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Paper No. 35
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUVASIVE, INC.,
Petitioner,

v.

WARSAW ORTHOPEDIC, INC.,
Patent Owner.

Case IPR2013-00396
Patent 8,444,696 B2

Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Petitioner, NuVasive Inc. ("NuVasive"), filed a Corrected Petition requesting *inter partes* review of claims 7–12 ("the challenged claims") of U.S. Patent No. 8,444,696 B2 ("the '696 patent"). Paper 5 ("Pet."). Patent Owner, Warsaw Orthopedic, Inc. ("Warsaw"), did not file a Patent Owner

Preliminary Response. We determined that the information presented in the Petition demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 7-12 as unpatentable under 35 U.S.C. § 103(a). Pursuant to 35 U.S.C. § 314, the Board instituted trial on December 20, 2013, as to the challenged claims of the '696 patent. Paper 11 ("Institution Decision"; "Dec. Inst.").

Patent Owner filed a Response (Paper 23, "PO Resp."), but did not file a motion to amend. Petitioner subsequently filed a Reply. Paper 24 ("Reply"). An oral hearing was held on July 31, 2014. The transcript of the hearing has been entered into the record. Paper 34.

We have jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a). Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 7–12 of the '696 patent are unpatentable.

B. Related Proceedings

Petitioner filed concurrently with the instant Petition another petition for an *inter partes* review of the '696 patent. That proceeding, IPR2013-00395, involves claims 1–6 of the patent. Petitioner indicates further that Patent Owner has asked the court for permission to add the '696 patent to the case *Warsaw Orthopedic, Inc. v. NuVasive Inc.*, Case No. 3:12-cv-02738-CAB (S.D. Cal.). Pet. 1.

C. The '696 Patent

The '696 patent issued on May 21, 2013, with Gary Karlin Michelson as the listed inventor. The '696 patent is drawn to an interbody spinal fusion implant that is "configured to restore and maintain two adjacent vertebrae of the spine in correct anatomical angular relationship." Ex. 1102, 1:20–23.

As taught by the ’696 patent, the cervical and lumbar areas of the human spine are lordotic in a healthy state, that is, they are “curved convex forward.” *Id.* at 1:25–27. In degenerative conditions of the spine, the lordosis may be lost. *Id.* at 1:27–28. Surgical treatment of such degenerative conditions often involves spinal fusion, where adjacent vertebrae are joined together through an area of shared bone. *Id.* at 1:36–40.

The ’696 patent discloses spinal implants that are sized to fit within the disc space that is created when the disc material between two adjacent vertebrae is removed, and that conform “wholly or in part to the disc space created.” *Id.* at 1:61–64. The implants have upper and lower surfaces that form a support structure for the adjacent vertebrae, and, in a preferred embodiment, the upper and lower surfaces “are disposed in a converging angular relationship to each other such that the implants of the present invention have an overall ‘wedged-shape’ in an elevational side view.” *Id.* at 1:67–2:4.

As taught by the ’696 patent, the various faces of the implant may be curved to allow the implant “to conform to the shape of the vertebral surfaces.” *Id.* at 2:23–25. That is, “the upper and/or lower surfaces may be convex, and/or the front and/or rear surfaces may be convex.” *Id.* at 2:26–27. The surfaces of the implants may have openings, which may or may not pass all the way through the implant, but that connect through a central chamber. *Id.* at 2:27–31. The opening may be of random size, shape, and/or distribution. *Id.* at 2:31–32.

Figure 14 of the '696 patent is reproduced below:

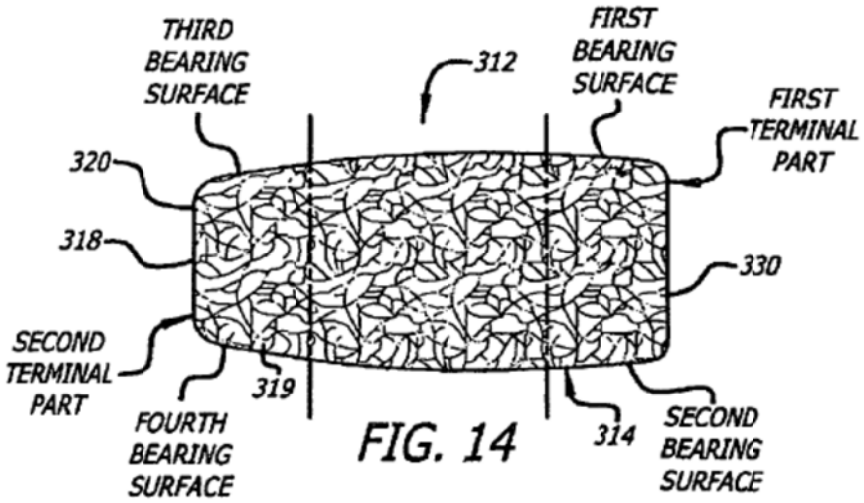

FIG. 14

Figure 14, above, is a left side elevational view of a lordotic interbody spinal fusion implant. *Id.* at 5:11–12. The implant shown in Figure 14 has insertion end 320 and trailing end 330. *Id.* at 9:18–19. In addition,

> the implant . . . includes a first terminal part defining a first bearing surface adapted to bear against an endplate of the vertebrae V_1, and an opposite second bearing surface adapted to bear against an endplate of the vertebrae V_2. The implant . . . also includes a second terminal part opposite the first terminal part. The second terminal part defines a third bearing surface adapted to bear against the endplate of the vertebrae V_1 and a fourth bearing surface adapted to bear against the endplate of the vertebrae V_2.

Id. at 9:20–29.

The ’696 patent also discloses an embodiment with ratcheting. Figure 9 of the patent is reproduced below:

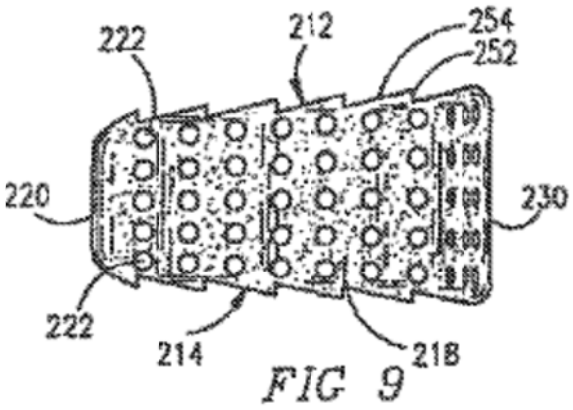

FIG 9

Figure 9 is a side elevational view of a lordotic interbody spinal fusion implant. *Id.* at 4:63–67. As seen in the Figure, the ratchetings are oriented in the direction of insertion end, 220, allowing for one-way insertion of the implant, and bone engaging end, 252, prevents the implant from backing out once implanted. *Id.* at 8:40–49.

The ’696 patent teaches further that when a posterior lumbar interbody fusion is performed, it is not possible to replace the removed portions of the disc with a single, large implant. *Id.* at 2:35–38. In such cases, a “modular implant[ ]” may be used. *Id.* at 2:40–42. The modular implants are as long as the length of the disc material that is removed, but are narrower, and thus, can be “introduced into the disc space from the posterior aspect to either side of the dural sac, and then aligned side to side within the disc space so that a number of them each having a length consistent with the depth of the disc removed in that area would in combination have a width equal to the width of the disc material removed.” *Id.* at 2:42–50.

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