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.

2011-1215,-1257

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

Decided: November 13, 2012

JOHN E. NATHAN, Paul, Weiss, Rifkind, Wharton & Garrison, LLP, of New York, New York, argued for plaintiffs-cross appellants. With him on the brief were CATHERINE NYARADY, KRIPA RAMAN, BRIAN P. EGAN and ROBERT A. WEINSTOCK. Of counsel on the brief was JACK B. BLUMENFELD, of Wilmington, Delaware.

JEFFREY W. SARLES, Mayer Brown LLP, of Chicago, Illinois, argued for defendants-appellants. With him on the brief were JAMES R. FERGUSON, MELISSA A. ANYETEI and BRENT A. BATZER. Of counsel on the brief were DONALD M. FALK and RITA K. LOMIO, of Palo Alto, California.

Before RADER, *Chief Judge*, NEWMAN and PROST, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* NEWMAN.

Concurring opinion filed by *Circuit Judge* PROST.

NEWMAN, *Circuit Judge*.

Edwards Lifesciences AG and Edwards Lifesciences LLC (collectively "Edwards") sued defendants CoreValve, Inc. and its successor in interest Medtronic CoreValve, LLC (collectively "CoreValve") for infringement of United States Patent No. 5,411,552 ("the '552 patent") issued May 2, 1995, entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting Such Valve Prosthesis." Two other patents, initially in suit, are not at issue. The inventors are Dr. Henning R. Andersen, an interventional cardiologist at Aarhus Medical School in Denmark, his surgical colleague Dr. John M. Hasenkam, and then medical student Lars L. Knudsen.

The invention is a prosthetic device called a "transcatheter heart valve." The valve is mounted on a stent and implanted in the heart by catheter, thereby avoiding open heart surgery and its associated risks. Suit for infringement was brought in the United States District Court for the District of Delaware, trial was to a jury, and the verdict was that the '552 patent is valid, that CoreValve's Generation 3 ReValving System infringed patent claim 1, and that

the infringement was willful. The jury awarded damages of $72,645,555 in lost profits and $1,284,861 as a reasonable royalty.[1]

The district court entered judgment on the verdict, but declined to enhance damages for the willful infringement. The court also declined to issue an injunction against future infringement, apparently on CoreValve's representation that, if enjoined, it would move its manufacturing operations to Mexico. The court also denied Edwards' request to modify the litigation-agreed protective order and to permit Edwards' patent counsel and technical expert to participate in the ongoing reexamination proceedings of the patent in suit and related patents. Each party appeals the rulings adverse to it.

We affirm the district court's rulings, except that we remand for reconsideration of the court's denial of an injunction in view of the representation of changed circumstances, and for reconsideration of the court's ruling on the protective order as applied to patents not in suit, to the extent that this issue has not become moot.

I

VALIDITY OF THE '552 PATENT

The '552 patent is directed to a collapsible stent that carries a valve for insertion into the heart by balloon catheter. Figure 1 of the '552 patent shows the collapsible stent with projecting apices at **4**. Figure 2 includes the elastically collapsible valve **6** held to the apices at commissural points **5**:

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[1] *Edwards Lifesciences AG v. Medtronic, Inc.*, No. 09-873-GMS, 2011 U.S. Dist. LEXIS 12022 (D. Del. Feb. 7, 2011).

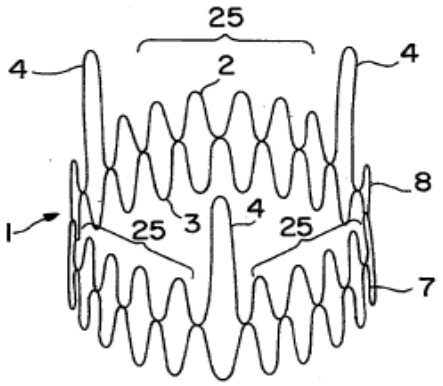


FIG. 1

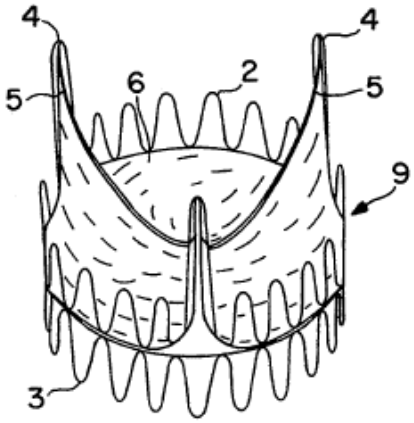


FIG. 2

To implant the valve, the stent and valve are compressed into a balloon catheter, and moved through a blood vessel for release at the implantation site, where the balloon expands the stent and wedges it into the desired location for the valve. The patent illustrates various placements of the valve in the heart. Figure 8 describes "a position between

the coronary arteries **20** and the left ventricle of the heart **21**:"

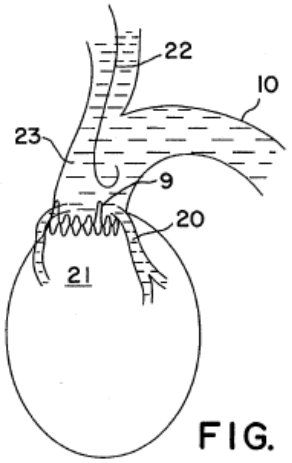


FIG. 8

The only ground on which CoreValve challenged validity of the patent was for lack of enablement based on the undisputed fact that at the time the '552 patent application was filed the stent/valve prosthesis had been implanted only in pigs. CoreValve also pointed out that the various experimental implants in pigs were not always successful, and that design changes were made after the patent application was filed.

Edwards agrees that more developmental work was required at the time of filing. Co-inventor Knudsen wrote, in a contemporaneous report, that "questions such as size reduction, material and design optimization, and stent valve sterilization, remain unsolved," and that "much more work had to be done before anybody ever even contemplated using this for a human." Edwards' expert witness Dr. Buller testified that at the time the patent application was filed, it was "a device to perform testing on" and "not a device to move in and treat patients." The jury was instructed on the issue of enablement as follows:

> The Patent Laws require that the patent be sufficiently detailed to enable those skilled in the art to practice the invention. The purpose of this requirement is to ensure that the public, in exchange for the patent rights given to the inventor, obtains from the inventor a full disclosure of how to make and use the invention.
>
> If the inventors failed to provide an enabling disclosure, the patent is invalid. However, because descriptions in patents are addressed to those skilled in the art to which the invention pertains, an applicant for a patent need not expressly set forth in his specification subject matter which is commonly understood by persons skilled in the art.
>
> The enablement defense does not require an intent to withhold; all that is required is a failure to teach how to practice the full scope of the claimed invention. In other words, if a person of ordinary skill in the art could not make and use the invention disclosed in the patent without undue experimentation, the patent is invalid. However, some routine amount of experimentation to make and use the invention is allowable.
>
> The patent need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art to which the invention pertains will be able to practice it without an undue amount of experimentation.

Final Jury Instructions at 25 (April 1, 2010).

This instruction correctly states the law. Precedent establishes that "[t]he enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (quoting *Engel Indus., Inc. v.*

Lockformer Co., 946 F.2d 1528, 1533 (Fed. Cir. 1991)). *See also Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1307 (Fed. Cir. 2010) ("the district court erroneously required Transocean to enable the most efficient commercial embodiment, rather than the claims"); *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1307 (Fed. Cir. 2001) ("If the disclosure enables a person of ordinary skill in the art to make a particular metal oxide coating from at least one of the suggested precursors, the enablement requirement for that oxide coating is satisfied"). Continuing development is often contemplated and necessary, while early filing is often essential.

CoreValve argues that in no event does testing in pigs enable use in humans. However, it has long been recognized that when experimentation on human subjects is inappropriate, as in the testing and development of drugs and medical devices, the enablement requirement may be met by animal tests or *in vitro* data. *See* MPEP §2164.02 ("An *in vitro* or *in vivo* animal model example in the specification, in effect, constitutes a 'working example' if that example 'correlates' with a disclosed or claimed method invention."). This general rule has been elaborated in various situations, *e.g.*, *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995) ("one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment in humans"); *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994) ("Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration. Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office proceedings.").

Useful criteria for determination of enablement for purposes of section 112 are summarized in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Factors to be considered in determining whether the subject matter requires undue experimentation include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (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 or unpredictability of the art, and (8) the breadth of the claims." *Id.* at 737.

There was evidence that the stent/valve prosthetic device was successfully implanted in pigs, in accordance with the procedure described in the '552 specification. It was explained that pigs were a standard experimental animal for heart valve research. Witnesses for both sides discussed the vascular anatomies of pigs and the established use of porcine valves in humans. Witnesses discussed the nature of the ongoing experimentation, in light of the district court's instruction on the enablement requirement. We agree with the district court that substantial evidence supported the jury verdict that invalidity on the ground of non-enablement had not been proved by clear and convincing evidence. The judgment of validity is affirmed.

II

INFRINGEMENT

There was evidence at trial on the origin and development of the patented device by the Danish inventors and their licensees. Witnesses described the initial professional skepticism including refusal of medical journals to publish the inventors' results; the persistence of the inventors; and the eventual recognition of their work as "most exciting" and

"pioneering." The record includes praise for the inventors from the CoreValve founder and the CoreValve CEO.

The litigation began with "claim construction," including two *Markman* hearings and opinions. Claim 1 of the '552 patent is as follows, with emphasis added to the terms that were the focus of the dispute as to infringement:

> 1. 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.

'522 patent col.7 1.57-col.8 1.19.

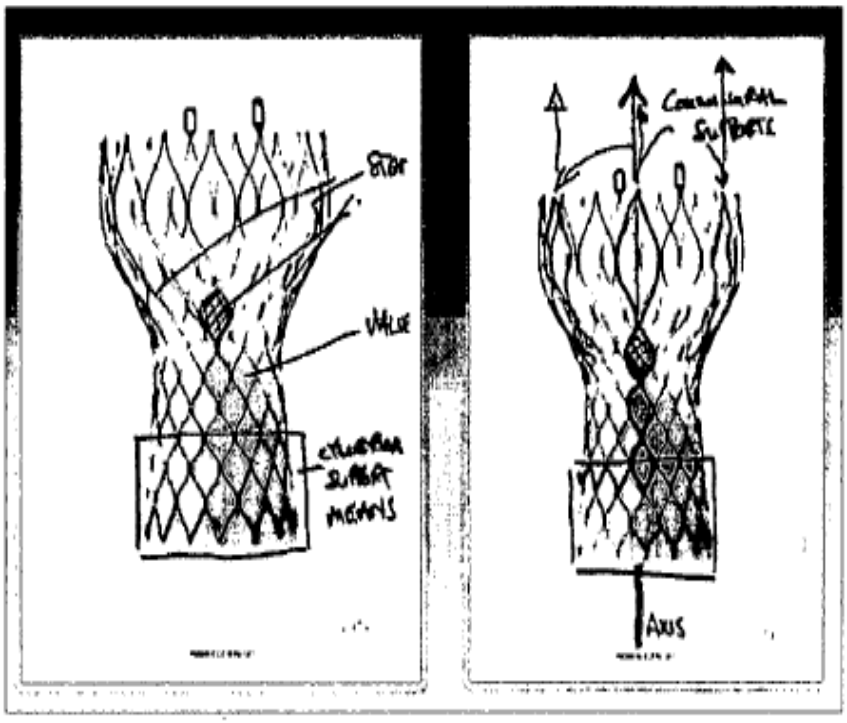
The district court construed "cylindrical support means" as "a portion of the stent supporting the valve that has a shape of or relating to a cylinder." The court ruled that the portion supporting the valve had to be cylindrical, but that the entire stent did not have to be of uniform cylindrical shape. The court instructed the jury as follows:

> "cylindrical support means" means "a portion of the stent supporting the valve that has a shape of or relating to a cylinder." 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.

Final Jury Instructions at 16-17 (April 1, 2010).

The district court instructed the jury as to the "projecting" term of the claim, as follows: "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."

The accused Medtronic/CoreValve Generation 3 is shown in the trial exhibit marked by Dr. Buller in conjunction with his testimony on whether this device met the claim limitations:



The jury found infringement. The parties agreed that "projecting" and "generally parallel" should be given their plain and ordinary meaning. On this appeal, CoreValve states that the district court's claim construction and thus the jury instructions were incorrect, and that on the correct construction, no reasonable jury could find infringement of the claim terms "cylindrical support means" and "commissural supports projecting . . . in a direction generally parallel."

Jury instructions are reviewed for correctness as a matter of law. Claim terms are construed in accordance with their usage in the patent specification, and as elaborated in

the prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc).

A

CoreValve argues that the district court improperly instructed the jury, by construing "cylindrical support means" sufficiently broadly that it could include the stent of the Generation 3. CoreValve states that "cylindrical support means" should be defined as a "stent structure where the mesh has a diameter that is constant along a longitudinal axis." CoreValve argues that the court's construction erroneously enlarged the ordinary meaning of "cylindrical" beyond its established meaning as a geometric term, and that the drawings in the '552 patent show that the inventors contemplated only the simple cylindrical shape that is illustrated in Figure 1. CoreValve states that the correct definitions exclude the Generation 3 device.

The district court explained in its *Markman* opinions that CoreValve's proposed construction "imports limitations that are not supported by the patent specification or the prosecution history . . . . Specifically, the term 'mesh' and the limitation that the diameter be 'constant along the longitudinal axis' are not found in the specification." We agree that the court's construction comports with the specification. Applying this construction, Dr. Buller testified that the portion of the Generation 3 that supports the valve is cylindrical, and that the Generation 3 device is a "cylindrical support means which is radially collapsible for introduction within the body channel." CoreValve argued to the jury that the general shape of the Generation 3 is not "cylindrical." Edwards pointed out that the specification describes a device designed for "implantation in a body channel," and that anatomical channels are rarely perfect cylinders. Witnesses for both sides agreed that the Genera-

tion 3 shape is designed to fit at the conjunction of the aorta and the left ventricle in order to inhibit migration of the stent after implantation, and Dr. Buller testified that the lower portion of the Generation 3 is the "cylindrical support means" for the commissural supports for the valve.

The record shows that there was substantial evidence to support a jury finding that the cylindrical support means of the claim is embodied in the Generation 3 device.

B

CoreValve also argued to the jury that the commissural supports in the Generation 3 are not "generally parallel" to the longitudinal axis of the stent, as required by claim 1. CoreValve argues on this appeal that "parallel" should have been strictly construed as a geometric term with no flexibility of meaning or application, citing *International Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1371 (Fed. Cir. 2004), where the court construed "polygonal" as requiring straight edges for only a straight-edged polygon was exemplified in the specification.

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." The parties presented testimony and argument on the embodiment of these elements in the accused prosthesis.

Dr. Buller in his testimony acknowledged that the drawings of the '552 patent show the commissural supports as taller than in the Generation 3 device.[2] He testified that the

[2] It was undisputed that the two small loops at the top of the Generation 3 device are not the commissural supports; they serve to attach the stent to the catheter.

Generation 3 device meets the "projecting" limitation because the "whole structure, one can say, is projecting generally upwards," drawing the upward axis on the exhibit as shown *supra*. CoreValve witnesses testified that the Generation 3 commissural supports are an "integrated wire mesh" of "rounded, interconnecting diamonds" that do not protrude or jut out from the stent and that are at a 30 degree angle from the longitudinal axis, and are not "generally parallel." CoreValve stressed the advantages of its structure that anchors the device in the aorta, as compared with the shape in the '552 patent. Edwards' witnesses disputed CoreValve's argument that the Generation 3 commissural supports do not project from the stent structure. Edwards argued that "projecting" is not limited to "sticking out" or "protruding," and its witnesses testified that the CoreValve commissural supports project in a direction generally parallel to the longitudinal axis of the supporting stent.

The district court noted that "Dr. Buller testified that the 'top' portion of CoreValve's device as shown in PTX 2136-37 contained the commissural supports (Tr. 768:21-771-2; PTX 2137) while the 'bottom' portion contained the cylindrical support means." *Edwards*, at *7 n.4. The court remarked that the jury could have believed Edwards' experts and not CoreValve's experts, as to the way the devices were structured and operated.

The testimony at trial was in direct conflict. "In determining whether the evidence at trial was sufficient to sustain the verdict, the court may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version." *Lightning Tube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993) (citation omitted). *See Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984) (the court may not "sub-

stitute its choice for that of the jury between conflicting elements of the evidence").

On the entirety of the proceedings at trial, there was substantial evidence to support the jury verdict that the Generation 3 device infringes claim 1 of the '552 patent. The judgment of infringement is affirmed.

III

REMEDIES

A

The record states that in 2004 CoreValve moved its manufacturing from France to California and hired former Edwards engineers, and that CoreValve's first implantation in humans was in 2006. The jury awarded Edwards its lost profits for the infringement, finding that Edwards could have met the demand, starting with the initiation of the Generation 3 design in January 2006. The jury also found that the infringement was willful.

CoreValve argues that the criteria for award of lost profits were not met, stating that it "could have manufactured its device overseas by March 2007," CoreValve Br. 3, and thus would have avoided all liability for infringement, by avoiding infringement. CoreValve argues that this eliminates liability for damages based on its manufacture in the United States, or that at most it should be liable for only a modest royalty. Neither the jury nor the district court was persuaded by this argument. Nor are we. Whether or not CoreValve could have avoided infringement, it did not do so, although it was notified as early as 2005 of Edwards' position, and the record showed CoreValve's familiarity with the patents and the inventors.

We affirm the district court's ruling sustaining the jury's damages award. *See Brooktree Corp. v. Advance Micro Devices*, 977 F.2d 1555, 1580 (Fed. Cir. 1992) ("the jury's finding must be upheld unless the damages award is 'grossly excessive or monstrous,' clearly not supported by the evidence, or based only on speculation or guesswork"). With respect to the verdict of willful infringement, although this finding was sustained by the district court, the court declined to enhance damages or award attorney fees, stating that the issues were "sufficiently close" and the defenses not frivolous. *See Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1005 (Fed. Cir. 2012) (enhancement of damages is not automatic). We do not discern abuse of discretion in the court's decision not to enhance damages.

B

Edwards requested entry of an injunction against future infringement, and cited several equitable considerations, including the importance of establishing customer relationships now that FDA approval has been obtained, and the fact that Medtronic, as a large medical device manufacture, could overwhelm the much smaller Edwards.

A patentee's right to exclude is a fundamental tenet of patent law. *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1247 (Fed. Cir. 1989) ("The right to exclude recognized in a patent is but the essence of the concept of property.") (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). The innovation incentive of the patent is grounded on the market exclusivity whereby the inventor profits from his invention. Absent adverse equitable considerations, the winner of a judgment of validity and infringement may normally expect to regain the exclusivity that was lost with the infringement. Edwards argues that

the Court's ruling in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) supports its position, for the willfulness of the infringement and other equitable aspects weigh in favor of restoration of the exclusive patent right.

The Court in *eBay* did not hold that there is a presumption against exclusivity on successful infringement litigation. The Court did not cancel 35 U.S.C. §154, which states that "Every patent shall contain . . . a grant . . . of the right to exclude others from making, using, offering for sale, or selling the invention," nor did the Court overrule Article I section 8 of the Constitution, which grants Congress the power to "secur[e] for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." The Court held that equitable aspects should always be considered, stating: "We hold only that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." *eBay*, 547 U.S. at 394. Statutory and historical as well as commercial considerations impinge on every equitable determination.

Precedent illustrates the variety of equitable considerations, and responsive equitable remedy in patent cases; for example, the grant of a royalty-bearing license instead of imposing an injunction in situations where the patentee would experience no competitive injury, as in *ActiveVideo Networks, Inc. v. Verizon Communications, Inc.*, U.S. App. LEXIS 18032, at *67-68 (Fed. Cir. Aug. 24, 2012); or where there is an overriding public interest in continued provision of the infringing product, as in *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. 03-CV-0597 (D. Ariz. July 21, 2010), where the Gore vascular graft materials were not available from the successful patentee Bard.

Another form of equitable response is illustrated in *Broadcom Corp. v. Qualcomm Inc.,* 543 F.3d 683, 704 (Fed. Cir. 2008), where the court postponed the effective date of an injunction for twenty months, to relieve hardship on the infringer.

In *Advanced Cardiovascular Sys. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554 (D. Del. 2008), the court observed that: "Courts awarding permanent injunctions typically do so under circumstances where plaintiff practices its invention and is a direct market competitor." *Id.* at 558. Edwards argues that these conditions here prevail. However, the district court declined to impose the requested injunction. First, the district court responded to Edwards' argument that without exclusivity it would lose first-mover advantage and market share and reputation, by stating that these had already been lost – although Edwards states that this is incorrect, for sales in the United States had not yet been authorized by the FDA, as to either the Edwards or the CoreValve/Medtronic product. The district court also stated that Edwards had given up exclusivity by licensing the '552 patent to another competitor. CoreValve does not dispute that the district court erred in its view of that transaction, and that no such license exists.

The district court's explanation of why it was withholding an injunction placed significant weight on CoreValve's statements that it was immediately moving this manufacturing operation to Mexico, and thus that infringement would terminate. *Edwards* at *29 ("The remaining two eBay factors do not alter the court's analysis, since the only practical effect of a permanent injunction would be that CoreValve would be forced to move its United States manufacturing operations for the accused product to Mexico."). The district court stated that if CoreValve should renew its infringing manufacture in the United States, then "[a]s it

did in this case, Edwards can bring suit against CoreValve and seek damages if CoreValve continues its infringing manufacturing operations in spite of the judgment of infringement." *Id.* at *28. Edwards states on this appeal, and CoreValve does not deny, that CoreValve never stopped its infringing manufacture in California. Whether or not that representation was known to be false when made, the situation before us reflects, at least, changed circumstances.

In *TiVo Inc. v. Echostar Corp.*, 646 F.3d 869, 890 n.9 (Fed. Cir. 2011) this court *en banc* noted that "district courts are in the best position to fashion an injunction tailored to prevent or remedy infringement." Recognizing that the circumstances have not been fully explored in the record before us, we vacate the denial of the injunction, and remand to the district court for consideration in light of ensuing events and any other relevant factors.

IV

PROTECTIVE ORDER

The parties had stipulated to a protective order with a "patent prosecution bar," which precludes all persons who had access to the opponent's confidential information produced for this trial, from "working on patent prosecution" on this subject matter. Edwards asked the district court to confirm that this restraint did not apply to patent reexamination, pointing out that Medtronic had filed several reexamination requests against Edwards' patents. Edwards states that confidential information is not likely to be involved, but that this restriction would deprive Edwards of the services of its patent attorneys and technical expert who know most about Edwards' patents and this technology.

The risk of inadvertent disclosure or improper use of confidential information is balanced against the potential harm of restricting a party's right to continued representation by its counsel. In *In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1381 (Fed. Cir. 2010), the court held that "a party seeking imposition of a patent prosecution bar must show that the information designated to trigger the bar, the scope of activities prohibited by the bar, the duration of the bar, and the subject matter covered by the bar reasonably reflect the risk presented by the disclosure of proprietary competitive information." The district court, denying Edwards' request for relief, stated that it "would create a high risk that confidential CoreValve/Medtronic information would be used or disclosed." Meanwhile, Edwards advises that the reexamination of the '552 patent has now terminated (in Edwards' favor) by Order of May 20, 2011. Edwards argues that the balance of equities weighs on the side of permitting Edwards to have the services of its experienced patent attorneys and technical expert, in connection with the ongoing reexaminations of other patents.

Since the '552 patent is no longer undergoing reexamination, if the question is not moot as to other patents, on remand the district court may reconsider its protective order.

SUMMARY

The judgment of the district court is affirmed, with the exception that we remand for reconsideration by the district court, in view of changed circumstances, of the court's rulings on the permanent injunction and the protective order.

AFFIRMED IN PART, REMANDED IN PART

United States Court of Appeals for the Federal Circuit

EDWARDS LIFESCIENCES AG AND EDWARDS LIFESCIENCES LLC,
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v.

COREVALVE, INC. AND MEDTRONIC COREVALVE, LLC,
Defendants-Appellants.

2011-1215, -1257

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

PROST, *Circuit Judge*, concurring.

I join this opinion in all respects except one—the majority's discussion of the permanent injunction standard. The majority opines that "[a]bsent adverse equitable considerations, the winner of a judgment of validity and infringement may normally expect to regain the exclusivity that was lost with the infringement." Majority Op. 16. To the extent that one reads this statement as creating the presumption of an injunction once the plaintiff prevails, which must be rebutted by the defendant, that is not the law.

Nor do the selected portions of *eBay* cited by the majority provide support for its position. First, while I agree with the majority that in *eBay* the Supreme Court did not cancel 35 U.S.C. § 154, the majority overlooks the Court's explanation that "the creation of a right is distinct from the provision of remedies for violations of that right," such that "injunctive relief 'may' issue only 'in accordance with the principles of equity.'" *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392 (2006) (quoting 35 U.S.C. § 283). Second, the majority excludes from its analysis the four-factor equitable standard, the preamble of which states that "the plaintiff must demonstrate" these factors. Indeed, the majority's analysis might be read to suggest that the defendant, not the plaintiff, bears the burden of establishing the equitable factors.

Some complain of areas of patent law in which our guidance is mixed or muddled. This is not—or should not be—one of those areas after the Supreme Court's clear pronouncement in *eBay*. *eBay* made clear that there is no general rule that a successful plaintiff is entitled to an injunction; rather, the plaintiff bears the burden of establishing the four equitable factors that weigh in its favor in order to obtain a permanent injunction. We should take care to avoid possible misinterpretation of an otherwise clear Supreme Court standard. Because the majority's statements appear to me to deviate from the standard articulated by the Supreme Court and our court, I respectfully concur. *See Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011) (recognizing that "*eBay* abolishes our general rule that an injunction normally will issue when a patent is found to have been valid and infringed").