

## IN THE UNITED STATES DISTRICT COURT

## FOR THE DISTRICT OF DELAWARE

ST. JUDE MEDICAL, et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Civil Action No. 10-631-RGA
	:	
VOLCANO CORPORATION,	:	
	:	
Defendant.	:	

**MEMORANDUM ORDER**

Before the Court is Defendant's Motion to Exclude Improper Expert Testimony. (D.I. 263). It is fully briefed. (D.I. 264, 333, 355). For the reasons stated below, it will be

**GRANTED IN PART and DENIED IN PART.**

This motion is a *Daubert* motion. Federal Rule of Evidence 702 states:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

The Court of Appeals has explained:

Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit. Qualification refers to the requirement that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that "a broad range of knowledge, skills, and training qualify an expert." Secondly, the testimony must be reliable; it "must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity." Finally, Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact. The Supreme Court explained in *Daubert* that "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to

admissibility.”

By means of a so-called “*Daubert* hearing,” the district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury. *See Daubert* (“Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a) [of the Federal Rules of Evidence] whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.”).

*Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404-05 (3d Cir. 2003).<sup>1</sup>

The Defendant’s Motion seeks to exclude portions of the testimony of Dr. Popma and/or Dr. Durfee regarding secondary considerations of non-obviousness (commercial success being the specified example, *see* D.I. 265, Exh. A, ¶76), and of Dr. Bugay in regard to the WaveWire device.

Dr. Popma is indisputably an expert in, at a minimum, interventional cardiology. His testimony is about the Plaintiff’s “Pressure Wire products.” The objection to his testimony is that he does not provide a nexus between specific models of the Pressure Wire products and the asserted patent claims. There is some dispute as to whether each of the Pressure Wire products is shown to be covered by the asserted patent claims. The Plaintiffs state that Dr. Durfee provides such an analysis, and that Dr. Popma is relying upon Dr. Durfee for the nexus. The argument thus moves from Dr. Popma to Dr. Durfee. Dr. Durfee provides a basis for concluding that at least some of the Pressure Wire products are covered by the asserted patent claims. The Court agrees with Volcano that if the sales of any one of the generations of the Pressure Wire products are going to be counted toward commercial success, then there needs to be a foundational showing (presumably from Dr. Durfee) that that particular generation is covered by at least one

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<sup>1</sup> The Court of Appeals wrote under an earlier version of Rule 702, but the recent amendments to it were not intended to make any substantive change.

asserted patent claim. It is not clear to the Court whether Dr. Durfee will, or will not, do this. Thus, the Court will not grant the Motion in Limine, but expects that Dr. Popma will not testify until after Dr. Durfee has testified, or until after Plaintiff has proffered the relevant portions of Dr. Durfee's testimony.

Dr. Bugay is indisputably an expert in, at a minimum, analytical chemistry. The specific objection is to his testimony about how following the manufacturing instructions would lead to results different from what Defendant's experts (Mr. Ward and Dr. Kenny) concluded. (D.I. 265, Exh. C, ¶¶ 22-31). The objection is that there is not much chemistry in his analysis. Maybe there is none. To the extent the objection is based upon Dr. Bugay's capacity to follow the manufacturing directions, that is not expert testimony and does not purport to be. If it were interwoven with testimony within his expertise, I would not see a problem. There is, however, no chemistry component at all in ¶¶ 22-26, and thus the conclusion offered in ¶ 26 – that Mr. Ward's photos are inconsistent with the manufacturing instructions – will not be allowed. There is little chemistry to follow, with the closest thing to chemistry being the statement that "curing" something means that it will harden, which would not come as a surprise to anyone who has ever done some caulking. Thus, unless Plaintiffs, by proffer or otherwise, can explain why (and Plaintiffs' written submission does not, *see* D.I. 333, pp. 3-4) Dr. Bugay's testimony on this point is expert testimony, it is excluded.

  
United States District Judge

October 5, 2012  
Wilmington, Delaware