

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 ORTHOPEDIC, INC.  
Patent Owner

Patent Number: 8,251,997 B2  
Issue Date: August 28, 2012

Case IPR2013-00206

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**DECLARATION OF DR. ROBERT E. JACOBSON, M.D.**

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Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

I, Dr. Robert E. Jacobson, M.D., of Miami, Florida, declare that:

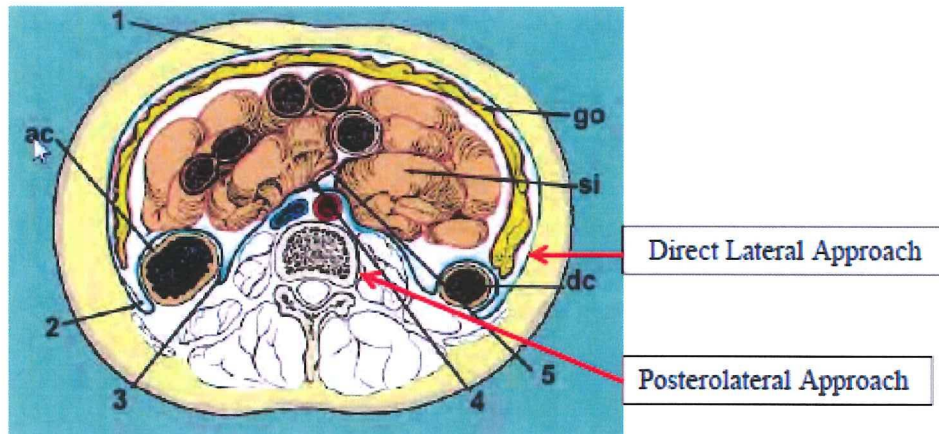
I. Qualifications

1. I am a neurosurgeon with a specialty in spine surgery including spinal discectomy and fusion procedures. I graduated from medical school in 1969, and performed general neurosurgery residencies with a research concentration on spine from 1970 through 1975. I also performed a clinical fellowship in cervical and lumbar spine surgery under Professor Henk Verbiest from July 1975 to March 1976 in Utrecht, Netherlands. I am the inventor of the spinal surgery methods and equipment described, among other places, in U.S. Patent No. 4,545,374 (“’374 patent”) (Exhibit 1004), entitled “Method and instruments for performing a percutaneous lumbar discectomy,” which is a patent I had filed on September 3, 1982, and which issued on October 8, 1985.

2. I have been asked to provide rebuttal testimony to the declaration testimony of Dr. Barton Sachs regarding what is disclosed in my ‘374 patent. In this regard, I have reviewed ¶¶ 75-93 of Dr. Sachs’ declaration (Exhibit 2038, hereafter “Dr. Sachs Decl.”), where he provides his opinions regarding my ‘374 patent. I am very familiar with my own ‘374 patent, although I reviewed my ‘374 patent again as part of my study in providing this declaration. I also reviewed other documents referenced in my testimony set forth below.

3. Dr. Sachs, in his declaration, states that “[t]hough Jacobson uses the word ‘lateral,’ the term does not mean direct lateral.” Dr. Sachs Decl., ¶ 75. Dr. Sachs also states that “Jacobson does not teach a direct lateral approach to the spine,” and further

states that he “believe[s] he [Dr. Jacobson] is teaching a similar approach that is posterolateral.” Dr. Sachs Decl., ¶ 76. Copied below is the figure from Dr. Sachs declaration where he illustrates a “posterolateral approach,” and also illustrates a “direct lateral approach.”



Source: <http://home.comcast.net/~wnor/peritoneum.htm>

4. I agree with Dr. Sachs that a posterolateral approach (as labeled in the figure copied above from his declaration) is different from a direct lateral approach (as also labeled in the figure copied above). (I note, however, that approaches referred to as “posterolateral” may be, and in fact are typically, more posterior than the posteriolateral approach shown in the figure above.) I disagree, however, with Dr. Sachs’ opinion that my ‘374 patent teaches a posterolateral approach and not a direct lateral approach. My ‘374 patent clearly teaches a direct lateral approach, not a posterolateral approach. Indeed, the approach that I had developed and used at the time was a direct lateral approach, not a posterolateral approach. I believe it is clear – from the figures and the text of my ‘374 patent, especially in

view of the timeframe of the early 1980s during which I developed and had a patent filed on my lateral procedure – that my ‘374 patent discloses a direct lateral approach. For example, the patient in my method of the ‘374 patent is always placed in a lateral decubitus (side) position, and the three access instruments including the final access cannula are passed to the spine using a direct lateral approach. See, e.g., my ‘374 patent, Exhibit 1004, column 5, lines 5-6 (“To begin the procedure, the patient 6 is placed in the lateral decubitus position ...”), column 5, lines 27-28 (“As shown in FIG. 3, the needle is inserted laterally through the patient’s side above the pelvic crest ....”), column 5, lines 49-50 (“The speculum 10 is laterally inserted through body tissue ....”), column 5, lines 60-62 (“Once the speculum is properly positioned, the surgeon spreads its jaw blades thereby creating a channel for cannula insertion.”), Figures 3-6. In this regard, Figure 5 is particularly clear in illustrating the direct lateral nature of the approach, given that the distal end of the cannula 11 is depicted in the figure with a straight horizontal line (i.e., not in perspective), thereby indicating the view of the cannula 11 is a side view or in other words the cannula 11 lies in a plane that is parallel with the page. Also in Figure 5, the transverse processes that extend from the two vertebral bodies are sized to be about the same size, thus indicating the view in Figure 5 of the spine is directly from the front of the spine. In addition, my ‘374 patent describes that the entry to the disc space is from the side opposite the disc bulge, such that the instruments pass all the way across the disc in order to get to the bulge. See, e.g., my ‘374 patent, Exhibit 1004, column 7, line 67 to column 8, line 5. Extending instruments

across the disc to a bulge on the other side of the disc would not be possible with a posterolateral approach and the instruments I describe in my '374 patent.

5. When I was in the process of developing the method shown in my '374 patent during the early 1980s and working with attorneys from the law firm of Pennie & Edmonds on the patent application that became my '374 patent, the phrase "direct lateral" was not a phrase that I used in the technical parlance of my profession, and in fact, at that time I had never heard the phrase "direct lateral" to describe a 90 degree lateral approach to the spine. Instead, in the early 1980s, I (and others) simply used the term "lateral" when referring to a 90 degree lateral approach to the spine. When we wanted to refer to a posterolateral approach to the spine (which was also known at the time), we called that approach a posterolateral approach. It is only recently in the last few years that I first heard the phrase "direct lateral" in referring to a 90 degree lateral approach.

6. The posterolateral approach to the spine was well known when I was doing my work developing my lateral method in the early 1980s. The posterolateral approach dates back to the 1940s with procedures that made injections into the spinal disc. For example, a posterolateral approach to the spine was used in the procedure discussed in the background section of my '374 patent to inject a chymopapain enzyme into the disc with a spinal needle. See my '374 patent, column 1, line 65 through column 2, line 5. In the 1980s, around the same time I was developing my lateral approach procedure, Dr. Parviz Kambin was developing his posterolateral procedure that involves providing an access

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