtronic will be Edwards sole competitor in the United States should it enter the market. Unless Medtronic is convinced its

efforts to sell the CoreValve Generation 3 will be utterly unsuccessful, in which case its vigorous opposition to the instant motion is baffling, it is likely that at least some, if not all of the sales that Medtronic makes will be sales that Edwards could have made. It is implausible that Edwards would not lose market share if forced to compete against a much larger company with far greater resources.

Second, it is noteworthy that Medtronic does not deny Edwards' allegations about the speed with which Medtronic was able to capture a significant segment of the European market as soon as Medtronic entered. (*See, e.g.*, D.I. 560 at 13-16.) The court acknowledges that the European market is not necessarily identical to the American market. Nonetheless, the court would be naïve to believe that having successfully competed against Edwards in selling THV devices in Europe, Medtronic has not learned from those experiences and is not poised to repeat them in the United States.

Third, in her own declaration, Ms. Robb contradicts Medtronic's assertion that it will not take advantage of Edwards' efforts with hospitals. Indeed, Ms. Robb writes that "Medtronic will attempt to sell its product in some of the 284 sites in which Edwards sells its SAPIEN THV....This is due in part to the limited number of available TAVR-qualified sites in the United States." (D.I. 566 at ¶ 11.) The court accepts the representations of Medtronic's own Vice President and concludes that Medtronic will certainly co-opt and turn against Edwards the extensive efforts and investments that Edwards has made to prepare hospitals to be THV-qualified.

There can be no doubt that loss of market share, sales, and business opportunities constitutes irreparable harm. *See Celsis*, 664 F.3d at 930 (Affirming district court's finding that plaintiff would suffer irreparable harm because "[p]rice erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm.");

Abbott Labs v. Sandoz, 544 F.3d 1341, 1362 (Fed. Cir. 2008) (Affirming district court's conclusion that loss of market share and revenue constitutes irreparable harm.); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382-83 (Fed. Cir. 2006) (Affirming district court's finding that "decrease in demand for [the plaintiff's product]" established irreparable harm.). Consequently, the court concludes that Edwards has amply demonstrated that it will suffer irreparable harm without a preliminary injunction.

2. Price Erosion

Apart from loss of market share, sales, and business opportunities, there are other reasons to find irreparable harm established here. One such reason is the likelihood of price erosion. Based on Medtronic's history of undercutting Edwards' prices in Europe, Edwards warns that Medtronic's entry into the United States market will cause similar erosion in the price of THVs. (D.I. 549 at 16-17; D.I. 550 at ¶ 8.) Edwards argues that this erosion would not be ameliorated by a later injunction because Edwards' customers would be disgruntled should Edwards attempt to restore the original price. (D.I. 549 at 17; D.I. 550 at ¶ 8.) In response, Medtronic denies that it plans to sell the CoreValve Generation 3 at a lower price than Edwards' own price, referencing a third party report that Edwards charges "approximately $32,500 per commercial device in the US." (D.I. 566 at ¶ 12.) Medtronic does not state what the price is that it will charge for the CoreValve Generation 3, however. (*See, e.g.*, D.I. 566 at ¶ 12 (admitting that it "has not yet determined the list price").) Medtronic claims only that the price "likely will be higher than the $30,000 per device price at which the CoreValve THV system is sold clinically in the US." (*Id.*)

The court finds unconvincing Medtronic's assertion that it will not price the CoreValve Generation 3 at a lower point than the SAPIEN and SAPIEN XT in order to gain a competitive advantage. From a business standpoint alone, Medtronic would hardly be much of a competitor if it did not seek to undercut the opposition. In addition, Edwards' uncontroverted account of the

developments in the European market provide strong support for Edwards' concerns about price erosion. The court must also note that Medtronic's history of making representations to the court that are of demonstrably questionable veracity suggests caution is warranted in accepting Medtronic's statements at face value.[7] Ultimately, the likelihood of price erosion should Medtronic enter the market is sufficient to establish irreparable harm. *See Celsis*, 664 F.3d at 930 (Affirming district court's finding that price erosion was one reason plaintiff would suffer irreparable harm.); *Sanofi-Synthelabo*, 470 F.3d at 1382-83 (Affirming district court's finding that potentially "irreversible price erosion" constituted irreparable harm.).

In the end, there can be little doubt in light of the available evidence that Edwards stands to be irreparably injured should Medtronic, a willful infringer, be allowed to commence

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[7] For instance, in its opposition to a permanent injunction that Edwards was seeking in July 2010, Medtronic represented to the court that it was moving its manufacturing operations out of the United States to Mexico and that its Mexico facility was fully capable of replacing its facility in Irvine, California. (*See, e.g.*, D.I. 402). Based on this representation, the court concluded that a permanent injunction would not affect the irreparable harm that Edwards was alleging since "CoreValve would be able to move its remaining manufacturing operations to Mexico almost immediately if the court enjoined it from continuing to manufacture its products in the United States." *See Edwards Lifesciences AG v. CoreValve, Inc.*, No. 8-91-GMS, 2011 U.S. Dist. LEXIS 12022, at *47 (D. Del. Feb. 7, 2011).

Later, however, James Sparks, Medtronic's senior director of manufacturing, admitted during a deposition that Medtronic had misrepresented its Mexico operations. (*See* D.I. 552-1, Ex. G, 333:15-339:21 (admitting that he authored document in April 2010 directing employees at the Irvine manufacturing facility to increase production of the infringing products in anticipation of an injunction and acknowledging that Medtronic knew in April 2010 that "manufacturing capacity in Medtronic CoreValve's Mexico facility will not fully match the current output from its Irvine facility until about the middle of 2011.")

In vacating this court's denial of Edwards' motion for permanent injunction, the Federal Circuit recognized that Medtronic's misleading statements about its ability to move its operations to Mexico should it be enjoined in the United States deprived this court of the opportunity to consider the circumstances as they truly were. *Edwards Lifesciences AG v. CoreValve, Inc.*, 699 F.3d 1305, 1315-16 (Fed. Cir. 2012). Specifically, the Federal Circuit acknowledged that "[t]he district court's explanation of why it was withholding an injunction placed significant weight on CoreValve's statements that it was immediately moving this manufacturing operation to Mexico, and thus that infringement would terminate." *Id.* at 1315. The Federal Circuit then noted that "Edwards states on this appeal, and CoreValve does not deny, that CoreValve never stopped its infringing manufacture in California. Whether or not that representation was known to be false when made, the situation before us reflects, at least, changed circumstances." *Id.* at 1315-16 (Concluding that "'district courts are in the best position to fashion an injunction tailored to prevent or remedy infringement.' Recognizing that the circumstances have not been fully explored in the record before us, we vacate the denial of the injunction, and remand to the district court for consideration in light of ensuing events and any other relevant factors.") As Dr. Sparks's testimony showed, Medtronic was well aware that its representation was false when made.

commercial sales of the CoreValve Generation 3 in the United States. Indeed, the Federal Circuit's observations in *Polymer Technologies, Inc. v. Bridwell* are particularly salient here:

> Competitors change the marketplace. Years after infringement has begun, it may be impossible to restore a patentee's (or an exclusive licensee's) exclusive position by an award of damages and a permanent injunction. Customers may have established relationships with infringers. The market is rarely the same when a market of multiple sellers is suddenly converted to one with a single seller by legal fiat. Requiring purchasers to pay higher prices after years of paying lower prices to infringers is not a reliable business option.

103 F.3d 970, 975-76 (Fed. Cir. 1996) (reversing district court's denial of a preliminary injunction).[8]

C. Balance of Hardships

Edwards argues that the balance of hardships weighs in its favor because, without a preliminary injunction, Edwards would effectively be forced to compete against its own patented invention. (D.I. 549 at 18.) In contrast, Edwards argues, any hardship done to Medtronic by an injunction would be due to Medtronic's decision to accelerate FDA approval before a permanent injunction ruling. (*Id.*) Edwards also highlights the fact that THVs are its "lifeblood", constituting more than 70% of its business while constituting less than 7% of Medtronic's business. (*Id.*) For its part, Medtronic argues in conclusory fashion that "[t]he harm to Medtronic of any injunction based on expired patent rights 'is much greater than the harm to plaintiffs should the injunction

[8] An award of an ongoing royalty is not unheard of where the court determines that a party is entitled to an injunction, but the party expresses its willingness to accept a royalty in lieu of an injunction and the court finds that the appropriate amount for such a royalty can be determined. *See, e.g., Boston Sci. Corp. v. Cordis Corp.*, 838 F. Supp. 2d 259 (D. Del. 2012). In light of the court's conclusion that Edwards would be irreparably harmed should Medtronic be permitted to commence commercial sales of the CoreValve Generation 3 without any limit at all and Edwards' insistence that a monetary remedy would be insufficient, however, a royalty award would not seem an appropriate and adequate resolution in this matter.

not issue at all.'" (D.I. 560 (citation omitted).) Medtronic offers little explanation or support for this contention, however.[9]

The court concludes that the balance of hardships favors granting a preliminary injunction. Without a preliminary injunction, the core right protected by Edwards' patent – the right to exclude – would effectively be rendered meaningless. *See, e.g.*, *Celsis*, 664 F.3d at 931 (Affirming district court's finding that the balance of hardships favored the plaintiff because "[a]bsent a preliminary injunction, [the plaintiff] would lose the value of its patent".) Additionally, any harm to Medtronic is the result of its willful infringement and deliberate flouting of the jury verdict against it, and thus cannot be counted in its favor. *See id.* at 931 (Affirming district court's conclusion that "[the defendant]'s losses were the result of its own calculated risk in selling the product with knowledge of [the plaintiff]'s patent."); *Sanofi-Synthelabo*, 470 F.3d at 1383 (Concluding that the district court "did not clearly err in finding that [the defendant]'s harms were 'almost entirely preventable' and were the result of its own calculated risk to launch its product pre-judgment.")

D. Public Interest

Edwards contends that the public interest weighs in its favor because of the policy inherent in the patent laws favors protecting a patentee's investment in research and development through exclusive patent rights. (D.I. 549 at 20.) The parties do not disagree that there is a strong policy in favor of enforcing patent rights. Where the parties diverge, however, is regarding whether there exist countervailing considerations sufficient to trump the mandate that patent rights be enforced.

Medtronic argues that enforcing Edwards' patent rights would leave patients so at risk of inferior care or no care at all that the public interest requires Medtronic be allowed to sell the

[9] In addition to its bare assertion regarding harm to itself, Medtronic expands at length on the hardship to patients in the extreme risk category who might be deprived of its device should an injunction issue. (D.I. 560 at 20.) The harm to third parties goes to the public interest factor, however, not the balance of hardships among the litigants.

CoreValve Generation 3. (*See, e.g.*, D.I. 560 at 17 (arguing that "the injunction Edwards proposes would leave no treatment option for patients on the verge of death".).) For the most part, Edwards denies Medtronic's assertions. By means of expert declarations and testimony at the evidentiary hearing, both parties have introduced evidence in support of their arguments. The parties' arguments fall into three main categories, each of which the court considers below.

1. Extreme Risk Patients with Small Vessel Sizes

Medtronic contends that among extreme risk patients,[10] there are those whose blood vessels are too small to permit the SAPIEN to be implanted in them by the safest means possible – transfemoral catheterization.[11] (*See, e.g.*, D.I. 560 at 7, 16.) Medtronic argues that these extreme risk patients are best served by the CoreValve Generation 3 and would be put at a greater risk of injury and death if the SAPIEN was the only device on the market. (*Id.*) Predictably, Edwards disputes Medtronic's assertions. (D.I. 549 at 8-9.) Edwards argues that the SAPIEN can be used to treat patients with small access vessel sizes because other routes apart from the femoral artery exist through which the device can be introduced into the body. (*See, e.g.*, Direct Examination of Dr. Martyn Thomas, D.I. 593 at 38:1-39:5 (Explaining that other means of access include through the iliac, aortic, subclavian, and carotid arteries.).) Edwards further argues that, once approved, the SAPIEN XT will be able to be passed transfemorally.

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[10] As described in the parties' briefs and declarations and during the evidentiary hearing, extreme risk patients are those whose health is so fragile that they are barred from open heart surgery due to doctors' serious doubts about these patients' ability to survive the operation. (*See, e.g.*, Declaration of Blase Carabello, D.I. 564 at ¶ 4 (Explaining that "none of these extreme risk patients are candidates for surgical valve replacement procedure.").) For these patients, THV implantation is the only treatment option.

[11] Transfemoral catheterization involves passing the THV through the femoral artery at the top of the leg. (*See, e.g.*, Direct Examination of Dr. Martyn Thomas, D.I. 593 at 38:1-39:5.) It is the most commonly used approach. (*Id.* at 38:1-3.) A second, less desirable option is the transiliac route, in which physicians pass the THV through the left side of the chest when the patient's vasculature is not large enough to permit delivery of the catheter transfemorally. (*See, e.g.*, Direct Examination of Dr. Martyn Thomas, D.I. 593 at 38:1-7, 14-19.) Other methods of catheterization include the aortic, subclavian, and carotid approaches. (*See, e.g.*, Direct Examination of Dr. Martyn Thomas, D.I. 593 at 38:19-39:5.)

Expert testimony establishes that the transfemoral route is the preferred method because it is the safest. (*See, e.g.*, Direct Examination of Dr. Martyn Thomas, D.I. 593 at 38:1-3 (Describing transfemoral access as "the most commonly used approach"; Cross Examination of Dr. Martyn Thomas, D.I. 593 at 75:14-21 (Admitting that transfemoral access is his first choice because it is significantly less invasive than all other forms of access); Direct Examination of Dr. Mark Russo, D.I. 593 at 88:4-12 (Explaining that the transfemoral approach is "most commonly used" and "most people prefer it" because "it is the least invasive" and "the patients tend to recover most quickly".).) The evidence also indicates that the SAPIEN is too large to be introduced transfemorally in some extreme risk patients. (*See, e.g.*, Declaration of Blase Carabello,[12] D.I. 564 at ¶ 4 (Explaining that "access vessel size" prevents the SAPIEN from being used in some extreme risk patients.); Declaration of Jeffrey Popma,[13] D.I. 565 at ¶ 9 (Stating that 40% of extreme risk patients in the CoreValve Pivotal Trial had vessel sizes that were too small for the SAPIEN); Direct Examination of Larry Wood, D.I. 593 at 104:6-15.) Expert testimony suggests, however, that, unlike the SAPIEN, the SAPIEN XT can be introduced transfemorally in patients with small vessel sizes. (*See, e.g.*, Cross Examination of Dr. Martyn Thomas, 76:13-16 (Admitting that "one of the big points of developing the Sapien XT was to have something small enough to do more patients transfemorally".); Direct Examination of Larry Wood, D.I. 593 at 104:6-15 (Explaining, regarding the difference between the SAPIEN and the SAPIEN XT, that "The XT is also a lower profile, so the mix between transapical and transfemoral is different between the platforms.").) Thus, inasmuch as the SAPIEN XT will be available for commercial sale very soon, it appears that

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[12] Dr. Carabello is a cardiologist.

[13] Dr. Popma is Director of the Interventional Cardiology Clinical Services at the Beth Israel Deaconess Medical Center. (D.I. 565.)

patients with small vessel sizes will be well served even if the CoreValve Generation 3 cannot be sold due to an injunction.

2. Extreme Risk Patients with Large Annulus Sizes

Medtronic asserts that, among the same extreme risk group, there are those in whom neither the SAPIEN nor the SAPIEN XT can be implanted because their annulus sizes are larger than 27mm in diameter. (D.I. 560 at 17-19.) Medtronic claims that only the CoreValve Generation 3 can be implanted in these patients and that these patients would outright be denied potentially life-saving implants if its CoreValve Generation 3 was enjoined.[14] (*Id.*) Edwards concedes that neither the SAPIEN nor SAPIEN XT can be used to treat patients with annulus sizes exceeding 27mm. (D.I. 549 at 8-9.) Nonetheless, Edwards argues that the carve-out it proposes in its proposed preliminary injunction order, (D.I. 548 at 3-4), will ensure that these patients have access to the CoreValve Generation 3 by allowing Medtronic to sell no more than 63 units per month to be implanted in these patients.[15] (D.I. 570 at 8.)

As both parties rightly acknowledge, the available evidence confirms that there are extreme risk patients with annulus sizes such that neither the SAPIEN nor the SAPIEN XT can be implanted. (*See, e.g.*, Declaration of Blase Carabello, D.I. 564 at ¶ 4; Declaration of Jeffrey Popma, D.I. 565 at ¶ 10-12 (Stating that 50% of the extreme risk patients treated in the continued access arm of the clinical trial had annular diameter sizes too large for the SAPIEN's 25mm

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[14] As previously noted, the continuing access program through which extreme risk patients were receiving the CoreValve Generation 3 has now been discontinued because the FDA approved the CoreValve Generation 3 without also approving extension of the continued access program through which Medtronic was providing the CoreValve Generation 3 to extreme risk patients. (D.I. 582-1.)

[15] Edwards does not explain in the briefing and declarations submitted regarding the preliminary injunction motion what the origin is of its 63 unit per month limit. In a declaration submitted in mid-2013 in conjunction with its motion for permanent injunction, however, Dr. Gregory K. Leonard explains that he arrived at the number by estimating that 3.4% of the possibly 18,000 patients in the TAVR market have annulus sizes greater than 27mm. (D.I. 539 at ¶¶ 7-9.) The resulting number is 51 and Edwards added 12 extra implants supposedly out of magnanimity. (*Id.*; D.I. 570 at 8, FN 8 (explaining that "Edwards also allowed 12 extra implants per month, going out of its way to ensure that every TAVR patient can be treated.").)

maximum to accommodate, with 38% unable to be treated by the SAPIEN XT also.).) These patients require the CoreValve Generation 3 in order to have any hope of treatment. (*See, e.g.*, Declaration of Dr. Blase Carabello, D.I. 564 at ¶ 4 (Concluding that if the CoreValve Generation 3 was not commercially available upon FDA approval, these extreme risk patients would not be able to receive transcatheter aortic valve replacement at all.).) The court concludes based on this that, despite the three preliminary injunction factors that establish Edwards' entitlement to the injunction, the public interest requires making some accommodation that would grant patients with large annulus sizes access to the CoreValve Generation 3. The assertions regarding the number of these patients and the percentage of the overall population of patients who need THV implants that these patients constitute are contradictory at best, however.[16] (*Compare, e.g.*, D.I. 560 at 6 (estimating that 20-30% of the expected 18,000 candidates for THV in the United States have annulus diameters too large to be treated with the SAPIEN) *with* D.I. 539 at ¶¶ 7-9 (estimating no more than 3.4%) *and* D.I. 593 at 11:2-23 (estimating that, currently 10.4% of patients cannot be treated with the SAPIEN, but that once the SAPIEN XT is approved, that number will be "about 3.4 percent".) Thus, it would be premature to adopt at this time Edwards' proposed 63-unit-a-month cap on how many devices may be sold to serve to serve these patients.

3. Best Outcomes Among All Patients

Medtronic contends that for all patients—not just those whose vessel sizes are too small or whose annulus sizes are too large—the CoreValve Generation 3 is safer and leads to a longer and healthier life due to a lower risk of stroke, paravalvular leak, and death, among other things. (*See, e.g.*, D.I. 560 at 17-19.) Edwards argues in response that Medtronic's conclusions are unreliable

[16] Neither counsel for the parties nor the experts provided much detail on this matter during the evidentiary hearing.

and skewed. (D.I. 570 at 9-10.) It accuses Medtronic of "hid[ing] the underlying data", "cherry-pick[ing]", and "ignoring the knowledge and skills learned in the past five years", among other things. (*Id.*) Ultimately, Edwards concludes "when Medtronic's own proctors controlled for pretreatment differences in patients, SAPIEN and SAPIEN XT matched or beat ReValving on every measure." (*Id.* at 10.)

It is clear that the SAPIEN, the SAPIEN XT, and the CoreValve Generation 3 are all excellent devices. Indeed, experts on both sides have attested to this. (*See, e.g.*, Direct Examination of Dr. Martyn Thomas, D.I. 593 at 55:4-7 ("When I look at all of this data, I think we have two excellent devices.").) There are not yet any randomized clinical studies available in which the SAPIEN and the CoreValve Generation 3 have been compared head-to-head. (*See, e.g.*, Direct Examination of Dr. George Michael Deeb, D.I. 593 at 173:11-22 ("There has never been a head-to-head randomized prospective clinical trial done that's been adjudicated.").) Rather, both devices have been compared to open heart surgery, which remains a common treatment option for patients who can survive the operation.[17] (*See, e.g.*, Direct Examination of Dr. Mark Russo, D.I. 593 at 85:25-86:14 (Explaining that the clinical trials of one device are being compared to the clinical trial of another device, rather than the two devices being compared directly.); Cross Examination of Dr. George Michael Deeb, D.I. 593 at 163:21-12 (Explaining that "[t]he thing

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[17] In his declaration, Dr. Jeffrey Popma made many assertions about the safety of the CoreValve Generation 3 over the SAPIEN. For instance, Dr. Popma explained that rates of mortality, stroke, and paravalvular leak were lower among extreme risk patients who received the CoreValve Generation 3 half that of those who was 25.5%, compared to 50% for those who received the SAPIEN. (D.I. 565 at ¶¶ 8, 14, 16-17.) He further added that 30.7% of patients using the SAPIEN THV died of all-cause mortality after 12 months, as compared to 24% of the extreme risk patients in the pivotal study who used the CoreValve Generation 3. (*Id.* at ¶ 14.) Dr. Popma attributed the CoreValve Generation 3's apparent superiority to its design, which results in "small size and flexibility, minimally invasive method of insertion, greater ease of deployment, and greater accuracy in placement." (*Id.* at ¶ 16.) After reviewing a host of complications and risk factors that are associated with the SAPIEN, Dr. Popma concluded that the clinical data and his experience as a clinician indicate that "there will be a significant adverse public health impact on patients and physicians in the United States if the CoreValve THV device is not commercially available in the United States." (*Id.*at 23.) These conclusions were drawn from comparing the results of one study on the CoreValve Generation 3, the CoreValve Pivotal Trial, to the results of another study on the SAPIEN. There is no indication that Dr. Popma conducted or considered any study that directly compared the two.

about these two trials...is that they are both being compared to the gold standard, which is surgery. Their valves are not being compared to one another.").)

The experts' interpretations of the available studies' results are somewhat mixed, varying mostly according to the party for whom they were called to testify. (*Compare, e.g.*, Direct Examination of Dr. Martyn Thomas, D.I. 593 at 55:19-57:18, 58:21-25 (Stating that the outcomes of the CoreValve Generation 3 were similar to those of the SAPIEN for a host of risk factors and characteristics and that "I have never seen an important signal that stroke is higher in one compared to the other") *with* Direct Examination of Dr. George Michael Deeb,[18] D.I. 593 at 140:4-10 (Explaining that annular size and access problems make the CoreValve Generation 3 superior.).) Overall, however, expert testimony does suggest that the CoreValve Generation 3 offers greater advantages over open heart surgery than the SAPIEN does. (*See, e.g.*, Declaration of Jeffrey Popma, D.I. 565 at ¶¶ 8, 14, 16-17 (Summarizing the results of the CoreValve Pivotal Trial); Cross Examination of Dr. Martyn Thomas, D.I. 593 at 68:14-69:7 (Admitting that the results of a fully randomized study published in the New England Journal of Medicine show that "at one year the risk of mortality was higher with surgery than with the CoreValve[]" and that "in the FDA trials that Sapien [*sic*] has conducted, it has never shown that it was superior to surgery."); Cross Examination of Larry Wood, D.I. 593 at 118:13-21 (Admitting that the self-expandable system of the CoreValve Generation 3 was the "gold standard" over the balloon-expandable method of Edwards' devices.); Direct Examination of Dr. George Michael Deeb, D.I. 593 at 143:5-8

[18] Although he was called to testify by Medtronic, Dr. George Michael Deeb was not paid for his testimony. (Direct Examination, D.I. 593 at 132:1-6 (Testifying that he was not paid and was present at the hearing because "I am an advocate for patient care and I am advocate for both of the valves.") The court was impressed by the neutrality of Dr. Deeb's testimony. Indeed, his statements about the utility and drawbacks of both the Edwards devices and the CoreValve Generation 3, as well as the importance of not constraining doctors' discretion over their patients' care, were very helpful to the court.

("[A]bsolutely, there are times when I believe just based on the deployment technique, it is much safer for a patient population to undergo the CoreValve usage. Same things goes with access.").)

4. The Public Interest in Light of All Considerations

The expert testimony suggests that patients with large annulus sizes must be allowed ongoing access to the CoreValve Generation 3. The testimony also indicates that the CoreValve Generation 3 may be to some degree the safer, better option for most patients. In addition, the court found credible the experts' assertions regarding the devastating effect on patient care and outcomes that would result from the CoreValve Generation 3 being banned for the duration of Edwards' patent extension. (*See, e.g.*, Direct Examination of Dr. Michael Deeb, D.I. 593 at 133:14-20 ("I think it would have a distinct negative impact on the patients' outcome if there were to be a restriction of usage of CoreValve for transcatheter aortic valve replacement."); Direct Examination of Dr. Jeffrey Popma, D.I. 593 at 189:19-8 (Stating that removing the CoreValve Generation 3 would have a "devastating effect" and that this "would put at risk a substantial portion of general population with aortic valve disease who are not suitable candidates for surgery.").) As Dr. Deeb passionately emphasized, "these valves are not interchangeable[]", (D.I. 593 at 142:12), and some room must be made for doctors to choose from both devices in determining which one is most suitable for each patient. (*Id.* at134:17-136:17 (Explaining regarding the possibility of banning the CoreValve Generation 3 that "I think by eliminating the physician, and tying their arm behind their back in deliverance of care, I think that is a huge mistake for the patient population out there that is being treated.").) All of this indicates that the public interest is well served in permitting at least some number of CoreValve Generation 3 devices to be sold on the market.

Nevertheless, the court cannot downplay the strong public interest favoring enforcement of patent rights. *See, e.g.*, *Sanofi-Synthelabo*, 470 F.3d at 1383-84 (Affirming district court's finding that the public interest favored enforcement of the plaintiff's patent over availability of

multiple options to patients because "'encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.") (Citation omitted); *Pfizer Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) (Explaining that the public interest is not promoted by "entirely eliminating the exclusionary rights conveyed by pharmaceutical patents. Nor does the statutory framework encourage or excuse infringement of valid pharmaceutical patents."). Enforcing patent rights is especially important where there is egregious conduct to be addressed and deterred, as there is here. Medtronic disregarded the law in infringing Edwards' patent and boldly continued to thumb its nose at the law by continuing its conduct even after being found to be a willful infringer. The court cannot ignore the fact that it would serve as a reward of sorts to Medtronic and an incentive for onlookers to behave as Medtronic has should the court permit Medtronic to freely commence sales of its device. In light of all the relevant considerations, the court finds that the public interest weighs in favor of granting Edwards a preliminary injunction, subject to an accommodation for Medtronic to sell its devices to those patients who cannot be helped by Edwards' devices.

V. CONCLUSION

The court concludes that Edwards has demonstrated its entitlement to a preliminary injunction under 35 U.S.C. § 283. The court also concludes, however, that the preliminary injunction must be tailored to the present circumstances and the considerable public interest at issue. Thus, Medtronic must be permitted to sell a number of CoreValve Generation 3 devices sufficient to meet the needs of patients that Edwards concedes cannot be served by Edwards' devices. Thus, the court will grant in part and deny in part Edwards' Motion for a Preliminary Injunction, (D.I. 548).

Dated: April 15, 2014

CHIEF, UNITED STATES DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE LLC, Defendants.	)	C.A. No. 08-91 (GMS)

ORDER

For the reasons stated in the court's Memorandum of this same date, IT IS HEREBY ORDERED that:

1. Edwards' motion for a preliminary injunction, (D.I. 548), is GRANTED IN PART AND DENIED IN PART;

2. Until the date on which the extended term of the '552 patent ends, Medtronic and any of its subsidiaries, affiliates, parent companies, officers, agents, servants, employees, and successors are hereby enjoined from infringing claim 1 of the '552 patent by selling and/or offering to sell in the United States, its territories or possessions ("the United States") any of the following products: The CoreValve Generation 3 ReValving System ("CoreValve Generation 3"), sold commercially as the ReValving System and the Medtronic CoreValve System, and any device not more than colorably different from the CoreValve Generation 3 ReValving System;

3. Since the FDA has approved the CoreValve General 3 for commercial sale,

Paragraphs 2 and 3 of Edwards' proposed preliminary injunction order, (D.I. 548 at 4), are no longer relevant;[19]

4. The parties shall immediately enter upon discussions to jointly determine a mechanism by which a sufficient number of CoreValve Generation 3 devices can be provided to the hospitals and clinics that are currently already trained in use of the CoreValve Generation 3. The purpose of providing these THV sites with a sufficient number of CoreValve Generation 3 devices shall be to enable physicians to make clinical, patient-by-patient determinations as to whether to implant the CoreValve Generation 3 or Edwards' SAPIEN and SAPIEN XT without being constrained by the number of CoreValve Generation 3 devices available.

5. On May 21, 2014 at 10:00a.m., the parties shall apprise the court via teleconference of the status of their discussions.

Dated: April 17, 2014

CHIEF, UNITED STATES DISTRICT COURT

[19] In paragraph 2, Edwards carved out the number of CoreValve Generation 3 units that Medtronic may continue to sell and/or offer for sale in the United States in order to conduct the pivotal clinical trial for FDA premarket approval. In paragraph 3, Edwards set out the number of CoreValve Generation 3 units that Medtronic may continue to sell and/or offer for sale in the United States in order to carry on continued access implants in extreme risk patients. These paragraphs are no longer relevant in light of the FDA having approved the CoreValve Generation 3 because both the pivotal clinical trial for FDA premarket approval and the continued access program ended upon approval.