

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

In re *Inter Partes* Review of:

U.S. Patent No. 8,623,057 B2

Inventors: Jahng et al.

Filed: Jun. 17, 2011

Issued: Jan. 7, 2014

For: SPINAL STABILIZATION  
DEVICE

Case No.: IPR2014-TBA

Atty. Docket No. 60330.01014

**DECLARATION OF PAUL McAFEE, M.D., M.B.A.**

I, Dr. McAfee, declare as follows:

**I. INTRODUCTION AND QUALIFICATIONS**

1. I am over 18 years of age. This following declaration is based on facts within my personal knowledge and if called as a witness I could and would testify as to such facts.

2. A copy of my *curriculum vitae* is attached hereto as Exhibit 1008 and contains a detailed description of my background.

3. I have been asked by the Petitioner, Globus Medical Inc. (hereinafter “Petitioner”), to provide my opinions about the technical issues addressed below. I am being compensated for my time spent on this matter, including independent study, document review, analysis, and writing, at an hourly consulting rate. My

compensation is not dependent upon my testimony or the outcome of this proceeding or any pending litigation.

4. I have been informed that the USPTO applies a “broadest reasonable interpretation” standard when interpreting claims. I have been informed that this means that the claims are understood from the perspective of a person having ordinary skill in the art (“POSITA”) after reading the specification. I have been informed that claim terms themselves are given their plain and ordinary meaning consistent with the specification if the specification itself does not provide a definition for that claim term. In view of the subject matter of the ’057 patent, a POSITA was typically a person who had a bachelor’s degree in mechanical engineering, or equivalent degree, and at least two years of experience in the design, fabrication, and testing of implants or an orthopedic surgeon with experience in spinal surgery and experience in the design of implants.

5. In connection with my opinions, I have reviewed the ’057 patent, and the prior art references cited in the Petition. In my opinion, the features recited in claims of the ’057 patent were well-known in the art before the ’057 patent’s earliest claim to priority.

## **II. DISCUSSION OF THE TECHNOLOGY AND PRIOR ART**

10. The concept of “overhanging” spinal implants like the Panjabi patent have been utilized to provide the necessary spacing to have the implant function

properly. There is only a very small amount of space from pedicle to pedicle so if one wants to use a cushioning, dampening, or elastomeric material there is only a small amount of material that can be used. By utilizing an overhanging implant this increases, in fact almost doubles the amount of cushioning material that can be used in a semi-rigid implant. This is especially important at L5-S1 where there is very minimal pedicle-to-pedicle distance.

11. Concerning the types of materials utilized for this type of technology, there is no perfect material—it depends what part of the balance or compromise that one wants to make. The materials all have a different modulus of elasticity. The functional spinal unit (actually previously defined by Panjabi—White, AA Panjabi, M, Clinical Biomechanics of the Spine, 2<sup>nd</sup> Ed. Philadelphia, Lippincott, 1990, pages 1 – 25)(Exhibit 1009), is comprised by the disk which is a cushion with a low modulus of elasticity and the cortical bone which has a high modulus of elasticity. Titanium is better than stainless steel because it is more flexible, i.e., it has a lower modulus—i.e., closer to the modulus of the spine. Some materials are even more flexible than titanium but these metals have higher crack propagation—once a microcrack appears it extends across the entire diameter of the rod and it breaks faster. In this regard stainless steel would be better.

12. Another disadvantage of a metal implant is that it causes stress shielding—the stiffness is so great that it interferes with bone fusion. The correct

amount of micromovement in a rod is approximately a strain rate of 2% to 10% (change in length divided by the original length). There is also stress-related osteoporosis which can occur over a long period of time, meaning the metal, because it is so much more rigid than the biologic materials in the spine (disc and cortical bone) causes the bone to become weaker and osteoporotic. Bone resorbs if it is adjacent to a rigid rod.

13. PCU, Dacron bands, and UHMWPE are softer materials which would be advantageous in reducing the incidence of stress-shielding, reduce the incidence of stress-related osteoporosis, and might be better within the optimal strain window. The disadvantages are the increased infection rate of a woven material, the spine is not as rigidly held so there is more potential for neurologic compression due to great spinal movement. The surgeon is performing the surgery to correct an unstable situation, fracture, dislocation, spondylolisthesis—an elastomeric material holds the spine in a less rigid or a less stable position than a metal implant.

14. Concerning in-line vis-à-vis off-set implants, in-line has less rotational force or torque on the screws. There is a higher incidence of screw loosening with off-set implants. The off-set implants allow placement of the longitudinal member in a medial location which allows room for more bone grafts posterolaterally. This leads to a higher fusion rate. Off-set implants are easier to insert due to the easier

ability to separate the screwdriver mechanism (inserting the pedicle screw) from the rod-tightening mechanism—less “fiddle factor”. For the same reason the off-set implant housing is less bulky, the tulips of the in-line implants are larger, more bulbous and this allows less room for elastomeric material between pedicles and less room for the bone graft.

15. Concerning the internal structure of Panjabi’s figure 8 with respect to the alignment rod 250, the alignment rod is like structure 152 in Figure 5. It works by having two springs that are aligned from the pedicle to a midline peg stopper (abutment member) which is anchored by a central alignment rod. There are two telescoping pistons external to the two in-line springs which keep the springs from buckling, deforming, or dislodging. The springs are used to become more “tight” in compression and more elongated in tension. The spine property which is hardest to replicate is the viscoelastic property—as the pedicle-to-pedicle distance gets closer (lumbar spine extension) the tightness has to exponentially increase towards the terminal limit. The spring combination has to offer more resistance in greater proportion as the extension becomes faster and more towards the end of the range of motion. Structure 250 and 230 are basically a covering around the central element illustrated in Figure 5 comprised by two telescoping pistons with two springs in alignment.

16. In 2003 Panjabi (in Panjabi, MM: Clinical spinal instability and low back pain, Journal of Electromyography and Kinesiology 13, (2003) 371 – 379) made famous the “ball-in-bowl” concept to describe the Neutral Zone. Figure 3 left side of the diagram there is a steeper edge of the more acute side of a champagne glass than a soup bowl. As a ball rolls back and forth in these two extremes of stiffness parameters, the ball starts to lose energy as it rolls up the sides of a glass or soup bowl—this represents the dampening of motion that has to occur to replicate the viscoelastic property of the spinal construct. Any PCU, spring, pillow, or UHMWPE material has to have a changing stiffness, represented by the motion of a ball as it rolls from side to side (and rapidly comes to a stop at the end of the range of motion of the functional spinal unit).

17. Panjabi states that the arrangement of the alignment pin 250, first and second attachment members 260, 266 and first and second springs 230, 232 allows for resistive translation of the alignment pin 250 relative to the vertebrae, I understand this to be “telescoping.” The longitudinal rods comprise telescoping tubes which contain compression springs. The springs are inserted in a collapsed or compressed manner by inserting a rod which is longer at rest than before being jammed between two abutment members. The “sliding” word would imply slippage or spondylolisthesis or translation of the spine—these concepts imply a forwards-backwards motion or displacement (unwanted in a spinal implant).

Sliding or anteroposterior translation should only be 2.5 mm or less in the lumbar spine or it is unstable and results in an increased incidence of neurologic complications.

18. Given this disclosure, “[t]he first spring 230 is positioned to extend between the first attachment member 260 and the second attachment member 266, while the second spring 232 is positioned to extend between the second attachment member 266 and the abutment member 256 at the free end 258 of the alignment pin 250,” see Panjabi, 13:12-17, I would consider this condition “the spacer metallic portion being located entirely between the first rigid portion and the second rigid portion such that along the length of the connection unit no portion of the spacer metallic portion overlaps with any portion of the first or second rigid portion” to be satisfied. My reasoning is that the spacer metallic portion would include a metal spring and the spring does overlap the alignment rod.

19. For the spacers, materials such as PCU, UHMWPE, Dacron, silicone, metal springs, accordion type or billows type cuts in a metal rod to make it a spring—titanium or nitinol metal (bendable but not easily breakable) would be used.

20. Spinal implants are attached to the vertebrae by pedicles screws with attachment clamps.

21. Panjabi and McAfee are related because they achieve the same goals but in McAfee the material in the spacer is what provides the elastomeric capability. In Panjabi it is the mechanical arrangement of the metal springs that provides the variability in pedicle-to-pedicle distance.

22. If part of a spinal implant was described as a cable, I would understand a cable to mean, interwoven monofilament wires or threads. A group of multiple longitudinal fibers that is twisted or woven together such that they are intermingled or interwoven to increase the strength. The strength is increased because the crack propagation can only extend across each strand independently instead of “in one fell swoop” like it would be in a homogeneous single wire.

23. After reviewing the Panjabi disclosure and my understanding of spinal implants, I can state that aperture 290 with attachment member 266 has a larger diameter than the alignment pin 250 so that the attachment member 266 can slide along the alignment pin 250. My reasoning is the construct would not be dynamic if this was not the case since the structure 266 has to slide along the central pin 250 which must have a smaller diameter.

24. The overhang has to be shorter than the springs otherwise the springs could not be pre-loaded in compression. The overhang is relatively short because of the lumbar lordosis the rod would be abutting the sacrum or abutting the adjacent facet joint. If the overhanging portion is extended below the construct



(caudad) at S1 then it tends to hit the sacrum. If the overhanging portion is inserted at the cephalad end then it would tend to disrupt the function of the normal adjacent facet joint above. Therefore the overhanging portion has an anatomic confining reason to be relatively short, that is, at most the length of the pedicle to pedicle distance.

25. Panjabi satisfies this statement: “wherein the first and second elastomeric spacer portions limit the sliding of the spacer metallic portion along the flexible member in response to external forces of the magnitude experienced from movement of the spine applied to the first rigid portion and the spacer metallic portion” given its disclosure of the ‘neutral zone’ when standing since the neutral zone is the “floppy zone” or the zone that does provide movement but does not allow plastic deformation of the longitudinal member. In Panjabi’s ball-in-bowl analogy it is the trough at the bottom of the bowl where the ball can roll back and forth without much energy—the range of motion at the bottom the bowl. This corresponds to spinal motion without requiring great muscle effort and certainly not stretching any surrounding ligaments. It means there are large variations in displacement with minimal disturbing of the internal structure of the artificial spinal construct.

26. By constructing Panjabi to be in-line or fit within a pedicle screw it would necessarily be cylindrical in order to fit inside the tulip.

27. It is common that the anchoring pedicle screws would be the same size, same length and diameter as the vertebrae transition from large to small in a gradual manner as one progresses from caudad to cephalad.

28. The reason that the second attachment member 266 would tend to be metal material, there is less wear debris with utilization of similar materials. There would be more deleterious wear debris if one uses similar metal materials, rather than having a metal-PCU interface, for example. The volume and shape and inflammatory nature of wear debris is invariably worse when dealing with an interface of two dissimilar materials.

29. There is a finite number of elastic materials that can be used for dampening—metal springs, PCU, silicon, UHMWPE, nitinol memory metals.

30. I agree with the explanation of the working portion of Panjabi using the claim language on pages 35 to 37.

31. One reason PCU is the material that would first come to mind is that at the time of the invention—the most common implant used in Europe was the Dynesys—over 10,000 cases. The dynamic dampening material used for this implant is PCU cut into cylinders or sleeves interposed between pedicle screws, so of course this would be the material of choice. It was already proven to be safe in Europe. One of the main hurdles in developing a new dynamic product would be

biocompatibility and proof that the wear debris is relatively non-inflammatory. PCU was already proven thru the Dynesys experience in Europe.

32. Dependent claim 5 conditions the elastomeric spacers limiting the sliding of the rigid spacer along the flexible member in response to forces generated by movement of the spine applied to the rigid portion and rigid spacer. With Panjabi the longitudinal rod slides back and forth thru the cephalad pedicle screw attachment. Below this attachment portion, which is between the pedicles, by definition the spring coils have to slide along the central rod as the spring compresses and elongates. This is an elemental property of how a spring works and why it would be chosen as the dampening mechanism. If one were to put a rod inside a spring and stretch and compress a spring, Claim 5 has to be satisfied. The Panjabi spring has to be defined as a flexible member.

33. In the '057 patent, Figure 56, there are a hollow tube structures (two) 314 and (1) 316 which comprise structure 310 – they merely function as a spring which slides back and forth along a rod (306). Structure 302 is the abutment member.

**STATEMENT UNDER 18 U.S.C. § 1001**

I declare under penalty of perjury under the laws of the United States that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed this 13 day of October 2013.

  
\_\_\_\_\_  
Paul McAfee, M.D., MSA