

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NUVASIVE, INC.  
Petitioner

v.

WARSAW ORTHOPEDICS, INC.  
Patent Owner

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Case IPR2013-00206  
Patent 8,251,997

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**PETITIONER'S RESPONSE TO THE MOTION FOR OBSERVATION REGARDING  
CROSS-EXAMINATION OF DR. BRANTIGAN**

### **Response to the Introduction**

This paper responds to Patent Owner's motion for observation regarding cross-examination of Dr. Brantigan, filed Apr. 22, 2014. Patent Owner states in an introductory paragraph that it filed its observations about "Dr. Brantigan's prior sworn testimony" "[i]n lieu of taking additional depositions." However, Petitioner made Dr. Brantigan, and declarants Mr. Miles, Dr. McAfee, and Dr. Jacobson, available to Patent Owner for deposition. It was Patent Owner's choice to comment on Dr. Brantigan's prior testimony and to forgo a deposition in which Dr. Brantigan could explain that the supposed inconsistencies do not exist. Petitioner disagrees with Patent Owner's characterization of Dr. Brantigan's prior testimony as explained below.

### **Response to Observation Nos. 1-3**

In Observation Nos. 1-3, Patent Owner discusses Dr. Brantigan's prior testimony concerning Figures 10 and 11 of his '327 patent. This testimony and Dr. Sach's mischaracterization of it, were addressed by Dr. Brantigan in his declaration at paragraphs 15-17. There, as in his prior testimony, Dr. Brantigan explains that Figure 10 shows two implants inserted using two different approaches at two different levels of the spine and that Figure 11 shows the lower level implant of the two implants in Figure 10.

While Patentee makes much of Dr. Brantigan's candid testimony that some small aspects of these figures are not accurately drawn, Dr. Brantigan never wavered from his position that the top part of Figure 10 shows an implant inserted using a direct lateral

approach. Dr. Brantigan has also been consistent in explaining that Figure 11 is not an illustration of the upper level of Figure 10, but rather Figure 11 shows the lower level of Figure 10 where the implant is inserted using an anterior approach. See Ex. 1041, page 1514, lines 16-19, page 1515, lines 10-12, 19-23 (“A. THAT SHOWS TWO ILLUSTRATIONS. THE LEVEL AT THE TOP WAS INSERTED Laterally, AND THE ‘Z’ SHAPE SHOWS A DIFFERENT WAY OF PUTTING IT IN.”). Dr. Brantigan’s testimony under cross examination at trial is entirely consistent with Dr. Brantigan’s statements in his declaration. Ex. 1031, ¶¶ 15-17. Patent Owner was afforded an additional opportunity to cross-examine Dr. Brantigan on these points, but chose not to, perhaps because the element numbering on Figures 10-11, as explained in paragraph 16 of Dr. Brantigan’s declaration, is so clearly consistent with his testimony.

#### **Response to Observation Nos. 4-6**

In Observation Nos. 4-6, Patent Owner references prior testimony by Dr. Brantigan discussing implant sizing with respect to the patient’s vertebral end plates. There is no contradiction with the declaration testimony of either Dr. Brantigan or Dr. McAfee. For example, in Exhibit 1041 at page 1495 lines 2-7, Dr. Brantigan testifies (with emphasis added):

Q. AND IS THE LENGTH OF YOUR IMPLANT IN YOUR '327 PATENT GREATER THAN HALF OF THE MEDIAL-LATERAL OR SIDE TO SIDE WIDTH OF THE VERTEBRA?

A. WE TEACH THEM ***IT SHOULD BE SUBSTANTIAL OF THE ENTIRE LENGTH OF THE VERTEBRAE***, YES.

Similarly, in Exhibit 1041 at page 1483 lines 8-21 Dr. Brantigan elaborates on this point (with emphasis added):

Q. HERE IT REFERENCES MEDIAL-LATERAL AND ANTERIOR-POSTERIOR DIMENSION AND SAME RATIO AS NORMAL VERTEBRAL BODIES; WHAT DOES THAT MEAN?  
A. THAT MEANS WHAT WE JUST TALKED ABOUT; THESE SHOULD ***SUBSTANTIALLY FILL THE ENTIRE DISC SPACE***. THEY ARE SIZED AND SHAPED TO MATCH THE DISC SPACE. AS WE SAID, DIMENSION 28 TO 42 BY 42 MATCH THE NORMAL RATIO OF THE DEPTH TO THE WIDTH OF THE NORMAL VERTEBRAL BODIES.

Q. THIS PORTION HERE THAT THE OPPOSING END FACES THE ADJOINING VERTEBRA -- I'M SORRY. THE RINGS ARE BOTTOMED ON THE OPPOSING END FACE OF THE ADJOINING VERTEBRA; WHAT IS THAT REFERRING TO?

A. THAT MEANS THEY ARE ***VERY TIGHTLY FIT WITHIN THE DISC SPACE*** TO ACHIEVE STRONG AND SNUG FIXATION.

Dr. Brantigan also testified that “[t]he bone of the end plate is very strong” (Ex. 1041, 1495:20-25) and affirmed numerous times that the implants of his ‘327 patent are sized to sit on and bite into the end plates. See Ex. 1041, 1465:20-23, 1483: 2-21, 1491:3-4,

1492:9-15, 1495:20-25, 1548:7-11. The difficulty, which Patent Owner attempts to portray as inconsistent testimony, is that there is no anatomic demarcation of the boundary between the vertebral end plate and apophyseal ring. This is particularly true in patients suffering from degenerative disk disease. See Ex. 1029 at ¶¶ 3. As such, Dr. Brantigan points out in his declaration exactly how his '327 patent describes the disclosed implants: that his implants are "generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column"; and that they "are bottomed on the hard bone faces or end plates of adjacent vertebrae and are generally oval shaped to conform with the general outline perimeter of the vertebrae." Ex. 1031 at ¶ 21. All of this testimony is relevant because it is consistent with Dr. Brantigan's testimony in his declaration and the disclosure of the '327 patent. See Ex. 1031, ¶ 21. It is also consistent with Dr. McAfee's testimony in his declaration that "the endplate is confluent with the apophyseal ring." See Ex. 1029, ¶¶ 3, 73.

### **Response to Observation No. 7**

In Observation No. 7, Patent Owner identifies Dr. Brantigan prior testimony regarding capillary growth. In Exhibit 1041 at page 1521 line 21 and page 1522, line 9, Dr. Brantigan twice tells counsel for Warsaw, who is conducting cross-examination, that he is mischaracterizing human anatomy. In Exhibit 1041 on page 1519, line 20 to page 1522, line 9, Dr. Brantigan attempts to explain capillary growth with respect to the '327 patent in greater detail to Warsaw's counsel. Having been precluded by Warsaw's counsel from

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