

2011-1215, -1257

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

EDWARDS LIFESCIENCES AG and
EDWARDS LIFESCIENCES LLC,

Plaintiffs-Cross Appellants,

v.

COREVALVE, INC. and
MEDTRONIC COREVALVE, LLC,

Defendants-Appellants.

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

**NON-CONFIDENTIAL OPENING BRIEF OF
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CERTIFICATE OF INTEREST

Counsel for Defendants-Appellants CoreValve, Inc. and Medtronic CoreValve, LLC certify the following:

1. The full names of every party or amicus represented by us are:
CoreValve, Inc. and Medtronic CoreValve, LLC
2. The names of the real parties in interest represented by us are:
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 us are:
Medtronic Inc.
4. The names of all law firms and the partners or associates that appeared for the parties or amicus now represented by us in the trial court or that are expected to appear in this Court are:

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The material omitted on pages 4-5 and 26 contains information regarding Edwards' request for damages from the Parties' Statement Regarding Accounting of Monetary Damages and Interest for the Period March 16, 2010 - February 7, 2011, that was filed under seal. (Dkt. No. 439).

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STATEMENT OF RELATED CASES

No other appeal in this civil action was previously before this Court or any other appellate court. Appellants' counsel are aware of one related district court case: *Edwards Lifesciences AG & Edwards Lifesciences LLC v. Medtronic, Inc., Medtronic CoreValve, LLC & Medtronic Vascular, Inc.*, No. 09-873-GMS (D. Del. filed Nov. 17, 2009).

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) because the asserted claims arise under the patent laws of the United States. A00113-A00153. On April 1, 2010, the jury returned a verdict in favor of Plaintiffs-Cross Appellants Edwards Lifesciences AG and Edwards Lifesciences LLC (collectively, "Edwards"). A00039-A00043. On April 29, 2010, Defendants-Appellants CoreValve, Inc. and Medtronic CoreValve LLC (collectively, "CoreValve") moved for judgment as a matter of law and a new trial. A08969-A08972, A08998-A09000. The district court entered judgment on the verdict on May 4, 2010. A00033-A00038. The court denied CoreValve's post-trial motions on February 7, 2011. A00001-A00032. On February 10, 2011, CoreValve filed a timely notice of appeal. A20036-A20038. This Court has jurisdiction under 28 U.S.C. § 1295(a)(1).

STATEMENT OF THE ISSUES

Claim 1 of Edwards' patent, U.S. Patent No. 5,411,552 (the "'552 patent"), is directed to a prosthetic aortic valve implantable by catheter. After over two decades of experimentation, neither the inventors nor their licensees have ever implanted a device taught by the '552 patent in a human patient. In contrast, the accused device, which was designed to mirror anatomical features of the aortic region, has been successfully implanted in over 10,000 human patients. A jury found the patent infringed and not invalid and awarded Edwards damages of over \$73 million (including \$72 million in lost profits), and the district court ordered an accounting of additional damages. The issues presented are:

1. Whether the district court erroneously construed the term "cylindrical" in Claim 1 to encompass any shape "relating to a cylinder" where the claim language contains no term modifying "cylindrical" and the court did not define either "cylinder" or "relating to."

2. Whether "commissural supports" that "project" from one side of the device in a direction "generally parallel" to the longitudinal axis, as required by Claim 1, are present in an accused device that supports the valve with an integrated structure angled at 30° to the longitudinal axis.

3. Whether Claim 1 was enabled where the patent is directed to a valve implantable in a human body, the device described in the patent was admittedly

unsuitable for human use, and no device based on the patent has been successfully implanted in a human body despite years of experimentation.

4. Whether the \$72 million lost profits award should be vacated where undisputed evidence showed (a) CoreValve made an identical valve structure as early as fall 2004, (b) the accused device would have been noninfringing if CoreValve made it overseas, (c) CoreValve could have manufactured its device overseas by March 2007, and (d) Edwards first sold a competing product in August 2007.

STATEMENT OF THE CASE

Edwards and CoreValve manufacture and sell heart valve prostheses that are implantable by catheter. In February 2008, Edwards sued CoreValve, alleging infringement of the '552 patent and two other patents. A00113-A00118, A00056-A00064. Only Claim 1 of the '552 patent was pursued at trial. A10339.

The district court construed disputed claim terms in a *Markman* order issued May 27, 2009 (A00044-A00048) and amended February 16, 2010 (A00049-A00053). CoreValve challenges the court's construction of "cylindrical support means" to mean "a portion of the stent supporting the valve that has a shape of or relating to a cylinder." A00050. CoreValve agreed to an ordinary meaning instruction for the term "projecting," but as shown below neither Edwards, the court, nor the jury applied the ordinary meaning of that term to bring CoreValve's integrated structure within the terms of Claim 1.

A jury returned a verdict in favor of Edwards. A11973-A11981. The jury found that the CoreValve device literally infringed Claim 1 and that the '552 patent is not invalid for lack of enablement. *Id.* The jury awarded Edwards \$72,645,555 in damages for lost profits and \$1,284,861 as a reasonable royalty. *Id.* The district court denied CoreValve's post-trial motions for judgment as a matter of law and for a new trial (A00001-A00032). The court also ordered an accounting of damages incurred after the jury verdict, [[

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MATERIAL OMITTED

]] A20305-A20364, A20365-A20368.

STATEMENT OF FACTS

A. Introduction

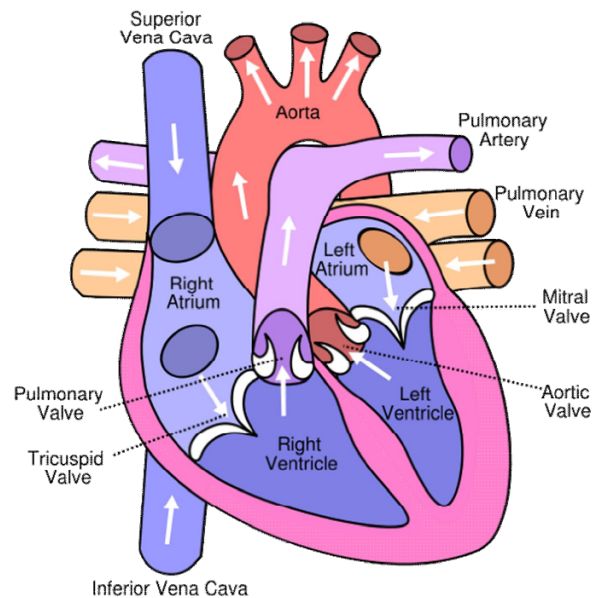
As described below, the accused device was the first prosthetic aortic valve ever approved for implantation in human patients via catheter rather than surgery. In the four years since that approval, surgeons have successfully implanted the device in more than 10,000 patients suffering from life-threatening aortic disease. This success resulted directly from CoreValve's innovative design changes to overcome defects in the prior art. In the case of the '552 patent, such defects prevented the patent licensees from developing a successful device suitable for human use despite more than two decades of experimentation.

Notwithstanding this striking contrast in both design and results, in the infringement proceedings below Edwards obtained a massive damages award and now seeks to enjoin CoreValve from continuing to make its device available to patients in need.

B. The Challenge: Impaired Aortic Valves

This case involves a new technology for medical devices used to replace defective heart valves. In the human body, several one-way valves regulate the flow of blood through the heart. A20080-A20081. For example, the aortic valve allows blood to pass from the left ventricle into the aorta when the heart beats, and

then snaps shut to prevent blood from moving back into the left ventricle between heart beats.



A12932.

The aortic valve can be impaired by aortic insufficiency or aortic stenosis. A20081-A20082. A diseased or damaged aortic valve can be replaced through open-heart surgery. A00061. In this procedure, a surgical team opens the patient's chest, stops the heart, circulates the blood through a machine, sews a replacement valve in place, restarts the heart, and closes the chest. *Id.* Like all major surgeries, open-heart surgery poses serious risks, especially for patients weakened by illness or age. *Id.* A less invasive, nonsurgical alternative to open-heart surgery is the implantation of a valve prosthesis—made up of a stent and valve—using a

catheter. CoreValve was the first to introduce a catheter-implanted valve prosthesis.

C. The '552 Patent

The '552 patent, entitled “Valve Pro[s]thesis For Implantation In The Body And A Catheter For Implanting Such Valve Pro[s]thesis,” issued in 1995 based on an application claiming priority to a Danish application filed in 1990. A00056. The named inventors were Henning Andersen, John Hasenkam, and Lars Knudsen. *Id.* Edwards has since acquired all rights in the patent. A20088, A08661.

The '552 patent discloses a prosthetic valve attached to a stent that includes a “cylindrical support means” and “projecting” supports for the valve. A00061, A00063-A00064. The stent without the valve is depicted in Figure 1:

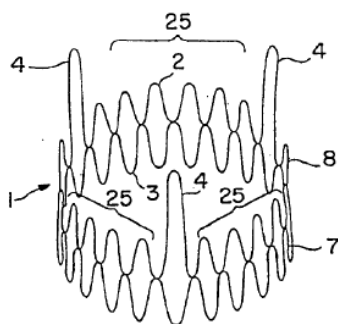


FIG. 1

A00057.

The specification identifies the three taller, “post”-like structures (4) in Figure 1 as “commissural supports.” A00063. The tissue valve is attached to these

“commissural supports.” “Commissural points” (5) are located where the valve leaflets meet just below the tips of the commissural supports, as shown below:

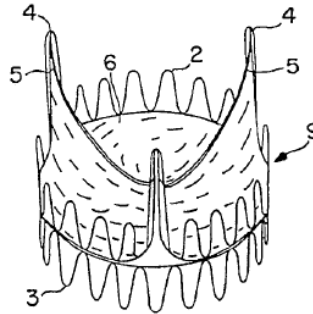
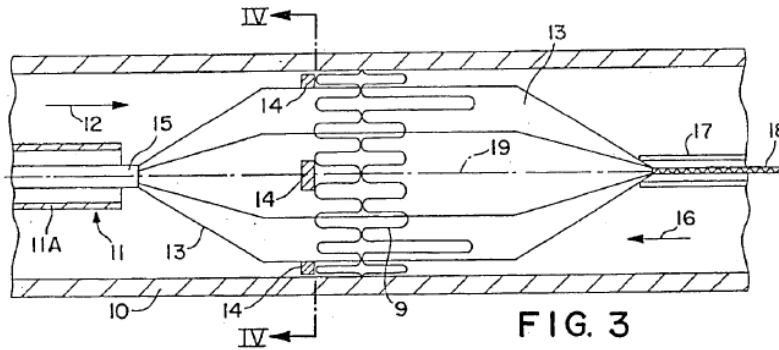


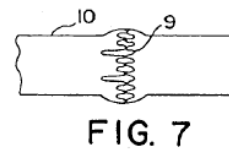
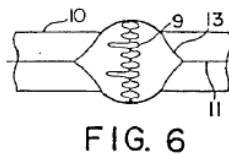
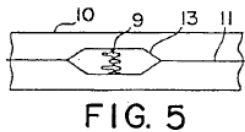
FIG. 2

A00057, A00063. The “commissural supports” must be “projecting” from one side of the “cylindrical support means” in a “direction generally parallel to the longitudinal axis.” A00064. This design provides a reduction in weight compared to an exclusively cylindrical stent. A00063.

To implant the valve, a physician compresses it onto a balloon catheter and moves the catheter through a blood vessel to the implantation site. A00061-A00062. Figure 3 shows a partially inflated balloon catheter (11) introduced into the aorta (10) in the direction of arrow 12 (left to right). A00063.



Once the valve prosthesis is properly positioned (Figure 5), the physician inflates the balloon to expand the stent and valve (Figure 6). The balloon is then deflated and the catheter removed, leaving the expanded valve prosthesis in place (Figure 7). A00063.



Claim 1 of the '552 patent—the only claim at issue in this case—reads:

A valve prosthesis for implantation in a body channel, the valve prosthesis comprising a collapsible elastical valve which is mounted on an elastical stent, the elastical valve having a plurality of commissural points, wherein the stent comprises:

cylindrical support means which is radially collapsible for introduction within the body channel and which has a plurality of circumferentially-expandable sections such that the *cylindrical support means* is radially expandable for being secured within the body channel; and

a plurality of commissural supports *projecting from one side of the cylindrical support means in a*

direction generally parallel to the longitudinal axis thereof for supporting the commissural points of the collapsible valve, at least one circumferentially-expandable section of the cylindrical support means lying between each of the commissural supports, such that the collapsible valve may be collapsed and expanded together with the cylindrical support means for implantation in the body channel by means of a technique of catheterization.

A00064 (emphasis added).

The United States Patent and Trademark Office (“PTO”) originally rejected the Andersen application under 35 U.S.C. §§ 102(b) and 103 in light of prior art disclosing valve prostheses comprising (1) a collapsible elastical valve with a plurality of commissural points and a radially expandable and collapsible stent (U.S. Patent No. 4,106,129 to Carpentier et al.); and (2) a collapsible elastical valve and a “flexible and bendable” stent (U.S. Patent No. 4,297,749 to Davis et al.). A20538-A20539, A20566-A20569. In response to the rejections, the applicants amended Claim 1 to add the language requiring the commissural supports to be “projecting” from the “cylindrical support means” in a “direction generally parallel to the longitudinal axis thereof.” A20571-A20574.

Claim 1 contains three limitations relevant to this appeal: (1) “cylindrical support means” in the valve prosthesis; (2) commissural supports “projecting” from the cylindrical support means “in a direction generally parallel to the longitudinal axis”; and (3) “implantation in a body channel.”

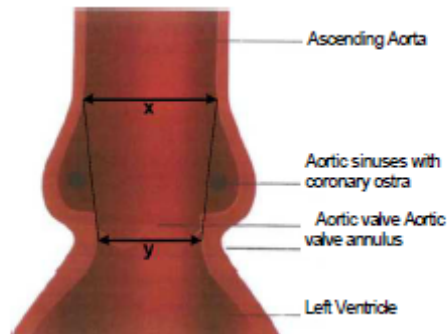
D. The Accused Device: CoreValve’s Catheter-Implanted Artificial Heart Valve

As described below, the CoreValve device was carefully designed to overcome the known weaknesses and defects of the prior art, including the ’552 patent.

In 2001, Dr. Jacques Seguin, a cardiologist who has performed over 7,000 open-heart surgeries, and Georg Bortlein founded CoreValve in France to develop a noninvasive catheter-based method of replacing aortic valves. A11116, A11250, A11260. Others had failed in their efforts, but CoreValve experimented with different materials, developed hundreds of prototypes, and extensively tested two “generations” of valves in humans before finalizing the design of the Generation 3 device (the “CoreValve device” that is accused here) in January 2006. A11118-A11146, A11496.

The CoreValve device reflected several fundamental design changes over the existing art—changes that led the PTO to issue patents covering the device’s design even though CoreValve submitted the ’552 patent to the PTO during patent prosecution. A31632, A33464. First, CoreValve designed the configuration of its device to mirror certain anatomical features of the implantation site—the junction between the ascending aorta and the left ventricle of the heart. A11285-A11288. As depicted below, at this site the diameter of the ascending aorta is more than

30% larger than the diameter of the small ring (or “annulus”) that constricts the entrance to the left ventricle (A17915, A13003):



As a result, the annulus imposes far greater pressure on a stent than does the aorta, particularly since the annulus (unlike the aorta) is a strong muscle. A13003.

Because of the narrow diameter of the annulus, a cylindrical stent is poorly suited for implantation at this site. A11703-A11705. If the cylinder’s diameter approximates the width of the annulus, it will not be securely anchored in either the aorta or the annulus. A11705-A11706. This can result in “migration” of the valve from the implantation site and death of the patient. A20190-A20191, A11703. Conversely, if the cylinder’s diameter approximates the width of the aorta, it will close off the orifice portion of the coronary arteries. A12990. Furthermore, the differences in diameter between the aorta and annulus are so great that a cylindrical stent, once compressed and snaked into place with a catheter, cannot be “expanded” after implantation to accommodate the diameters in both regions at the same time. *Id.*

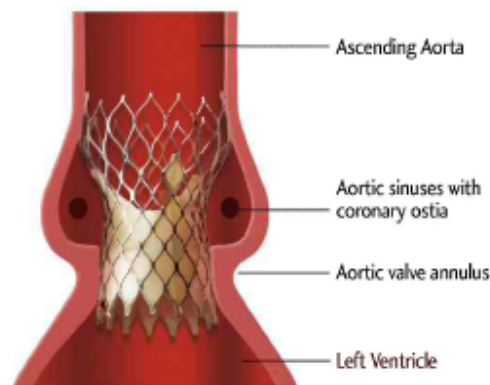
To solve these problems, CoreValve designed an integrated stent with diameters that vary significantly along its length. A11701-A11704. In this device, the upper end of the stent has a “bulbous” shape with a diameter that is more than twice the diameter of the bottom portion. A12946. This bulbous portion flares out at an angle of 30° from the center axis of the device. A11463, A11544-A11545. The stent’s middle portion (or “waist”) has a smaller diameter than the annulus, while the lower, “conical” portion gradually increases in diameter from the waist to the bottom at an angle of 5-7 degrees. A12989-A12990, A10737, A11285-A11286, A11565, A11901. The result is an integrated “chalice-shaped” device:



A12897.

This configuration provides important clinical advantages over a cylindrical stent. As depicted below, the upper “bulbous” portion of the stent optimizes anchoring in the aorta and thereby secures the stent in the vessel. A11286-

A11287, A11703-A11704. The stent's narrowed "waist" keeps the coronary arteries clear and enables the valve to function despite variations in the size of the aorta. A11286, A11720. The gradually increasing diameter of the "conical" lower portion secures the stent in the annulus and thereby prevents "migration" of the valve. A12987-A12990, A11703-A11704.



A12945.

The CoreValve inventors concluded that projecting posts would be prone to collapse under the stress of the valve's operation and therefore decided not to use them. A11131-A11132, A11693-A11694. Instead, the CoreValve device uses a "honeycomb" of "interlocking diamonds" to support the valve. A11541. The "diamonds" to which the valve is attached are on the 30° slope just above the narrow waist of the stent. A11463, A11542-A11543. The 30° angle enables the device to reduce the stress fatigue generated by the opening and closing of the

valve—much as an angled metal frame provides better support for a hammock suspended at the two ends of the frame. A11544-A11545.

In March 2007, the CoreValve device obtained European approval, making it the first catheter-delivered artificial aortic valve to be approved anywhere in the world for use in human patients. A11288, A20197-A20198. By the time of the trial below, physicians had implanted the device in approximately 10,000 patients. A11289.

E. European Litigation

In 2008, Edwards sued CoreValve in the United Kingdom and Germany, claiming that the CoreValve device infringed the European version of the '552 patent. A12929, A12961-A12962. The courts in both countries held that the CoreValve device did not meet the “cylindrical support means” limitation of the Edwards patent.¹

¹ The relevant claim in the European version of the '552 patent reads:

A valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastical valve which is mounted on an elastical stent wherein the commissural points of the elastical collapsible valve are mounted on the cylindrical surface of the elastical stent characterized in that the stent is made from a radially collapsible and re-expandable *cylindrical support means* for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

A17912.

The U.K. courts held that the term “cylindrical” should be given its “ordinary meaning,” which the courts defined as having a “uniform circular cross-section at right angles to the axis of the circular cross section.” A17914. The U.K. courts characterized Edwards’ assertion that “cylindrical” did not require a “substantially constant diameter” as “strik[ing] a limitation out altogether.” A17918-A17919. The U.K. courts further held that the CoreValve device did not meet the “cylindrical” limitation because it varied in diameter along its length to accommodate differences in diameter at the implantation site. A12946.

Similarly, the German courts construed the “cylindrical” limitation to require a “configuration having a circular diameter which remains essentially the same over the entire length of the device.” A13001. Like the U.K. courts, the German courts expressly rejected Edwards’ assertion that “cylindrical” did not require a constant diameter, reasoning that such a construction would render the term “superfluous.” A13002. The German courts concluded that the CoreValve device did not meet the “cylindrical” limitation because the device featured differences in diameter along its length. A12987-A12990, A13004-A13006.

F. District Court Proceedings: Claim Construction

While the European actions were pending, Edwards brought the present action. By the time of trial, Edwards asserted only Claim 1 of the ’552 patent, which the district court had construed after a *Markman* hearing. A10339.

The parties proposed the following constructions for “cylindrical support means”:

CoreValve

stent structure where the mesh has a diameter that is constant along the longitudinal axis

Edwards

a portion of the stent supporting the valve that has a shape of or relating to a cylinder, including a barrel-like shape, but not limited to a cylinder shape in the strict geometrical sense

A00335. CoreValve argued that the term “cylindrical” should be given its “ordinary meaning” as a “geometric” figure in which the diameter remains constant along the longitudinal axis of the stent. A00399-A00404. By contrast, Edwards argued that “cylindrical” should be construed to include shapes somehow “relating to the shape of a cylinder,” such as “barrel-like shapes” and other unspecified configurations that are not “geometric” cylinders. A00433-A00437.

The district court construed “cylindrical support means” to mean “a portion of the stent supporting the valve that has a *shape* of or *relating to* a cylinder.” A00045, A00050 (emphasis added). In rejecting CoreValve’s proposed construction, the court noted that “constant diameter along the longitudinal axis” does not appear in the specification. *Id.* The court did not explain why it adopted Edwards’ construction of “cylindrical support means” to include shapes “relating to a cylinder.” *Id.*

In construing the term “a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof,” the district court construed “commissural supports” to mean “the portions of the stent that support the commissural points of the valve,” and it construed “commissural points” to mean “points or locations where the leaflets of the valve are joined.” A00045-A00046, A00050-A00051. The parties agreed that “projecting” and “generally parallel” should be given their plain and ordinary meaning. A08858-A08859.

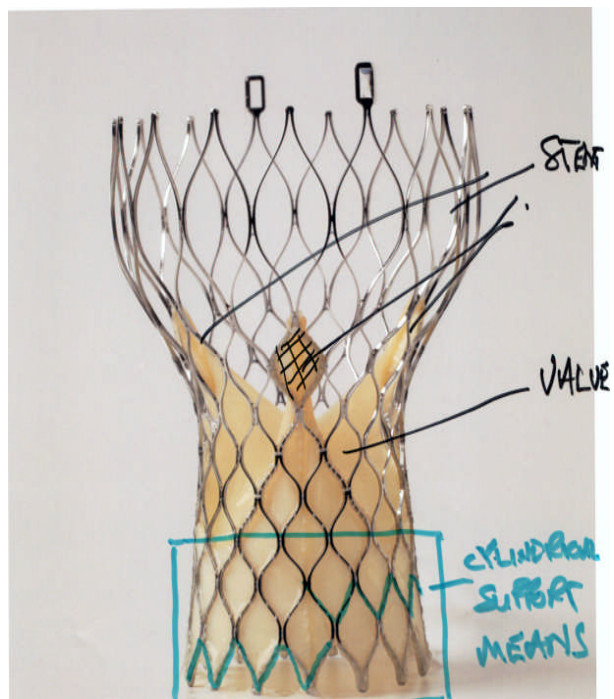
G. District Court Proceedings: Trial Evidence

An eight-day jury trial was held in March 2010. A00097-A00099. The witnesses included (1) the inventors of the '552 patent; (2) the developers of the accused CoreValve device; (3) other inventors who had developed an implantable heart valve without following the '552 patent; (4) the parties' liability experts—Dr. Leonard Pinchuk and Dr. Martin Rothman on behalf of CoreValve and Dr. Nigel Buller on behalf of Edwards; and (5) the parties' damages experts, Gregory Leonard for Edwards and Jeffrey Kinrich for CoreValve. The trial included substantial testimony relating to issues central to this appeal.

1. “Cylindrical support means”

To support its claim that the CoreValve device met the “cylindrical support means” limitation, Edwards relied on the testimony of its expert, Dr. Nigel Buller.

Noting that the district court’s claim construction required that only a “portion” of the CoreValve stent had to meet the “cylindrical support means” limitation (A10857), Dr. Buller used a blue marker to draw a box around the area of the CoreValve stent that purportedly constituted the “cylindrical support means”:



A31341. In testifying that the tapered section boxed above met the “cylindrical” limitation, Dr. Buller expressly relied on the district court’s construction of “cylindrical support means” to be any “portion” of the stent supporting the valve that “has a shape of or relating to a cylinder.” A10856.

In instructing the jury, the district court repeated its original claim construction language and added two new sentences stating that the “cylindrical support means” did *not* require a constant diameter along the length of its axis:

‘cylindrical support means’ means ‘a portion of the stent supporting the valve that has a shape of or relating to a cylinder.’ Now, *the term ‘cylindrical’ does not mean that the object described must be a cylinder with a diameter that is constant along its length or longitudinal axis.* To put it another way, the term ‘cylindrical’ as used in the patent in this case *does not require the presence of a perfect geometric cylinder.*

A11863 (emphasis added).

In closing argument, Edwards’ counsel repeatedly emphasized this instruction. He first stressed that, under the district court’s instruction, the term “cylindrical” was broad enough to include the “tapered” lower portion of the CoreValve device that Dr. Buller had circled:

And [Dr. Buller] demonstrated where the cylindrical support means was [in the CoreValve device]. *And, yes it is slightly tapered on the bottom.* But the Judge’s instructions make it clear that the word cylindrical support means does not require it to be *absolutely vertical.*

A11900-A11901 (emphasis added). Edwards’ counsel then argued that CoreValve’s description of the lower portion of the device as “cone-shaped” did not matter because the “judge has instructed you that *cylindrical doesn’t mean cylinder.*” A11958 (emphasis added).

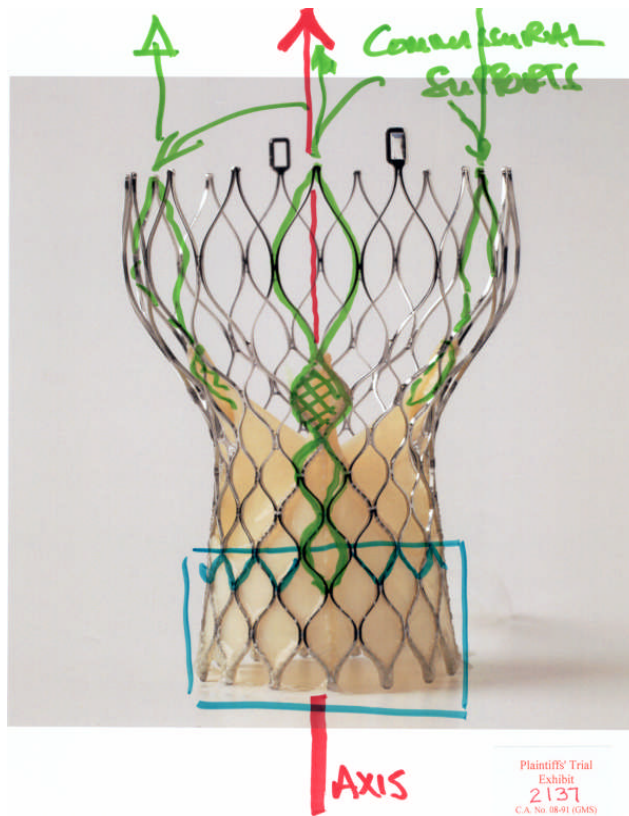
2. “Projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof”

In addressing the “projecting” limitation, the CoreValve experts (Pinchuk and Rothman) both testified that a skilled artisan in 1990 would have understood

the term “projecting from one side of the cylindrical support means” to refer to a commissural support that “protruded from” or “stuck out of” the cylindrical support means. A11538, A11707-A11709. They further testified that the CoreValve device does not meet this limitation because the device does not include identifiable commissural supports that “protrude” from any cylindrical support means. *Id.* Instead, the CoreValve device is an “integral structure”—“much like a honeycomb”—in which each of the “interlocking diamonds” is indistinguishable from the other. A11541.

In addressing the “generally parallel” limitation, CoreValve’s experts testified that a skilled person would have understood that the phrase “generally parallel” does not describe a vertical axis and a line that intersects the vertical axis at a 30° angle. A11543, A11714-A11718. The CoreValve experts therefore concluded that the CoreValve device also failed to meet the “generally parallel” limitation. A11543-A11545, A11714-A11718.

Dr. Buller testified on behalf of Edwards that the CoreValve device met both the “projecting” and “generally parallel” limitations. He used a red marker to draw the longitudinal axis on a photograph of the CoreValve device and then a green marker to draw what he claimed to be the “commissural supports”:



A31342.

Dr. Buller acknowledged that the preferred embodiments in the '552 patent depict the “projecting” commissural supports as taller loops that are clearly distinguishable from the rest of the cylindrical stent. A10937-A10940.² He nevertheless testified that the CoreValve device meets the “projecting” limitation because the “*whole structure, one can say, is projecting generally upwards.*” A10971 (emphasis added). Dr. Buller explained that by “whole structure,” he meant the “whole of the structure that *goes up to the end of the stent,*” even though

² Buller also acknowledged that the two rectangular tabs atop the CoreValve device are not commissural supports but simply lock the device onto the catheter. A10946-A10947.

the commissural points of the valve are mounted in the middle of that structure. *Id.* (emphasis added). He analogized the upper half of the CoreValve device to a spoon or fork that has “bends to it” (*i.e.*, the neck bends away from the vertical axis) but the “whole structure” still points “generally upwards.” *Id.* Finally, Dr. Buller contended that a skilled artisan might consider a 30° angle to be “generally parallel” to the longitudinal axis. A10972.

At the close of the evidence, the district court gave the following instruction on the “projecting” limitation:

“projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof” means “projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means.”

A11864.

3. Evidence pertinent to enablement

Addressing the enablement issue, the named inventors admitted that they never tried to implant their valve in a human body. A20133, A20234. Instead, from September 1989 to March 1992, they attempted to implant their device in 41 pigs, but were “successful” or “partially successful” only 14 times. See A23460-A24169. Even in the 14 “successful” trials, the pigs receiving an implanted valve lived no more than five hours, and most lived only one hour or less. A20119-A20121, A20172, A23460-A24169. In these cases, the inventors had “great

difficulty” in keeping the device in the annulus of the animal, primarily because of the “migration” of the stent away from the site of implantation. A10903-A10904.

The inventors acknowledged that their device was unsuitable for clinical use in humans. A20138-A20139. Rather, “many important questions remain[] to be answered about the stent-valve,” and “many more complex and long-term animal studies must be performed before even *speculation* concerning clinical use is begun.” A31403-A31409 (emphasis added).

The evidence at trial showed that neither Edwards nor any of the other ’552 patent licensees has ever been able to develop a device for human use based on the ’552 patent. Stanford Surgical (later renamed Heartport), which licensed the patent from 1993-2000, made no progress in developing a device suitable for human use. A20139-A20145, A11889, A24529. Nor did Percutaneous Valve Technology (“PVT”) after it purchased the license in December 2000, even though PVT enlisted highly regarded interventional cardiologist Alain Cribier to assist in the effort. A20257-A20264. Dr. Cribier ultimately concluded that the ’552 patent design was “impossible to use in clinical practice.” A11379-A11380. PVT agreed, concluding that the ’552 patent “sadly does not describe a method or design that, if constructed, is percutaneous and functional over any durable period.” A11674-A11675. PVT therefore abandoned its efforts to develop a valve prosthesis for human use based on the “projecting commissural supports”

described in the '552 patent. A11235-A11236, A24539-A24555 (at A24546), A31591-A31608 (at A31594). Instead, PVT developed the “Cribier valve” which did not use the projecting commissural supports required by the '552 patent. A11366-A11367, A11371, A11383.

Edwards acquired PVT in December 2003 and renamed the Cribier valve the “SAPIEN valve.” A20256-A20257, A20264, A10632, A23270-A23362. Edwards obtained approval in Europe to sell one version of its SAPIEN device in August 2007. A20266. At the time of trial, the SAPIEN device had not been approved for use in the United States. A10618, A20269.

H. District Court Proceedings: Verdict and Post-Trial Motions

The jury returned a verdict in favor of Edwards. A00039-A00043. As relevant here, the jury found that the CoreValve device literally infringes Claim 1 and that Claim 1 is not invalid for lack of enablement. *Id.* The jury awarded Edwards \$72,645,555 in lost profit damages—the full amount of estimated by Edwards’ expert—and \$1,284,861 in reasonable royalty damages. *Id.*

The district court denied CoreValve’s post-trial motions for JMOL and a new trial. A00001-A00032. Although the jury had found that CoreValve willfully infringed the '552 patent, the district court denied Edwards’ motions for enhanced damages and attorneys’ fees. A00021-A00024. It also denied Edwards’ motion for a permanent injunction to prohibit CoreValve from making the CoreValve

device in the United States. A00025-A00029. Finally, the court ordered an accounting of damages incurred since the date of the jury verdict. A00029.

[[

CONFIDENTIAL
MATERIAL OMITTED

]] A20305-A20364, A20365-

A20368.

I. Reexamination by the PTO

In July 2010, CoreValve submitted a request for *ex parte* reexamination of the '552 patent. A19929-A19976. CoreValve argued that several of Edwards' positions in this litigation raised a "substantial new question of patentability." *Id.* CoreValve submitted portions of the public record from the litigation, including (1) the district court's construction of "cylindrical support means"; (2) color copies of Dr. Buller's slides with his drawn-in-green "projecting commissural supports" in the CoreValve device; and (3) Dr. Buller's testimony that a 30° deviation could be "generally parallel" to the longitudinal axis. *Id.*

On September 10, 2010, the PTO granted the Request, finding that two prior art references, viewed in light of Edwards' positions in this litigation, raised a "substantial new question of patentability." *Order Granting Request for Ex Parte Reexamination*, USPTO Appl. No. 90/009779, Sept. 10, 2010, <http://portal.uspto.gov/external/portal/pair>. The PTO cited Dr. Buller's trial testimony that the CoreValve device meets the "cylindrical" limitation even though

its sides are not parallel. *Id.* at 6-8. The PTO also found “of particular interest” the slides that Dr. Buller “marked up” to show the “projecting commissural supports.” *Id.* The PTO therefore commenced an *ex parte* re-examination of the ’552 patent, which remains pending.

SUMMARY OF THE ARGUMENT

The ’552 patent inventors failed in their attempt to devise a catheter-delivered prosthetic aortic valve for human use. In over two decades of experimentation, neither they nor successive licensees were able to implant a device based on the ’552 patent in a human patient. The cylindrical shape and projecting supports that are central to the design of the claimed invention do not provide the stability and strength required for a workable replacement aortic valve. In contrast, the CoreValve inventors succeeded because they devised features directed to the actual anatomy of the human heart, enabling the CoreValve device to save many thousands of lives. Edwards now seeks to garner enormous damages from CoreValve’s innovation and success. This Court should reverse the judgment below to protect both lives and innovation.

CoreValve developed a chalice-shaped stent of varying diameters with a bulbous upper portion flaring 30° out from a narrow waist and a bottom portion with a more gradually increasing diameter. CoreValve also devised a stent structure consisting of a honeycomb of rounded, interconnecting diamonds, and it

attached the commissural points of the valve to the angled slope of the stent above the waist, with no need for projecting commissural supports that are prone to collapse. Precisely because of its differences from the '552 patent, this design provided optimal strength and stability.

The district court erred in construing “cylindrical” and in sustaining the jury verdict on infringement, non-enablement, and damages.

I.

The district court improperly construed “cylindrical support means” to include any structure that has a “*shape of or relating to a cylinder,*” thereby authorizing the jury to find that CoreValve’s noncylindrical device infringed Claim 1. The court should have given “cylindrical” its ordinary geometrical meaning, as this Court did with the term “polygonal” in *International Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363 (Fed. Cir. 2004). The claim language does not modify “cylindrical” with an adjective like “substantially” or “generally,” and the specification shows that the inventors intended “cylindrical” to bear its plain geometric meaning. By contrast, nothing in the claim language or specification indicates any intent to use a different meaning.

II.

The CoreValve device does not have commissural supports “projecting” in a direction “generally parallel” to the longitudinal axis of the support means. The

magic marker of Edwards' expert cannot change an integrated mesh stent into something that projects from one of its own ends.

The evidence was undisputed that nothing protrudes or sticks out from the CoreValve device, which supports the valve with the integrated honeycomb structure of its chalice-shaped stent. Edwards nonetheless contended, based solely on conclusory expert testimony, that the entire CoreValve device projects generally upwards, thereby meeting the "projecting" limitation. Such an expert *ipse dixit*, lacking factual support and conflicting with the ordinary meaning of claim terms, cannot sustain an infringement verdict.

Likewise lacking competent evidentiary support was the jury's conclusion that the CoreValve commissural supports project in a direction "generally parallel" to the longitudinal axis of the support means. The undisputed evidence showed that the commissural points lie on the 30°-angled slope above the waist of the CoreValve device. The infringement verdict cannot be sustained by Edwards' expert's strained analogy to a fork to characterize a 30° deviation as "generally parallel."

III.

Claim 1 of the '552 patent also is invalid because it fails to satisfy the enablement requirement of 35 U.S.C. § 112, ¶ 1. The specification makes clear that the full scope of the claim includes a valve suitable for implantation in a

human body channel. At the time of the patent application, there was no known means to achieve that purpose using the disclosed device. Most of the pigs in which the exemplary device was implanted died within minutes of implantation, and none survived more than five hours. Put bluntly, implantation of the device claimed in the '552 patent killed even the hardiest veterinary "patient," and no one dared implant it in a human. Indeed, after two decades of extensive experimentation, no one implementing the patent's teachings has developed a device suitable for human use. Accordingly, the full scope of Claim 1 was not enabled at the time of the patent application, mandating judgment of invalidity.

IV.

Finally, if the judgment is not otherwise reversed, the award of lost profits damages should be vacated as contrary to law. The date of first infringement triggers the hypothetical effort to use a noninfringing substitute, which here means manufacturing the same device overseas. The only evidence of *first* infringement places that date in fall 2004, when CoreValve first made its Generation 2 device. The frame structure of the Generation 2 device is indisputably identical to that in the accused Generation 3 device, making them identical for infringement purposes. In fall 2004, CoreValve's facilities were in Europe. Had CoreValve called off its then-impending move to California, manufacture of the Generation 3 device in Europe would not have infringed the '552 patent (assuming it otherwise would

have). The only evidence on the point showed that CoreValve could have manufactured its device overseas by March 2007, before Edwards was authorized to sell (and profit from) a single SAPIEN valve. The lost profits award should be vacated.

ARGUMENT

Standard of Review. Claim construction rulings are reviewed *de novo*. *Hologic, Inc. v. Senorx, Inc.*, ___ F.3d ___, 2011 WL 651791, at *4 (Fed. Cir. Feb. 24, 2011). Denials of motions for judgment as a matter of law also are reviewed *de novo* under the law of the Third Circuit, where the district court sits. *Marion v. TDI, Inc.*, 591 F.3d 137, 146 (3d Cir. 2010), cert. denied, 131 S. Ct. 1479 (2011). JMOL of non-infringement is mandated “where the record is critically deficient of the minimum quantum of evidence” necessary to support a jury verdict. *Becton, Dickinson & Co. v. Tyco Healthcare Group*, 616 F.3d 1249, 1253 (Fed. Cir. 2010). Compliance with the enablement requirement is a question of law reviewed *de novo*, based on underlying facts reviewed for clear error. *Automotive Techs. Int’l, Inc. v. BMW, Inc.*, 501 F.3d 1274, 1281 (Fed. Cir. 2007). Eligibility for lost profits is reviewed *de novo*, with findings on necessary elements reviewed for substantial evidence. *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, ___ F.3d ___, 2011 WL 651790, at *13 (Fed. Cir. Feb. 24, 2011).

As demonstrated below, CoreValve is entitled to a revised construction of the claim term “cylindrical support means,” to judgment as a matter of law on both infringement and invalidity, and to an order vacating the awarded lost profits.

I. THE DISTRICT COURT IMPROPERLY CONSTRUED “CYLINDRICAL SUPPORT MEANS” TO COVER NON-CYLINDRICAL STRUCTURES.

The district court construed “cylindrical support means” as “a portion of the stent supporting the valve that has *a shape of or relating to a cylinder.*” A00050 (emphasis added). As the court told the jury, under that construction “the term cylindrical does not mean that the object described must be a cylinder.” A11863. By encompassing any shape “relating to a cylinder,” the court’s construction erroneously departed from the ordinary meaning of “cylindrical,” which is simply the adjectival form of “cylinder,” a geometric term with a plain and precise meaning.

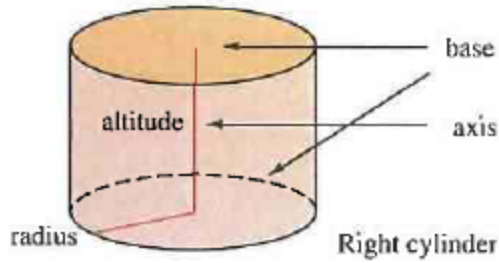
A geometric claim term without words of “modification or qualification” must be given its precise meaning. *Int’l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1372 (Fed. Cir. 2004) (construing “polygonal” in accordance with the precise geometric meaning of “polygon”). The district court’s construction of “cylindrical” to include any shape “relating to” a cylinder—without defining either “cylinder” or “relating to”—deviated from the term’s plain meaning and effectively read the “cylindrical” limitation out of the claim.

A. The Intrinsic Evidence Supports The Ordinary Geometric Meaning Of “Cylindrical.”

In construing claim terms, courts should rely primarily on the intrinsic record: the claim language, specification, and prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-17 (Fed. Cir. 2005) (en banc). In this case, the claim language and specification both support the conclusion that the term “cylindrical” should be given its ordinary geometric meaning (and the prosecution history is silent on the point).

Patent claim terms are to be given their “ordinary and customary meaning,” as understood by one skilled in the art at the time of filing, unless the patentee expressed a clear intent to deviate from that meaning. *Phillips*, 415 F.3d at 1312-13. Nothing in the ’552 patent reflects an intent—much less a clearly expressed intent—to give “cylindrical” anything other than its ordinary geometric meaning.

The term “cylindrical” is the adjectival form of the geometric term “cylinder.” A00635. As reflected in contemporaneous dictionaries and textbooks, a skilled artisan would have understood “cylinder” to be a geometric shape formed by moving a straight line in a circular path around another parallel line (or axis), resulting in a three-dimensional shape with a constant diameter. See A00635, A00637, A00641, A00645-A00646.



A00645.³

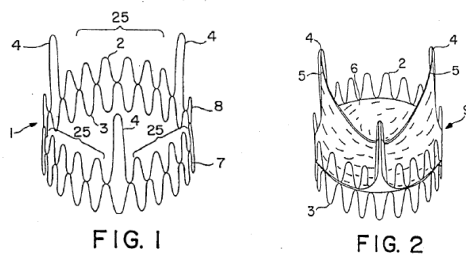
The plain language of Claim 1 describes “cylindrical support means” without using any words of “modification or qualification” such as “generally” or “substantially” to broaden the scope of the geometric term. *Int’l Rectifier*, 361 F.3d at 1372. Similar “descriptive terms are commonly used in patent claims to avoid a strict numerical boundary to the specified parameter.” *Anchor Wall Sys. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1310-11 (Fed. Cir. 2003). If a patentee uses a mathematical or geometric term *without* a modifier, however, the term receives its ordinary—and precise—meaning. *Id.*; *Int’l Rectifier*, 361 F.3d at 1372.

While the ’552 patent does not qualify “cylindrical” in Claim 1, it does use modifiers to broaden the meaning of other geometric terms. For example, Claim 1 uses the phrase “*generally* parallel” to describe the relationship between the “commissural supports” and the device’s longitudinal axis—showing that the two

³ The diagram shows a “right” cylinder, but all cylinders have constant diameters, even when the angle of the longitudinal axis deviates from 90°. See A00645.

lines need not be exactly “parallel” to satisfy the limitation. A00064 (emphasis added). Similarly, the specification uses “*substantially* cylindrical” to describe an embodiment in which one part of the structure is not a perfect geometric cylinder. A00063 (emphasis added). Because the ’552 patentees elsewhere used terms of “modification or qualification” to broaden the meaning of specific geometric terms, their decision to use the phrase “cylindrical support means” *without* qualification should be given especially heavy weight. *Int’l Rectifier*, 361 F.3d at 1372.

The ’552 specification confirms that “cylindrical” should be given its ordinary geometric meaning. First, the specification expresses no clear intent to depart from the ordinary geometric meaning of “cylindrical.” *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008). Second, the specification repeatedly describes the claimed invention using “cylindrical” in its geometric sense. For example, the figures in the specification show the support means as a cylinder with a constant diameter or uniform cross-section:



A00057.

Third, the specification provides “context” that reinforces the idea of a supporting stent in the shape of a cylinder. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1326-27 (Fed. Cir. 2002). For example, the specification describes the stent as constructed from wire “rings” that are sutured together—clearly indicating a stent with a uniform circumference (and hence a uniform diameter) along its axis. A00063-A00064. In addition, the specification repeatedly refers to the device’s singular “diameter” and “circumferentially-expandable sections,” further confirming that “cylindrical” is used in accordance with its ordinary geometric meaning. *Id.*

Confirming this meaning of “cylindrical,” the U.K. and German courts construed the term in the European version of the ’552 patent to reflect the geometric characteristics of a “cylinder” under its “ordinary and customary” meaning—a three-dimensional shape with a constant diameter (or, equivalently, a uniform cross-section):

Court	Construction of “Cylinder” or “Cylindrical”
U.K. lower court	A three dimensional shape having a “substantially constant diameter” (A12945)
U.K. appeals court	A three-dimensional shape having a “uniform circular cross-section at right angles to the axis of the circular cross-section” (A17914)
German lower court	A three dimensional shape having a “uniform diameter over its length” (A12970)

Court	Construction of “Cylinder” or “Cylindrical”
German appeals court	A three-dimensional shape having a “circular diameter which remains essentially the same over the entire length of the device” (A13001)

The German and U.K. courts expressly rejected Edwards’ assertion that the term “cylindrical” does not require a shape with a constant diameter, reasoning that such a construction would render the “cylindrical” limitation “superfluous” or “strike [the] limitation out altogether.” A13002, A17918-A17919.

Thus, as reflected in both the intrinsic and contemporaneous evidence and constructions of the European courts, the “ordinary and customary” meaning of “cylinder” is a three-dimensional geometric shape with a constant diameter.

B. The District Court Improperly Construed “Cylindrical” To Include Any Shape “Relating To A Cylinder.”

The district court agreed with Edwards that the “cylindrical” support need not have a “diameter ... constant along the longitudinal axis” but instead could have a shape that merely “relat[ed] to a cylinder.” A00050. In so doing, the court provided *no* analysis of the claim language, the specification, or any intrinsic evidence to support its construction. Instead, in a footnote the court simply dismissed CoreValve’s “diameter . . . constant along the longitudinal axis” construction on the ground that the phrase is not found in the specification. *Id.*

The court’s construction directly conflicts with this Court’s decision in *International Rectifier*, which construed a similar geometric term. There, the patent-in-suit claimed a semiconductor transistor in a base described as a “polygonal region.” *Int’l Rectifier*, 361 F.3d at 1370-72. The district court construed “polygonal” to require a base region that is “generally, but not necessarily perfectly, polygonal”—a “closed figure with generally (not necessarily perfectly) straight sides.” *Id.* at 1370.

In reversing that construction, this Court explained that the “ordinary and customary” meaning of “polygonal” is a “closed plane figure bounded by straight lines.” *Id.* The Court also noted that the patentee did not use any terms of modification to broaden the geometric meaning of “polygonal.” *Id.* at 1372. The Court therefore concluded that the district court erred by “relaxing” the requirements of “polygonal” to “allow round corners and not straight edges,” thereby ignoring the patentee’s “choice of words”:

The patentee . . . could have claimed the regions more broadly but chose to use the word “polygonal” without modification or qualification. The district court was not free to attribute new meaning to the term *or to excuse the patentee from the consequences of its own word choice.*

Id. at 1371-72 (emphasis added).

The same logic applies here. As in *International Rectifier*, 361 F.3d at 1371-72, the district court here “relax[ed]” the requirements of the geometric term

“cylindrical” and disregarded intrinsic evidence showing that the patentees used a well-known geometric term without “modification or qualification.” The court’s *Markman* opinion did not cite *International Rectifier* or discuss the “plain meaning” of the patentee’s own word choice. Instead, the court apparently accepted Edwards’ argument that the term “cylindrical” should be construed in light of a single dictionary definition. A00433; see A00611.

By elevating that dictionary definition over the intrinsic record, the district court flouted this Court’s repeated admonition that there is often “a disconnect between the patentee’s responsibility to describe and claim his invention, and the dictionary editors’ objective of aggregating all possible definitions for particular words.” *Phillips*, 415 F.3d at 1321. Hence, a claim term should not “presumptively receive its broadest dictionary definition or the aggregate of multiple dictionary definitions.” *Free Motion Fitness, Inc. v. Cybex Int’l, Inc.*, 423 F.3d 1343, 1349 (Fed. Cir. 2005). The rationale is clear: “if the district court starts with the broad dictionary definition [and] fails to fully appreciate how the specification implicitly limits that definition, the error will systematically cause the construction of the claim to be unduly expansive.” *Phillips*, 415 F.3d at 1321.

The Court’s admonition in *Phillips* identifies the precise error here: Instead of analyzing the intrinsic evidence, the district court adopted a dictionary definition of the broadest possible scope and construed “cylindrical” to encompass *any shape*

“relating to a cylinder.” The court then compounded its error by failing to define the term “cylinder” or provide any guidance on the meaning of the phrase “relating to a cylinder.”

The result was a construction of “cylindrical” that made no mention of the geometric characteristics of a cylinder—and did not define the claim’s limits. Instead, as Edwards made clear in closing argument, the court’s construction (and the resulting jury instruction) gave only negative guidance: “*cylindrical doesn’t mean cylinder.*” A11958 (emphasis added). This standardless construction permitted a finding of infringement so long as the shape of the accused device “related” in some unspecified way to an undefined geometric term (“cylinder”). On this basis, a triangular prism could be said to “relate to” a cylinder because both figures have parallel bases and a uniform length, or a sphere could be said to “relate to a cylinder” because both figures have diameters and curved surfaces.

By construing “cylindrical” to have no specific geometric meaning, the district court effectively read the limitation out of the claim and nullified its notice function. Its construction should be reversed and the infringement judgment vacated.

In addition, CoreValve is entitled to judgment as a matter of law of no literal infringement because, under the proper construction, no reasonable jury could find that the “support means” in the CoreValve device is “cylindrical.” While Dr.

Buller’s magic marker tried to isolate the conical bottom section from the rest of the stent, even Edwards had to admit that the bottom section is “tapered” (A11901), which necessarily means it lacks a constant diameter.

II. THE COREVALVE DEVICE DOES NOT INCLUDE COMMISSURAL SUPPORTS THAT PROJECT IN A DIRECTION GENERALLY PARALLEL TO THE LONGITUDINAL AXIS.

As described above, the CoreValve device was designed to meet anatomical constraints. Two design features provided the backdrop to the two primary infringement issues at trial: (1) does the CoreValve device include “commissural supports” that “project from” one side of the cylindrical support means?, and (2) if so, do they project in a direction “generally parallel” to the device’s longitudinal axis?

The district court construed “commissural points” to mean “points or locations where the leaflets of the valve are joined,” and “commissural supports” to mean “portions of the stent that support the commissural points of the valve.” A00050-A00051. Because the parties agreed that the ordinary meaning governed “projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof,” the district court simply construed “thereof” to reference the “cylindrical support means.” *Id.* Under these constructions, CoreValve’s commissural supports do not “project from” the

cylindrical support means, much less in a direction “generally parallel” to the vertical axis.

A. Edwards Failed To Prove That CoreValve’s Commissural Supports Are “Projecting From” The Cylindrical Support Means.

1. The undisputed evidence established that “projecting from” means “protruding from” or “sticking out of.”

The trial testimony on the “projecting” limitation was undisputed. The CoreValve experts testified that one skilled in the art in 1990 would understand the term “projecting” to refer to commissural supports that “protrude from” or “stick[] out of” the cylindrical support means. A11538, A11707, A11709. This testimony comported with contemporaneous dictionaries, which defined “projecting” as “protruding,” “jutting out,” or “extending forward or out.” A10183; see *Hewlett-Packard v. Mustek Sys., Inc.*, 340 F.3d 1314, 1321 n.3 (Fed. Cir. 2003) (“general purpose dictionaries” may be used in “interpreting jury instructions”).

Edwards’ expert, Dr. Buller, neither disputed this definition nor offered an alternative. Rather, he agreed that in Figures 1 and 2 in the ’552 patent the three commissural supports “project” from a cylindrical support means because they all “stick up” from the body of the stent. A10929-A10930. He also agreed that the three “posts” enable the stent to “achieve a much taller structure with less weight than compared with one that was all made up with little loops all the way to the

top.” A10809. He never suggested that “projecting” had some special meaning to skilled persons in 1990.

Finally, both sides’ experts agreed that Claim 1 requires the commissural supports to project from another separate component of the stent—the “cylindrical support means.” A10864, A11537-A11541. In this way, the claim requires two structural elements that serve as “reference points” for the “projecting from” limitation. See *Becton Dickinson*, 616 F.3d at 1255; *Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 908 (Fed. Cir. 2005) (“flattened” is a “comparative term” that requires a “reference point”). Under this requirement, the commissural supports must “project from” the “cylindrical support means,” not from some other part of the device.

2. CoreValve’s integrated support structure does not include a plurality of commissural supports “projecting from” a cylindrical support means.

No commissural supports “protrude from” or “stick out of” the support means in the CoreValve device, as they do in the embodiments of the ’552 patent. The CoreValve inventors concluded that “post” structures would likely collapse under the stress of the valve’s operation. A11131-A11132, A11693-A11694. For this reason, they fundamentally changed the support system for the commissural points, as is evident from visual comparison:

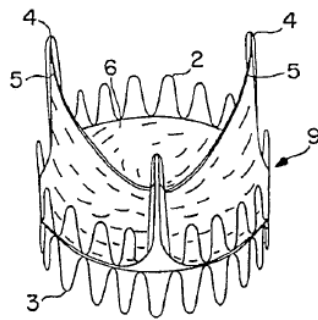


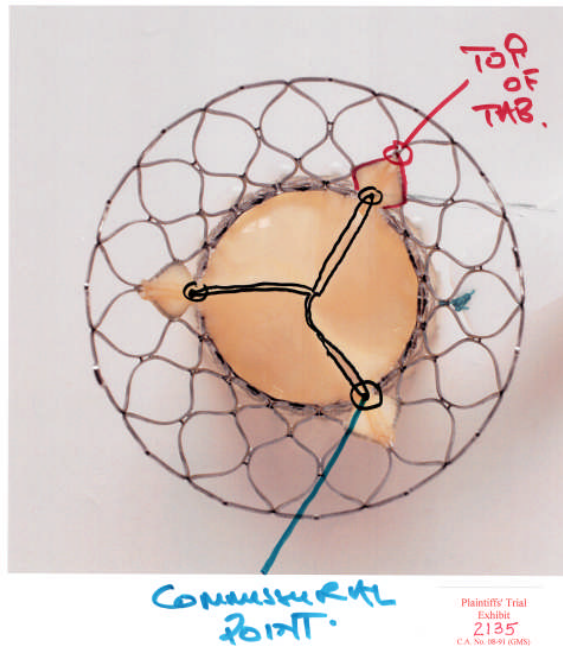
FIG. 2



A00057, A12897.

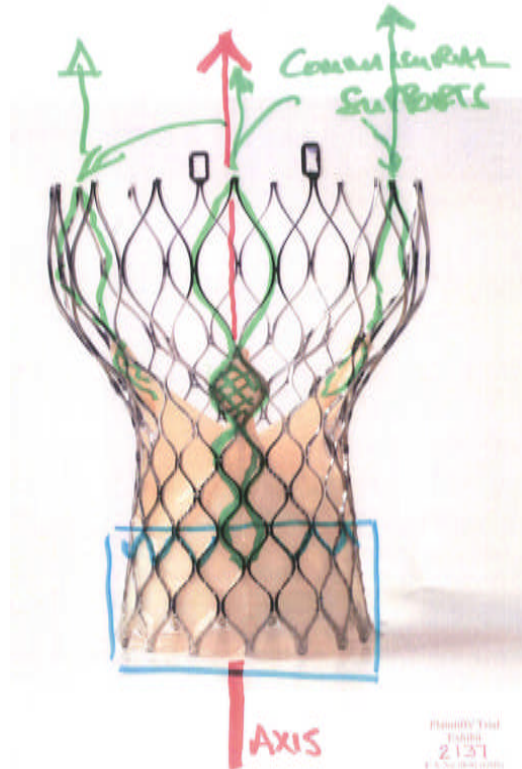
Rather than rely on three “projecting” posts, the CoreValve device supports the commissural points using an integrated wire mesh of rounded, interconnecting diamonds in which no part of the device “protrudes” or “juts out” from the rest of the stent. A11538. The commissural supports are integrated into the “honeycomb” of rounded diamonds that circle the middle of the stent at a 30° angle from the longitudinal axis. A11542-A11546, A11715-A11719. This design enables the stent to reduce stress more effectively by “sharing the load” among the network of supporting rounded diamonds. A11544-A11545, A11711.

Edwards did not dispute any of these points at trial. Dr. Buller, for example, freely admitted that in the CoreValve device the commissural points are not affixed to projecting “posts,” but instead lie in the *middle* of the stent—as he illustrated with a “top-down” photograph of the device:



A10855. Dr. Buller further admitted that, unlike the easily-identifiable posts in the '552 patent, the rounded diamonds used to support the commissural points in the CoreValve device cannot be distinguished from other diamonds until the valve is actually sutured in place. A10975-A10976.

Edwards nonetheless insisted at trial that the CoreValve device's commissural supports “project[] from [one side of] the cylindrical support means,” just like the three posts in the embodiments of the '552 patent. A10971, A10863-A10865, A10953. To support this assertion, Edwards relied solely on Dr. Buller's testimony and his use of a green marker to outline three “projecting” commissural supports on the *surface* of the accused device:



A31342. Based on this drawing, Dr. Buller testified that the CoreValve device’s commissural supports meet the “projecting” limitation because the device “as a whole” purportedly “projects generally upwards.” A10866-A10867, A10967-A10968.

Dr. Buller presented *no evidence of any kind* to support his unique view of “projecting.” He provided no test results or other data showing that the specific diamonds within his green outlines (and no other diamonds) support the commissural points in the accused device. Nor did he provide any particularized explanations to justify his conclusions. He did not explain, for example, how the rounded diamonds he marked differ from the other diamonds in the stent, or how

the diamonds at the top of the stent could possibly support commissural points lying in the middle of the stent. Instead, he simply presented *ipse dixit* conclusions in the form of his green outlines:

And the structure that supports the commissures is the column or tower that rises up from the cylinder support means to the top of the device.

And I'm outlining one of them. Again, one is shown at the front of the device. And this is the structure going up. It includes the tab on which the commissural point is mounted.

So I hope my green shows up at the back.

But this is the structure that projects upwards from the cylindrical supports means and is the structure that has the support for the commissural points.

A10864.

Such conclusory assertions cannot support a verdict of infringement. This Court repeatedly has set aside jury verdicts resting on generalized expert testimony that provided no "particularized" factual basis for the experts' conclusions. *Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1320 (Fed. Cir. 2006); *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567-68 (Fed. Cir. 1996). In *Kim*, for example, the Court upheld a district court decision vacating a jury verdict because the patentee's expert did not support her conclusory assertions with tests of the accused product. 465 F.3d at 1320. Similarly, in *Texas Instruments*, the Court set aside the jury's infringement verdict because the patentee's experts failed

to provide any “particularized” explanation of how the accused device infringed the patent. 90 F.3d at 1568; see also *Hewlett-Packard*, 340 F.3d at 1323 (evidence supporting infringement verdict must include “particularized testimony and linking argument”).

These decisions are especially applicable here where Edwards relied on expert testimony that was not only conclusory but also inconsistent. In his direct examination, Dr. Buller maintained that the CoreValve device has three commissural supports consisting of the diamonds located within each of his green outlines. On cross-examination, however, he conceded that *all* of the diamonds (or “cells”)—“the entire structure”—support the commissural points:

Q: So this cell here also supports the commissural point. Right?

A: *All of the cells to greater or lesser degree do. It’s an integral structure, just like Andersen is teaching.*

Q: *So all of the cells on this device are useful in supporting the commissural points. That’s what you are telling us?*

A: *All of them are useful yes.*

Q: So I could have picked this one or this one or this one or this one, and that would also be a portion of the valve that supports the commissural support—the commissural point. Right?

A: *All of the structure of both Andersen’s preferred embodiment and this infringing device, in my opinion, supports the valve.*

A10968 (emphasis added). Indeed, according to Dr. Buller, the device would fail if the metal between his green outlines were removed from the stent. A10950.

This concession transformed Dr. Buller’s theory of the nature of the “commissural supports” in the accused device. As noted above, the district court construed “commissural supports” to mean the “portions of the stent that support the commissural points of the valve.” A00051. But if the *entire structure* of the device supports the commissural points, then the entire structure—and not just the rounded diamonds he outlined in green—constitutes the “commissural supports.”

Dr. Buller’s testimony showed that the CoreValve device does not infringe the “projecting” limitation as a matter of law. Claim 1 requires the commissural supports to “project from” one side of a specific component of the stent—the cylindrical support means. These two required structural elements—commissural supports and cylindrical support means—plainly cannot be met if the “whole structure” constitutes the “commissural supports” because the “whole structure” cannot possibly “project from” one of its own component parts.

This Court addressed a similar infringement argument in *Becton Dickinson*, 616 F.3d at 1255. The Court rejected the patentees’ assertion that a claim requiring two “separate structural elements” (a “hinged arm” and a “spring”) could be met by a device containing a single component that performed both functions. The Court reasoned that “[i]f the hinged arm and the spring means are one and the

same, then the hinged arm must be connected to itself and must extend between itself and a mounting means, a physical impossibility.” *Id.* at 1256. The Court therefore concluded that the accused device did not infringe because it did “not contain a spring means that is a separate structural element from the hinged arm and its hinges.” *Id.*

Similarly, in this case, the “projecting” limitation requires “two separate structural elements”—the commissural supports must “project from” the cylindrical support means. But Dr. Buller’s testimony showed that the CoreValve commissural supports are the “whole structure” (which necessarily includes the cylindrical support means), and the “whole structure” cannot “project from” itself. *Becton Dickinson*, 616 F.3d at 1255-56. As a matter of law, then, the CoreValve device lacks “a plurality of commissural supports” that project from the cylindrical support means, entitling CoreValve to judgment in its favor on Edwards’ literal infringement claim. See also *Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004).

B. CoreValve’s Commissural Supports Do Not Project In A Direction “Generally Parallel” To The Longitudinal Axis.

Undisputed evidence also showed that the CoreValve commissural supports do not project “in a direction *generally parallel* to the longitudinal axis.” A00064 (Col. 8, Ins. 9-11) (emphasis added). This Court has held that “the phrase ‘generally parallel’ envisions some amount of deviation from exactly parallel.”

Anchor Wall, 340 F.3d at 1311. Consequently, CoreValve’s commissural supports need not project in a direction *perfectly parallel* to the longitudinal axis. But they cannot deviate so far from parallel as to make the “generally parallel” limitation “functionally meaningless.” *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 885 (Fed. Cir. 2008).

The district court instructed the jury to apply the plain meaning of “generally parallel” to one skilled in the art. A08858-A08859. Undisputed evidence showed that the CoreValve device has a chalice-like shape that includes a 30° angle to the longitudinal axis of the frame and a pronounced curvature in its bulbous upper half:



A10971, A11463, A11544-A11545. Undisputed evidence also showed that the CoreValve commissural points lie on the “slopes” of the 30° angle that circles the

middle of the stent just above its narrow waist. A10855, A10967, A10970, A11716, A11545-A11546.

CoreValve expressly designed the stent to have an angled structure (rather than parallel sides) to avoid contact with the walls of the aorta and to enable the valve to function correctly regardless of variations in the size of the vessel. A11719-A11720. In addition, the 30° angle provides an ideal attachment site for the valves by producing a hammock-like effect that enhances stability and reduces stress fatigue from the valve's operation. A11544-A11545.

The CoreValve experts testified that the 30° angle at which the commissural supports extend from the longitudinal axis could not be characterized as “generally parallel” under any interpretation of the phrase. A11543, A11714-A11718. Edwards did not dispute either the 30° angle or the pronounced curvature in the bulbous portion of the stent. Instead, Edwards relied exclusively on Dr. Buller's claim that CoreValve's commissural supports could be analogized to a fork that points “generally upwards” despite its “bends.” A10971. Dr. Buller insisted that the “fork” analogy applies because the “generally parallel” limitation means only that “the whole structure, *looked at from top to bottom*, has to be orientated in a direction generally in line with the longitudinal axis.” A10867 (emphasis added).

The validity of Dr. Buller's analogy depends entirely on his claim that CoreValve's commissural supports encompass the top part of the stent that extends

above the commissural points. A10866-A10867. But if the commissural supports encompass only the portion of the stent that ends with the commissural points (on the slope of the 30° angle), then the supports could not be analogized to a “fork” or otherwise be deemed “generally parallel” to the longitudinal axis. A00064 (Col. 8, lns. 9-11).

As noted above, Dr. Buller provided no test results or other data to support his counterintuitive view that CoreValve’s commissural supports include the entire top half of the stent, when the commissural *points* are affixed to the middle of the structure. See *Kim*, 465 F.3d at 1320. He simply drew a green outline on a photograph of the accused device and pronounced the figure a “commissural support.” See *supra*, p. 46. Such “conclusory” and highly “generalized” testimony cannot sustain an infringement verdict. See *Texas Instruments*, 90 F.3d at 1567-68.

In sum, CoreValve is independently entitled to entry of judgment of noninfringement as a matter of law on either of two alternative grounds—the “projecting” or the “generally parallel” limitations. See *Hewlett-Packard*, 340 F.3d at 1322-23 (JMOL rather than new trial is appropriate when patentee fails to present at trial sufficient evidence of infringement as a matter of law).

Edwards failed to prove literal infringement as a matter of law, and it cannot rely on the doctrine of equivalents. Although Claim 1 in the U.S. patent

application originally required (as in the analogous European patent) that the commissural points be “mounted on the cylinder surface of the elastical stent” (A20458), the patentees added the limitation requiring that the “commissural supports” be “projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis” in response to obviousness and anticipation objections. See *supra* p. 10, citing A20538-A20539, A20566-A20569, A20571-A20574. The patentees thereby disclaimed any equivalents to those limitations. See, e.g., *Voda v. Cordis Corp.*, 536 F.3d 1311, 1325 (Fed. Cir. 2008). They cannot regain that disclaimed subject matter now.

III. THE '552 PATENT IS NOT ENABLED FOR HUMAN USE.

No patent claim is valid unless the specification “enable[s] any person skilled in the art ... to make and use” the claimed invention. 35 U.S.C. § 112, ¶ 1. To be enabling, the patent specification “must teach those skilled in the art how to make and use the full scope of the claimed invention” as broadly as it is claimed and “without ‘undue experimentation.’” *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010). Enablement is determined as of the patent application’s effective filing date. *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999). A claimed invention with multiple aspects must enable the “full scope” of the claims. *Id.* Here, the evidence was clear and

convincing—indeed, materially undisputed—that the ’552 patent does not enable a valve prosthesis suitable for human use, as the full scope of Claim 1 requires.

Because no reasonable jury could have found the claimed invention enabled on this record, the district court should have granted judgment as a matter of law in favor of CoreValve.

A. Claim 1 Encompasses A Device Suitable For Human Use.

The full scope of Claim 1 indisputably includes a heart valve suitable for use in humans. Neither the parties nor the district court ever suggested that Claim 1 does not encompass a valve prosthesis suitable for human use. Indeed, Edwards’ opening statement told the jury that “[t]he patent is intended to replace open-heart surgery in human beings, not to do testing on animals.” A10554-A10555.

The patent itself substantiates that purpose. Claim 1 recites “a valve prosthesis for implantation in a body channel” (A00064 (Col. 7, lns. 57-59)), and the specification makes clear that “body” includes “human body.” It states that an aortic valve prosthesis will “make[] it possible for *the patient to resume a substantially normal life*” (A00061 (Col. 2, lns. 24-27) (emphasis added)), and notes that “patients” at high risk for surgery “can be offered implantation of ... cardiac valves.” A00062 (Col. 3, lns. 5-7). Only human “patients” can be “offered” treatment choices. The specification then observes that “the after-treatment will advantageously be shorter than normally, which means fewer

hospital days for *the patient*” (*id.*, Col. 3, lns. 8-10 (emphasis added)), many of whom are “elderly people who cannot be offered a surgical cardiac operation.” *Id.* (Col. 3, lns. 57-59).

In fact, the only reference to veterinary use is in the context of experimental development for human application. The specification describes the design used for pig testing and then states that “the cardiac valve prosthesis for use in human beings has a corresponding form.” A00063 (Col. 5, lns. 38-39).

That is not to say that the patent does not cover implantation in animals. But a claimed invention with multiple aspects must enable the “full scope” of the claim. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Thus, this Court recently affirmed a finding of non-enablement for a means of achieving extended release of a drug, where the claims encompassed both osmotic and non-osmotic means but the specification enabled only osmotic means. *Alza*, 603 F.3d at 940. The Court similarly held that technology claims that were “broad enough to cover both movies and video games” were not enabled because the specification did not teach how the required functions “would be accomplished in movies.” *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1000 (Fed. Cir. 2008); see also *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1378-79 (Fed. Cir. 2007) (where “the full scope of the claimed inventions includes injectors with and without a pressure jacket, [t]hat full scope must be enabled”); *Automotive Techs.*, 501 F.3d at

1285 (“the specification must enable the full scope of the claims that includes both electronic and mechanical side impact sensors, which the specification fails to do”).

Because the full scope of Claim 1 plainly includes suitability for use in humans, the claimed valve prosthesis must have been enabled for implantation in a human heart as of the patent’s effective filing date. Because it was not, Claim 1 is invalid.

B. The ’552 Patent Disclosure Does Not Disclose How To Make A Heart Valve Prosthesis For Human Use.

“Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). The ’552 patent provided, at most, “only a starting point, a direction for further research.” *Automotive Techs.*, 501 F.3d at 1284.

In assessing whether claims have been enabled, this Court applies the factors initially articulated in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); see *Alza*, 603 F.3d at 940. Those factors are: (1) the quantity of experimentation necessary; (2) the amount of guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability of the art; and (8) the breadth of the claims. *Id.* In this case, application of the *Wands* factors

shows that a person of skill in the art could not have made or used a heart valve prosthesis for implantation in a human body based on the '552 specification without undue experimentation. Indeed, no one has succeeded in doing so, although many have tried.

At the time of the patent application, the prospect of replacing an aortic valve in a human via catheterization was a “wild idea.” A20094. Yet the '552 patent provides no guidance and contains no working examples. After noting that the “valve prosthesis produced is used for performing tests in pigs,” the specification states only that a “corresponding form” is required for human implantation. A00063 (Col. 5, lns. 35-39). But it gives no indication as to what that “form” might be or how it would “correspond” to the described structure. The best evidence of this deficiency is the inability of anyone to develop the claimed invention for human use.

1. The quantity of experimentation needed shows that the '552 patent was not enabled.

In *AK Steel*, 344 F.3d at 1244, this Court found a patent non-enabled where the defendant “presented documentary and testimonial evidence [that] at least a significant amount of experimentation would have been necessary to practice the claimed invention.” Here, too, significant experimentation was necessary to make and use the asserted valve prosthesis for implantation in a human heart.

At trial, Edwards' witnesses acknowledged that, as of the filing date, the sole working embodiment could be used only in pigs (though it quickly killed even them) and that the inventors had not developed a device for use in humans. A20119-A20121, A20170-A20172, A10813-A10814, A10915-A10916. The inventors acknowledged that, at that time, a skilled artisan would have had to undertake extensive experimentation to solve distinct problems in developing the prosthesis for human use, in particular how to design a device sufficiently compressible to fit into human arteries and sufficiently stable to withstand the pressures of the valve's operation.

According to inventor Henning Andersen, "a lot of research" was required before their prototype based on the '552 patent could be used in humans. A20227-A20228. In fact, a 1993 article by Dr. Andersen stated that the prototype required "long term follow-up studies in laboratory animals before human application be considered," in part because "[t]he device's dimensions have to be reduced for femoral intrusion." A31536.

Inventor John Hasenkam also admitted that the prototype device based on the '552 patent "could not be implanted in a human" (A20167), noting that "many more complex and long term animal studies must be performed before even speculation concerning [human] clinical use is begun." A20184. For example, at the time of the patent filing, Hasenkam was "not able to determine certain very

important characteristics of the device such as whether it could stay fixed in the aortic annulus.” *Id.* Hasenkam also “knew back in 1990 that the stent valves that [he was] building were too bulky [for the] human femoral artery.” A20169.

In a contemporaneous paper, co-inventor Dr. Knudsen characterized “the experiments undertaken” as merely “a preliminary technical investigation.” A11663. He acknowledged that “many important questions still remain open,” and that “questions such as size reduction, material and design optimization, and stent valve sterilization, remain unsolved.” *Id.* He and his colleagues did not “attempt to resolve any of those important questions.” *Id.* Rather, “much more work had to be done before anybody ever even contemplated using this for a human.” A11663-A11664.

Edwards’ expert, Dr. Buller, agreed that the device disclosed in the ’552 patent “was a device to perform testing on” and “not a device to move in and treat patients.” A10815. He too called the pig implantation performed by the inventors “very preliminary work,” leaving “lots of questions remain[ing] to be answered.” A10904.

In sum, the inventors had nothing more than an interesting idea, and “[t]ossing out the mere germ of an idea does not constitute enabling disclosure.” *Genentech*, 108 F.3d at 1366.

2. The specification offers no guidance on how to make and use a prosthetic heart valve for human use.

Undisputed empirical evidence confirms that undue experimentation was necessary to make a heart valve prosthesis based on the '552 patent. In the 20 years since the initial patent application was filed, and despite strong financial incentives, no one, including Edwards, has been able to develop a human heart valve prosthesis according to the teachings of the '552 patent. As Dr. Rothman put it, no device “has been approved for human use that is designed according to the claim limitations of Claim 1.” A11742-A11743; see also A11525-A11529. That inability to develop the invention for the application touted in the specification is powerful evidence of nonenablement. *Alza*, 603 F.3d at 942.

The failures of these developers resulted from defects in the '552 patent design. Among other problems, the claimed invention could not withstand the blood pressure to which an aortic heart valve is subjected. A11528-A11531. Contemporaneous materials from the PVT developers said that its dimensions were “much too large for percutaneous placement.” A31538-A31544; see also A11693-A11694. Given these and other technical obstacles, it is not surprising that, despite repeated efforts, “[n]either Stanford Surgical nor Heartport ever developed a device for implantation in a human.” A20204.

It took many years before a valve prosthesis of any sort was percutaneously implanted in a human heart, and that was not developed based on the '552 patent.

Alain Cribier—co-founder of PVT and a person acknowledged to be “well regarded” in the field in 1990 (A10915-A10916)—had to devote ten years of development work before he could successfully implant a bioprosthetic heart valve sutured onto a balloon expandable stent into a human patient. A20146, A20264, A11366-A11367, A11371, A11383, A11389. To do so, Cribier had to use an *alternative* design, having concluded that “technical limitations impaired any human application” of the device described in the ’552 patent. A11381, A31924.

In *Alza*, this Court relied on testimony from the plaintiff’s own employees to conclude that their inability to develop non-osmotic dosage forms showed that the patent claims at issue were non-enabled. 603 F.3d at 942. The same conclusion follows here. Stan Rowe, one of the founders of PVT and now a product developer at Edwards, authored a document entitled “Andersen Patent Limitations” which contained his “criticism of the Andersen technology in general at that time.” A11665-A11667. He wrote that the ’552 patent “sadly does not describe a method or design that if constructed is percutaneous and functional over any durable period.” A11674, A31544. Rowe explained that the disclosed device was “much too large” and lacked “sufficient strength” for human implantation. A31544. PVT tested the patent disclosure and found it did not work, concluding that the “stent protrusions” did not “fulfill their function” of supporting the valve bend against hydraulic pressure. A24543, A31594.

Alain Cribier, who is now a paid consultant for Edwards (A11386), similarly found the design disclosed in the '552 patent useless for developing a device suitable for human implantation. In his own patent application, Cribier stated that the '552 design was “inherently fragile,” had “a high risk of massive regurgitation,” and was “impossible to use in clinical practice.” A31392 (Col. 2, lns. 66-67), A31393 (Col. 3, lns. 11-15), A11378-A11379. Among other problems, “such a light stent structure is too weak to allow the implantable valve to be forcibly imbedded into the aortic annulus.” A11378. At trial, Cribier reiterated his view that the '552 prototype had limitations “that would very likely prevent any possible human application ... because of the size, for example.” A11382.

Edwards now has rights to the SAPIEN valve, a commercial embodiment of the Cribier patent (see *supra* pp. 24-25). Development of the SAPIEN valve took over a decade after the priority date. A20264, A10631-A10632. According to Netanel Benichou, a former PVT employee now employed by Edwards who was one of the lead design engineers of the SAPIEN valve, the '552 patent contributed nothing to the development of that valve. A11386-A11387, A11398.

In sum, the evidence is clear and convincing that the '552 patent disclosures did not enable a person of ordinary skill in the art to make or use the claimed valve prosthesis for human use without undue experimentation. Accordingly, Claim 1 is

not enabled as a matter of law, the verdict should be reversed, and judgment of invalidity should be entered in favor of CoreValve.

IV. THE LOST PROFITS DAMAGES AWARD CANNOT BE SUSTAINED.

This Court has increasingly scrutinized and reversed damages awards that “relied on speculative and unreliable evidence divorced from proof of economic harm linked to the claimed invention.” *ResQNet.com v. Lansa, Inc.*, 594 F.3d 860, 868 (Fed. Cir. 2010). The \$72 million lost profits award here “is inconsistent with sound damages jurisprudence” and should be vacated. *Id.*

Infringement damages must rest on “a fair and accurate reconstruction of the ‘but for’ market” in the absence of infringement, taking into account “alternative actions the infringer foreseeably would have undertaken had he not infringed.” *Grain Processing Corp. v. American Maize-Prods. Co.*, 185 F.3d 1341, 1350-51 (Fed. Cir. 1999). Any such assessments must reflect “sound economic proof” (*id.* at 1350), which in turn “requires some grounding in sound economic and factual predicates.” *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1309 (Fed. Cir. 2006).

“[T]he availability of lost profits is a question of law for the court.” *Wechsler v. Macke Int’l Trade, Inc.*, 486 F.3d 1286, 1293 (Fed. Cir. 2007). Lost profits are unavailable unless the patent holder proves both its own “manufacturing and marketing capability to exploit the demand” and “an absence of acceptable noninfringing substitutes” available to the infringer. *Siemens*, 2011 WL 651790, at

*13. If noninfringing substitutes were available during the period of infringement, the infringer could have maintained its market position after it stopped infringing, making compensation by a reasonable royalty the only appropriate measure. See *Riles v. Shell Explor. & Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002).

The parties did not dispute that Edwards lacked any “capability to exploit the demand” for catheter-implantable artificial heart valves until August 2007, when it received regulatory approval in Europe. The parties also agreed that, in the “but for” world, CoreValve would have sold an “acceptable noninfringing substitute[]”—indeed, the same device it actually sold—by manufacturing the accused device in France or another country where Edwards lacked patent rights. A11034-A11037, A11615-A11617. Thus, the controlling question is *when* CoreValve would have been able to manufacture the devices overseas and sell products that were made without infringing a U.S. patent. If the latest date supported by the evidence is before August 2007, CoreValve is entitled to judgment on lost profits damages; if that date is any time before trial, CoreValve is entitled to a new trial on lost profits damages.

This Court examines “the nature of the market” at the dates of first infringement and of first claimed lost profits to determine whether and when the infringer would have been able to use an acceptable noninfringing alternative. *Grain Processing*, 185 F.3d at 1350, 1353. The parties agreed that CoreValve’s

hypothetical efforts to avoid infringement should be evaluated as of the date of first infringement.

The evidence indisputably showed that the CoreValve device first infringed (if it infringed at all) when CoreValve first made the Generation 2 stent frame in August or September 2004. A11495, A11518. Edwards admitted that CoreValve's Generation 2 frame was identical to the frame of the accused Generation 3 device for purposes of infringement. A11453, A10973-A10974. Indeed, Edwards accused the Generation 2 device of infringing the '552 patent in an April 2005 letter. A22940-A22941.

There was no dispute that CoreValve originally operated in France, and in fact continued to work on the catheter for the CoreValve device in Europe even after moving development of the stent and valve to California in September 2004. A11011, A11015, A11151-A11152. Nor is there any dispute that, had CoreValve sought to avoid infringing the '552 patent in fall 2004, it would not have moved its manufacturing and development operations to California, but would have moved operations to another site in Europe or elsewhere. A11323, A11478-A11480. Even if CoreValve had moved some operations to California and decided to move them *back* to Europe (or elsewhere) only after receiving Edwards' April 2005 cease-and-desist letter, the only evidence addressing the duration of the relocation process in that period indicated that CoreValve would have completed the move

before receiving approval to market the accused device in Europe in March 2007. A11482. CoreValve could have relocated much more quickly in those years, when it was only conducting clinical trials, than after it began commercial manufacturing. See *id.* The noninfringing substitute manufactured overseas would have been available and sold long before Edwards was in a position to make or lose any relevant profits.

The jury's lost profits award—which necessarily assumes that CoreValve would not have been able to manufacture overseas even by 2010—rests entirely on an unsupported premise: that the date of first infringement did not occur until January 2006, when CoreValve “froze” the design of the accused Generation 3 device. Edwards' expert, Gregory Leonard, assumed that was the date of first infringement solely because Edwards' lawyers so instructed him. A11034-A11035. He identified no evidence supporting that assumption, which could not possibly be correct. A design freeze is not an infringing act under 35 U.S.C. § 271(a), and the device design could not be “frozen” unless devices using that design had been made (and thus infringed) earlier.

In short, undisputed evidence “show[ed] that the substitute” of manufacturing in Europe “was ‘available’ during this period” after August 2007, when Edwards first obtained approval to market its own device, “based on alternative actions that [CoreValve] reasonably could have taken to avoid

infringement.” *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1331 (Fed. Cir. 2009) (quoting *Grain Processing*, 185 F.3d at 1353). The lost profits award should be vacated.

* * *

At bottom, Edwards seeks to use an unwarranted patent for a failed invention to block others from developing an innovative and radically different prosthetic valve that actually works. Whereas the CoreValve device is directed to actual anatomical features, enabling it to save many thousands of lives, the ’552 patent design—with its cylindrical shape and projecting supports—is fundamentally defective and has never been successfully implanted even in animals, much less human beings. Allowing Edwards to wield the ’552 patent to free-ride on—and garner enormous damages from—the success of the life-saving invention would be inconsistent with patent law and policy.

CONCLUSION

The judgment should be reversed and judgment entered in favor of CoreValve.

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The undersigned, an attorney, hereby certifies that on May 18, 2011 she caused two copies of the foregoing Non-Confidential Opening Brief of Defendants-Appellants to be served upon the following by United Postal Service overnight express and e-mail:

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1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B).

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