IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

MEDTRONIC VASCULAR, INC., ET AL.,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	CIVIL ACTION NO. 2:06-CV-78
	§	
BOSTON SCIENTIFIC CORP., ET AL.,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

I. Introduction

A jury was empaneled on May 2, 2008, and a trial commenced on November 16, 2007 in the above-titled action with respect to the plaintiffs' patent infringement claims against the defendants. At the close of the plaintiffs' case, the defendants moved for judgment as a matter of law on various issues. For the reasons stated in this opinion, the court GRANTS Paragraph 5 of the Defendants' Motions for Judgment as a Matter of Law Pursuant to Federal Rule of Civil Procedure 50 (Dkt. No. 200).

II. Factual Background and Procedural Posture

Plaintiffs Medtronic Vascular, Inc., Medtronic USA, Inc., Medronic Inc., and Medtronic Vascular Galway (collectively, "Medtronic" or "plaintiffs") accuse Defendants Boston Scientific Corp., Scimed Life Systems, Inc. and Boston Scientific Scimed, Inc. (collectively, "BSC" or "defendants") of infringing claims of United States Patent Nos. 6,190,358 ("the '358 patent"), 6,605,057 ("the '057 patent"), and 6,210,364 ("the '364 patent"). The '364 patent, which is the subject of this Order, is referred to as "the Anderson patent."

The Anderson patent relates to the materials and properties of the balloons used as

components of balloon dilation catheters. Traditionally, dilation catheter balloons fall into two groups: compliant (possessing a high distensibility, i.e. can expand well beyond their nominal diameter when inflated) and noncomplaint (possessing a high "elastic stress response," i.e. they can be repeatedly expanded without substantially increasing their nominal diameter). The Anderson patents are directed toward balloons that exhibit the advantages of both a high elastic stress response (as found in noncompliant balloons) and a high distensibility (as found in compliant balloons). Claim 9 of the '364 patent recites:

> 9. A balloon for a balloon dilatation catheter comprising:
> a radially expanded and axially stretched tubular member formed of a block copolymer composition including a block copolymer having regions of (I) hard segments defined by regions of inter-molecular chain interaction separated by (II) soft segments regions in which individual polymer portions of chains have the ability to uncoil, wherein the ratio of said hard segments to said soft segments is such as to provide said balloon with (a) an elastic stress response not greater than about 5.00, (b) a wall tensile strength of at least about 14,000 psi and (c) a distensibility of between about 5% and about 20%.

'364 Patent at 14:65-15:10.

Medtronic accused nine models of Boston Scientific balloon catheters of infringing claims 9 and 10 of the Anderson patent. Boston Scientific offers each model of balloon catheter in various diameters and lengths. The number of sizes in each catheter model ranges from twenty-six to fifty different sizes per model. Medtronic tested approximately five different sizes of each model using ten samples at each of the selected sizes.

This Order addresses the issues raised in Paragraph No. 5 of BSC's Motion for JMOL. Paragraph No. 5 of BSC's Motion for JMOL raises two issues pertaining to the '364 patent:

1. Whether "the evidence precludes a finding of infringement with respect to any product that Mr. Sheehan [Medtronic's expert] did not actually test." *See* Motion at

3-4 (emphasis omitted), and

2. Whether BSC is entitled to judgment of noninfringement for any accused product with an elastic stress response ("ESR") over 5.5.

III. Legal Principles

A. Judgment as a Matter of Law

Pursuant to Federal Rule of Civil Procedure 50(a), the court "may only render judgment as a matter of law where 'the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue.'" *Palasota v. Haggar Clothing, Co.*, 499 F.3d 474, 480 (5th Cir. 2007) (citing Fed. R. Civ. P. 50(a)). "In entertaining a Rule 50 motion for judgment as a matter of law [the court] must review all of the evidence in the record, draw all reasonable inferences in favor of the nonmoving party, and may not make determinations or weigh the evidence." *Id.* (citing *Ellis v. Weasler Eng'g Inc.*, 258 F.3d 326, 337 (5th Cir. 2001)). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Id.* (citing *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 151 (2000)). The court must "disregard all evidence favorable to the moving party that the jury is not required to believe." *Id.* (citing *Ellis*, 258 F.3d at 337).

IV. Analysis

A. Products Not Tested by Plaintiffs' Expert

BSC seeks judgment as a matter of law with respect to any product that Medtronic's expert did not actually test. For each product family, Mr. Sheehan employed a "four-corners-plus-middle" sampling method, wherein he selected certain sized catheters (measured by balloon length and balloon diameter, for example: 9mm length x 4mm diameter Maverick 2). This resulted in only a

portion of the various sizes available in a particular product family being tested. A complete list of the products that are the subject of this portion of BSC's Motion can be found at pages 4-5 of the Motion.[1]

A patentee bears the burden to prove infringement by a preponderance of the evidence. A showing of infringement requires a comparison of the claim to the accused device, and requires a determination that every claim limitation or its equivalent is found in the accused device. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). These comparisons are questions of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed.Cir.1998).

Medtronic argues that "[t]he purpose of averaging the data using the four-corners-plus-middle approach is to smooth out the measurements and manufacturing variances to obtain a true, representative results of the properties *across an entire model line*." Response at 11 (emphasis added). According to Medtronic, "infringement is determined on a model-by-model basis . . . ." *Id.* at 2. BSC contends that each size of catheter is an accused product, not the broader models.

The claim term at issue, elastic stress response, is directed to calculated value that is based on the accused balloon's performance properties. A patentee, however, "cannot simply 'assume' that all of [the accused] products are like the one [plaintiff's expert] tested and thereby shift to [the accused infringer] the burden to show that is not the case." *See L & W, Inc. v. Shertech, Inc.*, 471 F.3d 1311, 1318 (Fed. Cir. 2006). Medtronic points out that the record establishes that "[e]ach

[1] Medtronic notes that BSC did not move for judgment as a matter of law with respect to the non-tested sizes of the Express 2 products. *See* Response at fn. 1. As a result of agreement reached by the parties during the course of discovery, BSC agreed not to argue non-infringement of the Express2 model based on the failure to test. This is to compensate for the fact that BSC has no inventory of this product available for destructive testing. *See* Reply at 3.

balloon catheter of this model is made using the same material (PEBAX 7233) using the same manufacturing techniques." Response at 5. The plaintiffs failed to present evidence, however, showing that the ESR of a particular model of catheter would not vary with the length or diameter of the catheter.

Metronic makes two additional arguments supporting its use of the "four-corners-plus-middle" method: (1) BSC's use of this method in testing performed for FDA submissions, and (2) Medtronic's expense that would be required to test each size catheter. *Id.* at 1-2.

First, Medtronic argues that "[t]he fact that Medtronic used the same sampling methodology as Boston Scientific uses in its own FDA testing [i.e. the 'four-corners-plus middle'] should put to rest the notion that the four-corners-plus-middle testing methodology is somehow unreasonable." *Id.* at 2; *see also id*. at 6 ("There is no dispute in the record, nor did Boston Scientific proffer any contrary evidence, that the four-corners-plus-middle testing methodology followed by Medtronic in its infringement testing is the industry standard manner whereby the properties of the balloons for a given product family are computed, averaged and submitted to the FDA").

The court is not persuaded by this argument. How BSC (or any other company) performs testing to be submitted to the FDA has no bearing on Medtronic's burden to prove infringement by a preponderance of the evidence for *each* accused product.

Second, Medtronic argues that purchasing the catheters at every size "would have easily exceeded two million dollars." Response at 1. It is not clear that Medtronic would have needed to purchase catheters of all sizes to prove infringement. In any event, the plaintiffs do not cite any authority that suggests this court should consider the costs to the patentee of proving infringement. Assuming the validity of this position, the court is not persuaded that a two-million-dollar cost to

a plaintiff seeking over a quarter-of-a-billion dollars in damages relieves the plaintiff from presenting sufficient evidence to support a jury finding.

For the accused products not tested by Mr. Sheehan, or otherwise shown to meet the relevant claim limitation, the jury was not presented with any evidence upon which to base a finding of infringement. As a result, a reasonable jury would not have a legally sufficient evidentiary basis to find that the untested products infringe the Anderson patent. For these reasons, the court GRANTS BSC's JMOL No. 5 with respect to the untested catheters.

B. Products with an ESR Greater than 5.5

The issue before the court is whether the jury had a legally sufficient basis to find infringement when the plaintiffs' own expert testified that the measurement he made on individual products fell outside his range of infringement. Medtronic's expert, Mr. Sheehan, testified that in his opinion an accused device with an ESR of up to 5.5% infringes the Anderson patent.

In this Motion, BSC points to two catheters for which Mr. Sheehan's measurements fell above 5.5%. These catheters are the 9 mm x 4 mm Maverick 2 and the 9 mm x 4 mm Maverick Over-the-Wire ("OTW"). Mr. Sheehan's testing resulted in ESRs of 5.67% and 5.57%, respectively. BSC contends, in light of these admissions, that no legally sufficient basis exists to support a finding of infringement as to these catheters.

Medtronic presents two main responses. First, Medtronic argues that "[o]ne important fact ignored by [BSC] is that the various tests of catheters of different sizes must be averaged together to obtain scientifically representative results." Response at 9. This is another species of the argument rejected above. For the reasons described in the preceding section, the court is not persuaded by Medtronic's argument.

Second, Medtronic argues that "the jury was not bound by [Mr. Sheehan's] testimony" with respect to his 5.5% cut-off. Response at 13. In other words, "the jury could have reasonably concluded that, as a matter of fact, an average elastic stress response for one size of a product of 5.67% or 5.57% . . . was less than "about" 5% as required by the claim." *Id.* at 14. The court disagrees with Medtronic's characterization of this issue.

It is true that the "[a]pplication of the claim to the accused device is a question of fact, findings of which are accorded substantial deference on review." *See, e.g., Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1345 (Fed. Cir. 2001) (citing *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1348-49 (Fed. Cir. 2000)). The issue this court must address is whether there was a legally sufficient evidentiary basis for a reasonable jury to have found infringement.

The only case BSC sites in support of its position, *Centricut, LLC v. Esab Group, Inc.*, does not directly address the issue before this court. 390 F.3d 1361, 1370 (Fed. Cir. 2004) ("This case stands as an apt example of what may befall a patent law plaintiff who presents complex subject matter without inputs from experts qualified on the relevant points in issue when the accused infringer has negated infringement with its own expert"). Here, Medtronic did provide expert testimony supporting its infringement position. That expert, however, testified that the ESRs of the 9mm x 4mm Maverick 2 and Maverick OTW did not infringe. With respect to these two products, Medtronic's relied on the testimony of Mr. Sheehan, who retracted his opinion that these two specific products infringe. The plaintiffs have not offered any evidence that a person of ordinary skill in the art would conclude that an ESR of greater that 5.5 is an ESR of less than about 5. As a result, the record, read as a whole, does not provide a reasonable jury with a legally sufficient

evidentiary basis to concluded that an ESR of greater than 5.5 infringes.

For these reasons, the court GRANTS BSC's JMOL No. 5 with respect to the 9mm x 4mm Maverick 2 and Maverick OTW catheters.

V. Conclusion

For the foregoing reasons, the court GRANTS BSC's JMOL No. 5. The court concludes that there is no legally sufficient evidentiary basis to find that the BSC products at issue[2] infringe the claims of the '364 patent. The court orders the parties to submit a proposed reduction to the damages award within ten (10) days of the date of this Order.

SIGNED this 11th day of July, 2008.

T. JOHN WARD
UNITED STATES DISTRICT JUDGE

[2] The products are those listed on p. 4-5 of BSC's Motion for JMOL, as well as the 9mm x 4mm Maverick 2 and Maverick OTW catheters.