IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ST. JUDE MEDICAL, CARDIOLOGY DIVISION, INC., ST. JUDE MEDICAL SYSTEMS AB, and ST. JUDE MEDICAL S.C., INC.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 12-441-RGA
VOLCANO CORPORATION,	:	
Defendant.	:	

CLAIM CONSTRUCTION ORDER

The parties having briefed their positions on construction of the claims of United States Patent No. 6,565,514 (the "'514 patent"), and the Court having conducted a *Markman* hearing on May 21, 2013, it is hereby ordered that, as used in the '514 patent, the terms below are construed as follows:

1. "Displaying said graph" is construed to mean "displaying as a set of points, as a line or line segment, as a curve, or as an area" and "of the data resulting from said calculation" is construed to mean: in claim 1: "of a ratio P_d/P_a, which is based on the continuous detection of heart beats and continuously forming a ratio between two calculated average pressures"; in claims 14, 16 and 29: "of a ratio of P_d/P_a"; in claim 24: "of a ratio of P_d/P_a from the floating average."

With respect to the term "displaying said graph," the parties primarily dispute whether a graph can be a single point, marker, or numerical value. St. Jude's proposed construction of the

term "graph" would include a single point, marker, or numerical value. St. Jude's proposed construction, however, is inconsistent with the claims and specification of the '514 patent. For example, independent claims 14 and 16 require "marking . . . at least one interesting point or portion on the graph." If a graph could be a single point, there would be no need to graph the data, the "graph" would not need to be marked, and there could not be a "portion of the graph." Similarly, dependent claims 15 and 17 require that the marked interesting point be "a minimum value of the displayed graph." There is also no reason to be marking the minimum (or maximum) value of a graph of a single point because the minimum/maximum value is the single point. These claims address situations where marking a point is of assistance to the user of the invention.[1] As the '514 patent explains, "[t]he invented system also comprises an arrangement for the calculation of FFR_{myo} values . . . and element[s] being capable of continuously forming a ratio between two calculated average pressures." '514 patent at col.6 ll.35-41. The patent, thus, makes clear that the claimed graph is the result of the continuously formed ratio of pressures and not simply a single point reflecting the minimum value of those computed ratios.

With respect to the term "of the data resulting from said calculation," Volcano argues that this term is indefinite. The Court disagrees. Each claim teaches what "the data" refers to because each claim refers to a calculation that produces said data. The Court's construction of this term, therefore, is consistent with the calculations set forth in the claim language itself.

2. "Detecting continuously at least two physiological variables, arterial pressure (P_a) and distal coronary pressure (P_d), derived from the guidewire-mounted pressure sensor" is construed to mean "arterial pressure (P_a) is continuously detected, and distal coronary pressure

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[1] '514 patent at col.7 ll.24-28.

(P_d) is continuously detected using a guidewire-mounted pressure sensor." The dispute here is whether both arterial pressure (P_a) and distal coronary pressure (P_d) must be measured from a guidewire-mounted pressure sensor or whether arterial pressure (P_a) can be measured with a catheter.[2] Volcano argues that English grammar rules dictate that "derived from guidewire-mounted pressure sensor" modifies both arterial pressure (P_a) and distal coronary pressure (P_d). Although Volcano is correct as a matter of grammar,[3] the Court concludes that a person of ordinary skill in the art would understand that only the distal coronary pressure is measured with a guidewire. Claim 1 requires "the continuous detection of heart beats and continuously forming a ratio between two calculated average pressures" and then averaging the "measured heart pressure over a number of heart beats." Claim 1, therefore, requires that arterial pressure and distal coronary pressure be measured within the same heart beat, and the specification explains that both measurements are taken continuously. Because the continuous measurements take place within a single heartbeat, the measurements occur effectively simultaneously. The claims, thus, require at least two pressure sensors to be continuously in position – one distal to the stenosis and one proximal, usually in the aorta.

The specification also teaches the necessity of having two sensors on two different devices to measure FFR. The specification discusses calibrating "the two pressure sensors" before measurement and equalizing the measurements from the two sensors. *Id.* at col.6 l.51 to

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[2] Volcano's proposed construction recognizes the "at least two physiological variables" language but does not complain that St. Jude's proposed construction does not. (D.I. 47 at 55).

[3] The doctrine of last antecedent is, at most, a guideline, not a rule. *Finistar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1336-37 (Fed. Cir. 2008).

col.7 l.3. It would be impossible to equalize two sensors on the same guidewire in the aorta if the sensors are intended to be spaced apart such that they could simultaneously measure arterial pressure and distal coronary pressure. Accordingly, a person of ordinary skill in the art would understand the pressure measurements are not both "derived from the [guidewire] mounted pressure sensors" but that only the distal coronary pressure must be derived from the guidewire-mounted pressure sensor.

3. "Sensor element" is construed to mean "an assembly of sensing devices." The term "a sensor element" is found in independent claims 16, 24, and 29. Each of these claims describes "a sensor element, said sensor element being capable of detecting continuously at least two physiological variables, arterial pressure (P_a) and distal coronary pressure (P_d) and delivering processable signals to a unit being able to process said processable signals." For the same reasons that the term "[d]etecting continuously at least two physiological variables, arterial pressure (P_a) and distal coronary pressure (P_d), derived from the guidewire-mounted pressure sensor" includes at least the "[guidewire]/catheter assembly" described in the specification, "a sensor element" must include a guidewire/catheter assembly and must be comprised of at least two sensors. Because certain claims refer to a "sensor" and other claims refer to a "sensor element," these terms should have different meanings. Furthermore, dependent claim 26 requires that the sensor element be further capable of detecting venous pressure (P_v). Neither party has suggested that a single sensor exists that can detect pressure in a vein while also detecting two pressures in the heart. Thus, the "sensor element" in claim 26 that can detect three different pressures must have multiple sensors, not a single sensor.

Volcano argues that the specification supports its proposed construction of "sensor

(*See, e.g.*, *id.* at col.4 ll.3-9 ("FIG. 5 discloses a block diagram of a preferred embodiment of a measurement system 500 according to the invention. Said system comprises a monitoring unit 501, connected to at least two sensor elements 502, each sensor element 502 being capable of detecting continuously at least two physiological variables, arterial pressure P_a and distal coronary pressure P_d."); *id.* at col.4 ll.23-27 ("The sensor elements 502 being capable of detecting continuously at least two physiological variables, arterial pressure P_a and distal coronary pressure P_d can have separate transducing elements or be designed to deliver a processable signal, without a transducer element.")). As Volcano points out, in Figure 5, two boxes indicate two sensor elements 502. If a sensor element includes at least two sensors, Figure 5 should only include one sensor element.

The conflict between the claim language and Figure 5 is only part of the analysis, however, because the specification also supports St. Jude's proposed construction. In particular, the specification provides: "The [sensor] element being capable of detecting continuously P_v can be a [guidewire]/catheter assembly having transducers, such as pressure sensors attached thereto." '514 patent at col.5 ll.22-25. Thus, the specification distinguishes the sensor element from the "pressure sensors." Accordingly, the claim language itself as well as the specification (other than Figure 5) support the Court's construction.

Entered this 30th day of May, 2013.

Hon. Richard G. Andrews
United States District Judge