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Paper 73
Date: August 26, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SURGALIGN SPINE TECHNOLOGIES, INC.,
Petitioner,[1]

v.

LIFENET HEALTH,
Patent Owner.

IPR2019-00569
Patent 6,458,158 B1

Before GEORGE R. HOSKINS, TIMOTHY J. GOODSON, and CHRISTOPHER C. KENNEDY, *Administrative Patent Judges.*

GOODSON, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
Dismissing Petitioner's Motion to Exclude
Denying Patent Owner's Motion to Exclude
35 U.S.C. § 318(a)

[1] Petitioner recently filed Updated Mandatory Notices indicating that its name has changed from RTI Surgical, Inc. to Surgalign Spine Technologies, Inc. *See* Paper 72.

I. INTRODUCTION

A. Background and Summary

Petitioner filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1–15 of U.S. Patent No. 6,458,158 B1 (Ex. 1002, "the '158 patent"). Patent Owner filed a Preliminary Response. Paper 10. We instituted an *inter partes* review on all claims and all grounds asserted in the Petition. *See* Paper 15 ("Dec. on Inst.").

After institution of trial, Patent Owner filed a Patent Owner Response. Paper 31 ("PO Resp.").[2] Petitioner filed a Reply. Paper 42 ("Pet. Reply"). Patent Owner filed a Sur-Reply. Paper 57 ("Sur-Reply"). We held a hearing on June 2, 2020, a transcript of which is included in the record. *See* Paper 70 ("Tr.").

We have authority under 35 U.S.C. § 6. Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons discussed below, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1–15 of the '158 patent are unpatentable.

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[2] A public, redacted version of the Patent Owner Response was filed as Paper 30.

B. Real Parties in Interest

The parties list only themselves as real parties in interest. *See* Pet. 3; Paper 4, 1.

C. Related Matters

Patent Owner asserted the '158 patent against Petitioner in *LifeNet Health v. RTI Surgical, Inc.*, No. 1:18-cv-00146-MW-GRJ (N.D. Fla.), filed June 27, 2018. *See* Pet. 3; Paper 4, 1. The parties also list another proceeding at the Board as a related matter: Case IPR2019-00570, which challenges U.S. Patent No. 8,182,532. *See* Pet. 3; Paper 4, 1.

D. The '158 Patent

The '158 patent relates to a composite bone graft for spinal fusion. Ex. 1002, 1:10–16. Spinal fusion is a surgical procedure in which a patient's intervertebral disc is removed and replaced with an implant to fill the void between adjacent vertebrae. *See* Ex. 2001 ¶ 21. After the implantation procedure, the natural healing process of bones causes the vertebrae to fuse together over time. *Id.*; Ex. 1016 ¶¶ 21–23. Implants for spinal fusion can be made from various materials, including bone obtained from the patient, which is referred to as autologous bone, or bone obtained from a human donor, which is allogenic bone. *See* Ex. 1016 ¶ 25; Ex. 2001 ¶ 26. A bone graft made from autologous bone is an autograft, and a graft made from allogenic bone is called an allograft. *See* Ex. 1016 ¶ 25; Ex. 2001 ¶ 26.

The composite bone graft of the '158 patent includes a plurality of bone portions layered to form a graft unit and one or more biocompatible connectors that hold the graft unit together. Ex. 1002, code (57) (Abstract), 1:10–16, 2:26–28. In the "Background of the Invention," the '158 patent explains that the limited size of cortical bone grafts sometimes prevented their use for spinal fusions:

> Strong cortical bone (the outer layer) is required as a strut in the interbody position to prevent collapse of the disc space while healing occurs. For example, cortical bone obtained from a cadaver source fashioned into struts, is not wide enough for optimum load bearing. This natural limitation often excludes the use of a bone graft product.

Id. at 1:48–54. The '158 patent also states that "[b]one grafts for spinal application often fail because they are extruded from the implantation site due to shifting, rotation, and slippage of the graft, are not cellularized, or fail mechanically." *Id.* at 1:62–65.

The '158 patent purports to solve these problems with a composite bone graft that can be sized for any application, promotes the growth of patient bone at the implantation site, provides added stability and mechanical strength, and does not shift, extrude, or rotate after implantation. *Id.* at 1:26–33, 2:1–7. Figure 6 of the '158 patent is reproduced below:

FIG. 6

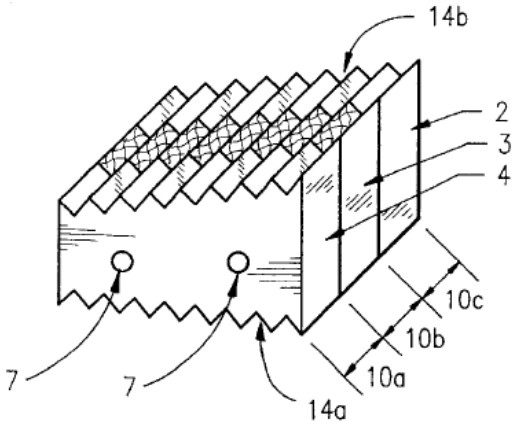

Figure 6 is a perspective view of a composite bone graft. *Id.* at 8:63–65.

As depicted in Figure 6, the composite bone graft is made up of a first cortical bone portion 2, a second cortical bone portion 4, and a cancellous bone portion 3 disposed between them. *Id.* at 19:61–63. Cortical bone pins 7 hold the bone portions together. *Id.* at 19:63–64. The graft also includes textured surfaces 14a and 14b. *Id.*

E. Illustrative Claim

Petitioner challenges claims 1–15, which are all of the claims in the '158 patent. Claims 1, 2, and 13–15 are independent claims. Claim 1 is illustrative of the challenged claims and is reproduced below, with additional line breaks to facilitate review:

1. A composite bone graft, comprising:

a first cortical bone portion;

a second cortical bone portion;

a cancellous bone portion disposed between said first cortical bone portion and said second cortical bone portion to form a graft unit; and

one or more bone pins for holding together said graft unit,

wherein said first cortical bone portion and said second cortical bone portion are not in physical contact, and

wherein said composite bone graft does not comprise an adhesive and

said bone graft is not demineralized.

Ex. 1002, 45:1–12 (additional line breaks added).

F. Prior Art References and Testimonial Evidence

Petitioner relies on the following references for its challenges:

Name	Description	Date	Exhibit
Wolter	Wolter et al., "Bone Transplantation in the Area of the Vertebral Column," *Accident Medicine: Scientific and Clinical Aspects of Bone Transplantation*, vol. 185, pp. 166–75 (1987).	1987	1010[3]

[3] Exhibit 1009 is the original, foreign language version of Wolter. Citations to Wolter in this decision refer to the English translation in Exhibit 1010.

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