Appeal No. 2014-_____

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

EDWARDS LIFESCIENCES AG AND
EDWARDS LIFESCIENCES, LLC,

Plaintiff-Appellee,

v.

COREVALVE, INC. AND
MEDTRONIC COREVALVE, LLC,

Defendants-Appellants.

Appeal from the United States District Court
for the District of Delaware,
Case No. 08-CV-0091,
Chief Judge Gregory M. Sleet.

APPELLANTS' *EMERGENCY* MOTION TO STAY PRELIMINARY INJUNCTION AND EXPEDITE THIS APPEAL

CERTIFICATE OF INTEREST

Counsel for Defendants-Appellants certifies the following:

1. **The full name of every party or amicus represented by me is:**

CoreValve, Inc. and Medtronic CoreValve, LLC.

2. **The name of the real party in interest (if the party named in the caption is not the real party in interested) represented by me is:**

N/A

3. **All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:**

Medtronic, Inc.

4. **The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or are expected to appear in this court are:**

Weil, Gotshal & Manges LLP – Edward R. Reines
Shaw Keller LLP – John W. Shaw, Karen E. Keller, David M. Fry
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INTRODUCTION

Defendants-Appellants CoreValve, Inc. and Medtronic CoreValve, LLC (collectively, "Medtronic") request an emergency stay of the preliminary injunction entered by the district court on April 11, 2014. Add. A at 4:18-5:8. At Medtronic's request, the district court stayed the injunction for seven days (until April 22, 2014) to allow this Court to address this emergency motion. [1] *Id*. at 5:12-6:14.

Medtronic also moves to expedite this appeal such that the briefing is complete by June 19 with a hearing as soon as practical. This motion establishes overwhelmingly that there is good cause for this expedited briefing schedule. Medtronic is prepared to file its principal appeal brief within 28 days (by May 12). It requested Edwards to agree to respond within 31 days (by June 12), but Edwards refused to agree even though this would only reduce its response time by nine days.[2] The only reason Edwards identified for refusing to agree to expedite the

[1] The court informed Medtronic at sidebar (after asking to go off record) that it planned to enter the injunction and would order the parties to try to negotiate some relief by May 21, but that the court definitely would *not* hold off on entering the injunction while the parties negotiate unless Medtronic voluntarily agrees immediately to cease all infringing conduct. Reines Decl.¶ 35. Medtronic declined because it would essentially be a self-imposed injunction, which is inappropriate as described in this motion. *Id.*

[2] Edwards has refused to agree to a stay of the injunction pending appeal or even during the court-ordered negotiations between the parties. Ex. 1.

appeal is that, if it were expedited, it would make it easier for this Court to grant the stay pending appeal over Edwards' opposition. Ex. 1.[3]

A stay should be entered and this appeal expedited because, if the injunction were permitted to go into effect, treatable patients may unnecessarily die in the name of already expired patent rights. Put simply, the calamity to public health that would result from the injunction is premised on a legally improper extension of patent rights. The injunction bans the sale of Medronic's life-saving CoreValve system ("MCS") and precludes the training of additional hospitals and other medical care facilities to use MCS. MCS is a unique and revolutionary minimally-invasive aortic heart valve replacement system that is fundamentally different than the only similar product in the U.S. market, which is the Sapien product line of Plaintiffs-Appellees Edwards Lifesciences AG and Edwards Lifesciences LLC's (collectively, "Edwards"). The MCS replaces diseased aortic heart valves in dying patients who may not survive traditional surgery.

The injunction here is intolerably against the public interest in life-saving medical remedies. The district court acknowledged that the enjoined MCS "is a safer device and that patients in whom it is implanted have better outcomes with a lower risk of death." Add. A at 4:8-11. Indeed, there are substantial numbers of patients for whom Edwards' Sapien is either not indicated at all or much less

[3] All citations in the format "Ex. __" are to the exhibits of the Reines Declaration unless noted otherwise.

efficacious. Exs. 3 § IV ¶¶ 1, 2, 9, § V ¶ 11; 4 ¶ 5; 2 ¶ 13; 6 ¶ 5; 7 ¶¶ 13, 19-21.[4] And, in the situations where both devices could be used, a team of doctors should make a case-by-case judgment based on all the circumstances to determine whether MCS provides a better and safer treatment. Ex. 6 ¶ 4. These life or death medical decisions simply are not susceptible to *a priori* judicial classification that can be regulated via an injunction. *Id*.

The loss of life threatened by the injunction is particularly unjustified because the patent rights on which it is based have expired. The district court's decision is based on an overly expansive interpretation of 35 U.S.C. § 156, which authorizes limited patent term-extensions. This decisive error in statutory interpretation is the improper premise for the injunction.

The '552 patent by its normal term expired on May 2, 2012. Pursuant to §156, Edwards applied for a term extension based on the time it took the FDA to approve Sapien, but thus far has only received "interim" extensions. Importantly, under §156, the scope of the patent right that is extended is ***not*** the full scope of the patent claims. Rather, by statute, the extended patent right is narrowed to the particular embodiment within the claim that corresponds to the specific product that was the subject of the FDA proceedings and its approved use. *Merck & Co.*,

[4] The transcript was not prepared in time to be included in this filing. As appropriate, Medtronic will supplement the appeal record when the transcript becomes available.

Inc. v. Kessler, 80 F.3d 1543, 1547 (Fed. Cir. 1996) (Under §156, "the restoration period of the patent does not extend to all products protected by the patent but only to the ***product*** on which the extension was based.").[5]

Here, the only portion of claim 1 of the '552 patent eligible to be extended is the segment of the patent right that matches Edwards' FDA-approved Sapien and the approved use for that device. The district court improperly interpreted §156 to narrow the claim only to the FDA approved use ***decoupled*** from the product approved by the FDA. Add. A at 2:5-7 ("Section 156(b)(1)(a) makes clear that it applies to *uses of devices*, not merely the actual devices and copies thereof."). This misinterpretation flies in the face of the statutory text. It also cannot be reconciled with this Court's precedent applying § 156, which routinely limits the extension to the ***product*** and not merely the approved use somehow decoupled from the particulars of the product.

Because the only patent right that could be extended under § 156 is limited to the FDA-approved Sapien product and Medtronic's MCS is radically different from Sapien, there is no infringement of any extended patent rights. Not only is there a likelihood of success on the merits of the appeal, as a matter of de novo statutory interpretation the appeal should be successful and the injunction vacated.

[5] Emphasis supplied unless otherwise specified.

The remaining stay factors also support this motion. The district court erroneously concluded that Edwards would suffer irreparable harm if Medtronic is allowed to sell MCS such that the public interest in life-saving medical treatment should be sacrificed. By already having awarded lost profit damages, the district court impliedly found that Edwards' harm for infringement of the '552 patent is reasonably quantifiable, such that an injunction is not warranted. Given Edwards' multi-year head start in the U.S. market, Edwards is not unduly harmed, let alone irreparably harmed, by Medtronic's sales of its MCS product.

BACKGROUND

Edwards filed suit on February 12, 2008. On April 1, 2010, the jury found Medtronic infringed claim 1 of the '552 patent, awarding $72,645,555 in lost profits and an additional $1,284,861 in royalties. The district court denied Edwards' permanent injunction motion. On appeal, this Court affirmed the damages award, but remanded Edwards' permanent injunction motion for further consideration based on changed circumstances. *Edwards Lifesciences AG, et al v. CoreValve Inc., et al*, 699 F.3d 1305 (Fed. Cir. 2012).

The '552 patent was set to expire in May 2012. The Patent Office granted Edwards interim term extensions, but not yet a final one.

On November 26, 2013, Edwards filed a ***preliminary*** injunction motion which alleged that the market for Edwards' products would be adversely impacted

by Medtronic's introduction of its MCS product following the anticipated FDA approval of that product. On January 16, 2014, the district court decided to hold a limited evidentiary hearing on the potential impact of an injunction on the public interest. That hearing was held on April 11, 2014 and at its conclusion the district court granted the preliminary injunction from the bench banning MCS sales. Add. A at 4:18-5:8.

Because the court was unable to identify a way to tailor the injunction to allow the use of the MCS when needed to save lives, it instead ordered the parties to negotiate to do so while imposing a blanket injunction against MCS sales. *Id.* The district court stated that it would ***not*** stay its injunction pending appeal and would ***not*** stay the injunction while the parties engaged in the Court-ordered negotiation to narrow the injunction. Add. A at 5:15-17; Reines Decl. ¶ 35.

ARGUMENT

I. LEGAL STANDARD GOVERNING THIS STAY REQUEST

Federal Rule of Appellate Procedure 8 authorizes this Court to enter a stay pending appeal. A four factor test applies: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Hilton v. Braunskill*, 481 U.S. 770, 776, (1987);

see, e.g. Standard Havens Prods, Inc. v. Gencor Indus., Inc., 897 F.2d 511, 512 (Fed. Cir. 1990) (applying this four factor test).

II. THE INJUNCTION WOULD HARM THE PUBLIC INTEREST IN LIFESAVING CURES

A. THERE IS A VITAL PUBLIC INTEREST IN THE AVAILABILITY OF IMPORTANT AND UNIQUE MEDICAL TREATMENTS

The public interest is critical in considering equitable relief, deserving "particular regard." *See Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 24 (2008) ("In exercising their sound discretion, courts of equity should pay ***particular regard*** for the public consequences in employing the extraordinary remedy of injunction."). There is, of course, a "strong public interest in maintaining diversity" in life-saving medical devices. *See, e.g., Datascope Corp. v. Kontron Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986) (affirming denial of injunction where public interest would be harmed in that some physicians prefer defendant's product); *Advanced Cardiovascular Systems, Inc. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554, 561 (D. Del. 2008) (strong public interest in diversity of market for coronary stents); *Bard Peripheral Vascular Inc. v. W.L. Gore & Associates, Inc.*, 2009 U.S. Dist. LEXIS 31328,*30 (D. Az. 2009) (public interest factor alone precludes injunction in view of important role that accused products play in aiding vascular surgeons who perform life-saving medical treatments); *see also Kimberly-Clark Worldwide, Inc. v. Tyco Healthcare Group LP*, 635 F. Supp. 2d 870, 882

(E.D. Wis. 2009) (denying injunction); *Conceptus, Inc. v. Hologic*, No. C 09-02280 WHA, 2012 U.S. Dist. LEXIS 2239, *9-10 (N.D. Cal. Jan. 9, 2012) (same); *Ethicon Endo-Surgery v. United States Surgical Corp.*, 855 F. Supp. 1500, 1517 (S.D. Oh. 1994) (same); *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, 712 F. Supp. 2d 1285, 1292-93 (M.D. Fla. 2010) (same).

Edwards concedes that Sapien cannot serve at least one category of patients that Medtronic can: patients with aortic annuli larger than 25 mm. Ex. 8 at 1. Accordingly, Edwards itself proposed that these patients be "carved out" from any injunction, so that they could receive life-saving treatment from Medtronic. *See* Ex. 9. However, following the day-long evidentiary hearing on the public interest, the district court found that these patients are far from the only ones who would be gravely injured by the removal of MCS from the market. Rather, the district court held without qualification that the enjoined MCS "is a safer device and that patients in whom it is implanted have better outcomes with a lower risk of death." Add. A at 4:8-11.

Notwithstanding this unequivocal finding—and Plaintiff's own concession about the limitations of its product—the district court entered a blanket injunction precluding sales of MCS and preventing Medtronic from training new sites on the use of MCS. According to the district court's findings, the injunction would leave no or an inferior treatment option for many patients on the verge of death due to

malfunctioning aortic valves. Further, because the injunction would prohibit the training of new sites on MCS, it would deprive countless patients of the very care that the district court held was safest simply because they do not live close enough to a previously trained center. Indeed, twenty four states do not have a MCS center, and 19 of the 50 largest metro service areas in the United States do not have a MCS center. Alkire Decl. ¶¶ 3-4. These 19 metro service areas encompass a total population of more than 33 million. *Id.* Simply put, millions would be left without access to the life-saving MCS device because the injunction limits the sites that can offer MCS.

B. MCS CAN HEAL THOUSANDS OF PATIENTS FACING DEATH FOR WHOM PHYSICIANS FEEL IT IS THE BEST THERAPY

It is uncontested that Edwards' Sapien product cannot be used for patients with aortic annulus diameters larger than 25mm and that Sapien XT, which has not yet been approved by the FDA, cannot be used for patients with aortic annulus diameters larger than 27mm. Exs. 3 § IV ¶ 1, § V ¶ 11; 8. In contrast, MCS is available in more sizes than Sapien and can be used for patients with up to a 29 mm annulus. *See* Ex. 10 at 5-6. At the evidentiary hearing, Medtronic intended to call Dr. Michael Reardon to testify that 40-50% of aortic stenosis patients have annulus sizes greater than 25 mm, and therefore can only be treated by MCS. The District Court ultimately did not permit Dr. Reardon to testify, and Medtronic

made a proffer of evidence that 40-50% of Americans with aortic stenosis cannot be treated by Sapien.

Sapien, unlike MCS, also cannot be used via transfemoral access for patients with small (less than 7mm) arteries. *Id.* § IV ¶ 9. Doctors often prefer a transfemoral procedure to alternative access routes such as the transapical procedure which requires incising the chest and cutting through the heart to reach the aorta. If MCS is enjoined, thousands of U.S. patients with smaller arteries, in particular women with smaller anatomies, would be placed at risk needlessly.

C. EVEN FOR THOSE PATIENTS WHO CAN BE TREATED BY BOTH DEVICES, MCS IS PROVEN SAFER THAN SAPIEN

Even patients who can theoretically be treated by either Sapien or MCS will be adversely impacted by the injunction. First, a recent groundbreaking FDA-approved study published in the New England Journal of Medicine found that MCS is the first non-invasive valve replacement to demonstrate superior rates of mortality and stroke as compared to open-heart surgery. Exs. 11; 12 at 26-27. MCS was superior to surgery for all patient groups—results did not vary by gender, age, disease condition, weight, or any other factor. Ex. 12 at 37-38. In contrast, Edwards' FDA study showed that as compared to surgery, Sapien merely is ***not inferior*** in terms of mortality, but results in a higher rate of stroke. Exs. 13 at 1; 14 at 8. In other words, as the district court found, MCS "is a safer device

and that patients in whom it is implanted have better outcomes with a lower risk of death." Add. A at 4:8-11.

This is extremely important for aortic stenosis patients because MCS recipients can forego the invasiveness of surgery and obtain better outcomes. Moreover, the MCS FDA trial also showed that for patients who are at too great a risk to undergo surgery, MCS is a safe and effective treatment. Ex. 10 at 1.

In addition, the determination of who will be better served by an MCS is a case-by-case physician determination that is not subject to the bright lines necessary for an administrable injunction. Doctors believe MCS is the safer valve for patients with a variety of medical and anatomical conditions, such as calcified annuli or valve leaflets, a prominent septal bulge within the left ventricular outflow tract, eccentric annuli, marked tortuosity and unfolding of the thoracic aorta, or patients in whom rapid ventricular pacing is a contraindication. Exs. 3 § IV ¶¶ 3-7, 10, § V 12, 13-15; 2 ¶¶ 14-16; 6 ¶¶ 8, 9, 11; 4 ¶¶ 10, 11; 5 at 45, 49. Additionally, unlike the balloon-expanding Sapien with a stainless steel frame, the self-expanding MCS with a nitinol frame conforms to a patient's anatomy. This conformability decreases the risk of annular rupture and stroke, and reduces leakage around and through the valve. The leakage factor is particularly significant as compared to Sapien XT, for which an FDA trial showed moderate or severe aortic regurgitation of nearly 30%. Ex. 15 at 39.

In sum, there are many combinations of factors that a medical team must consider to select the correct course of treatment for any particular patient. It is impossible to anticipate or enumerate every possible combination in which one treatment or another will provide the best results for the patient. In light of this medical reality, any categorical prohibition on the use of MCS will likely lead to outcomes in which patients suffer death or increased complications that could have been avoided had MCS treatment been available.

For this reason, the district court ruled that the injunction must "enable physicians to make a clinical judgment as to whether to implant a MCS or Edwards device." Add. A at 5:6-7. However, by enjoining all sales of MCS, the Court's order provides for no such judgment. And by only requiring Edwards to negotiate regarding future sales of MCS to sites currently trained in its use, Add. A at 5:1-8, the district court arbitrarily limits patient access and the exercise of physician judgment to those who happen to be near the "right" places, excluding millions of individuals. *See* Alkire Decl. ¶¶ 3-4. Staying the injunction pending appeal is therefore necessary to protect the public health.

III. MEDTRONIC HAS A STRONG LIKELIHOOD OF SUCCESS ON THE MERITS

Medtronic's appeal will establish that the district court erred in granting the injunction. The injunction will be measured by the same four factor test as this stay motion. *See Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1373-74 (Fed.

Cir. 2012). As documented above, in this instance the public interest factor deserves dispositive weight, precluding an injunction based on the district court's finding that MCS is better and safer than Sapien at saving lives. The remaining factors reinforce this conclusion.

A. THE DISTRICT COURT INCORRECTLY FOUND THAT EDWARDS' RIGHTS IN THE'552 PATENT EXTEND TO MCS

The district court's injunction is based on its misinterpretation of § 156. This is reviewed *de novo*. *Apple*, 695 F.3d at 1373. The '552 patent expired on May 2, 2012. Although the PTO granted three limited one-year ***interim*** extensions, it has yet to issue a final extension on the merits. Edwards' rights under the interim-extended '552 patent are limited to the use of the product on which its patent term extension was based: Sapien model 9000TFX, sizes 23mm and 26mm. *See* Exs. 16 (approving the Sapien "model 9000TFX, ***sizes 23mm and 26mm*** and accessories"); 8 (specifying only 23mm and 26 mm bioprosthesis sizes). Edwards' rights during the '552 patent's extended term do ***not*** cover MCS and thus the injunction is based on a misreading of the statute.

Under § 156, "the rights of a patentee during a term extension are limited in ways that do not normally apply to granted patents." *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1349 (Fed. Cir. 2010). This Court has specifically rejected "the faulty premise that the rights enjoyed by a patentee during the term of a patent are the same as the rights enjoyed by a patentee during

the term of an extension under § 156." *Id*.; *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996) ("[T]he restoration period of the patent does not extend to all products protected by the patent but only to the product on which the extension was based.").

The district court misinterpreted § 156. It ruled that the term-extended patent rights are ***not*** confined by the scope of the FDA-approved product on which the extension is based. Add. A at 2:5-7 ("Section 156(b)(1)(a) makes clear that it applies to uses of devices, not merely the actual devices and copies thereof."). Edwards led the district court to this error. Ex. 17 at 3 ("Accordingly, the scope of the '552 Patent, as extended, is limited only by the approved 'use' of Edwards' SAPIEN product, which is aortic valve replacement in patients with severe symptomatic native aortic valve stenosis. The ReValving products have the same use, and thus infringe the '552 Patent after extension, just as they did before.") (internal citations omitted).

The term-extension is limited to ***both*** the specific approved product ***and*** the approved use of that product. Indeed, the statute states that to be eligible for an extension the "***product*** [must have] been subject to a regulatory review period before its commercial marketing or use." 35 U.S.C. §156(a)(4). Subsection (b) refers to the same product as subsection (a) and states that the extension is "limited to any use approved for the ***product.***" *Id.*

This Court's precedent confirms conclusively that the term-extended patent rights under § 156(b) is limited to the particular FDA-approved ***product*** within the claim, not merely the approved use. In *Boehringer*, the extension was found to be limited to the particular drug pramipexole, which is only one specific chemical compound in the general class of chemical compounds that are within the scope of the many patent claims within the alleged extended term. *Boehringer*, 592 F.3d at 1349 ("Boehringer only 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.'").

Likewise, in *Merck,* this Court found that the extension was limited to the product on which the extension was based – not merely the approved use. *Merck*, 80 F.3d at 1547 (the extension under §156 is "only to the ***product*** on which the extension was based"). This Court has consistently focused on assessing the extent and scope of the ***product*** upon which the extension is based, not the decoupled ***use*** of that product. *See, e.g., Pfizer, Inc. v. Dr. Reddy's Labs, Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004) (assessing whether the scope of an extended patent covered salts or esters of amlodipine besylate, the active ingredient in the product under review – without discussing the ***use*** of an approved hypertension drug). Edwards' contention that the only limitation on the scope of an extended patent is the ***use*** of a product under review (and not the specific product itself) contradicts the Federal

Circuit's repeated focus on the product rather than the use in determining the confines of the term-extension under § 156.

Here, Edwards' extension is limited to the use of Sapien 9000TFX, sizes 23mm and 26mm or generic or other duplicates of that particular design because that is the product that went through the FDA approval process. Reading claim 1 of the '552 patent as properly limited to Sapien during its extended term, it is clear that claim 1 no longer covers MCS. For example, claim 1 requires a "cylindrical support means [that] is radially expandable."[6] Ex. 33, claim 1. Sapien, the covered embodiment, is balloon-expandable. Exs. 8; 18 ¶ 15. MCS, by contrast, is self-expanding, and therefore a different embodiment from Sapien, and not covered during the term extension. As another example, claim 1 recites an "elastical valve," which Sapien embodies with bovine tissue. Ex. 8. MCS, on the other hand, uses porcine tissue, a different embodiment from Sapien.

The MCS is physically and functionally very different from Sapien, separately patented, and the subject of full and independent FDA review, without use or reliance on any Sapien FDA filings or procedures. Exs. 19 ¶¶ 3, 4; 18 ¶¶ 3-11, 14, 16. It is undisputed that the MCS is not a copy of Sapien. Ex. 20 at 23.

[6] Medtronic is not re-arguing decided claim construction issues, but emphasizing how § 156(b) limits the claim scope of the '552 patent during its term extension to Sapien even under the previous claim constructions in this case.

The Sapien and MCS frames are made of different materials and the products are deployed in different manners. Ex. 18 ¶ 15; *see also* Ex. 21 at 2.

B. EVEN IF EDWARDS' RIGHTS EXTEND TO THE MCS, THE DISTRICT COURT ERRED IN FINDING THAT EDWARDS WOULD SUFFER IRREPARABLE HARM IF MEDTRONIC IS ALLOWED TO SELL MCS THAT WOULD JUSTIFY AN INJUNCTION

The district court erred in finding that Edwards would suffer irreparable harm if Medtronic is allowed to sell MCS.

1. EDWARDS WILL NOT SUFFER IRREPARABLE HARM THAT COULD JUSTIFY AN INJUNCTION

Edwards speculates that it will lose "market opportunities" and its status as "market leader" unless a preliminary injunction prevents a "head-start" by Medtronic. Ex. 22 at 14-17. But Edwards ignores that it has been exclusive in the United States for transcatheter aortic heart valves since it received approval in November 2011. Ex. 23 ¶ 6. Since then, it has used that exclusive position to establish itself in as many hospitals as possible, with 284 sites in the U.S. Ex. 24 at 6. Edwards now speculates that Medtronic will convince these hospitals to abandon Edwards, contradicting its own claim that, "hospitals, once they invest the staff time and resources to begin a THV program, stick with that THV product for an extended period of time, making it much harder to introduce a competing THV program at such hospitals." Exs. 25 ¶¶ 15, 19; 22 at 15; 26 ¶ 6.

2. MONEY DAMAGES ARE ADEQUATE TO COMPENSATE EDWARDS

Edwards already stands to collect at least $191 million in damages from this case. *See* Exs. 29 at 5 (awarding $72,645,555 in lost profits and $1,284,861 in past royalties); 30 at 1 (requesting court award additional $117,662,570 for post-trial period through May 1, 2012).

3. MEDTRONIC DID NOT MISREPRESENT THE STATUS OF ITS MEXICO MANUFACTURING TRANSITION

The district court based its irreparable harm finding on its erroneous assertion of "Medtronic's history of making dubious representations to the Court." The district court stated that Medtronic represented to the Court in July 2010 that "its facility in Mexico was fully equipped to take over manufacturing from the Irvine, California facility." Add. A at 3:11-12. But Medtronic made no such promise to the Court, and neither the Court nor Edwards has cited any specific instance of alleged misrepresentation with support in the record. Medtronic's July 2010 opposition to Edward's permanent injunction motion stated that, although it was developing manufacturing in Mexico, doing so "has proven more difficult than initially anticipated." Ex. 31 at 6. Thus, rather than representing that manufacturing could begin in Mexico immediately, Medtronic advised that it anticipated that "the Mexico operations will not match its current production in Irvine of 1000 units per month until mid-2011." *Id*.

Medtronic's actual transition to Mexico was roughly in line with its July 2010 estimates. By mid-2011, Mexico production was about equal to U.S. production, but not sufficient to meet all demand. Ex. 32 at 5. Since January 2013, the only commercial production in the U.S. has been for a very small number of valves for Brazil, Ecuador and Taiwan, countries that had not yet certified the Mexico production facility. *Id.* at 10. That is, since January 2013, the only commercial production in the U.S. was for sales ***outside*** the U.S. (or for a U.S. clinical trial). In short, Medtronic has always been candid about its need to produce valves in the U.S. for some period after 2010 while Mexico production ramped up so that Medtronic would be able to supply valves to physicians and hospitals ***outside*** the United States who were relying upon that supply

IV. MEDTRONIC WILL BE IRREPARABLY HARMED ABSENT A STAY.

If the injunction is not stayed, the injunction will irreparably harm Medtronic by preventing Medtronic from entering a market in which Edwards already has had a dominant lead for years. This harm would be particularly egregious and irreparable given that the injunction is based upon expired patent rights.

V. THE EQUITIES FAVOR A STAY

Because the public interest militates against an injunction and Medtronic has raised, at the very least, substantial legal questions for appeal, the equities

overwhelmingly favor a stay. *See, e.g., Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 516 (Fed. Cir. 1990).

VI. THE BRIEFING SCHEDULE FOR MEDTRONIC'S APPEAL SHOULD BE EXPEDITED

Federal Rule of Appellate Procedure 2 permits this Court "to expedite the determination of cases of pressing concern to the public or to the litigants by prescribing a time schedule other than that provided by the rules." Fed. R. App. P. 2 (Adv. Comm. Note). Medtronic respectfully requests that the Court adopt the following expedited briefing schedule for resolution of this matter:

Medtronic's Opening Brief	May 12, 2014
Edwards Opposition Brief	June 12, 2014
Medtronic's Reply Brief	June 19, 2014

For all the reasons set forth above, this schedule should be adopted.

Dated: April 14, 2014

Respectfully submitted,

By /s/ Edward R. Reines

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CERTIFICATE OF SERVICE

In accordance with Fed. R. App. P. 25 and Fed. Cir. R. 25, I certify that on this day April 14, 2014, I served the foregoing via email on the principal attorneys for each party. Additionally, for delivery on the next business day, two true paper copies of the foregoing were sent to counsel for each party, and an original and four paper copies of the foregoing were sent to the Clerk of the Court.

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