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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RTI SURGICAL, INC.,

Petitioner

v.

LIFENET HEALTH,

Patent Owner

Case IPR2019-00569

Patent No. 6,458,158

PETITION FOR *INTER PARTES* REVIEW

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PETITIONER'S EXHIBIT LIST

EX.	DESCRIPTION
1001	U.S. Patent No. 8,182,532 ("the 532 patent")
1002	U.S. Patent No. 6,458,158 ("the 158 patent")
1003	U.S. Patent Application Publication No. 2002/0138143 A1 ("Grooms")
1004	U.S. Patent Application No. 08/920,630 ("Grooms priority document")
1005	Reserved
1006	U.S. Patent No. 6,258,125 ("Paul")
1007	U.S. Provisional Patent Application No. 60/095,209 ("Paul priority document")
1008	U.S. Patent No. 5,989,289 ("Coates")
1009	Wolter et al., "Bone Transplantation in the Area of the Vertebral Column," Scientific and Clinical Aspects of Bone Transplantation, Springer Verlag 1987 ("Wolter")
1010	English Translation of Wolter et al., "Bone Transplantation in the Area of the Vertebral Column," Scientific and Clinical Aspects of Bone Transplantation, Springer Verlag 1987 ("Wolter")
1011	U.S. Patent No. 6,123,731 ("Boyce")
1012	U.S. Patent No. 5,397,364 ("Kozak")
1013	Reserved
1014	Portions of the File History from the 158 patent
1015	Declaration of Michael C. Sherman
1016	Declaration of Jeffrey Scott Fischgrund, M.D.
1017	Reserved
1018	Daniel. J. Miller and Michael G.Vitale, *Russell A. Hibbs: Pioneer of spinal fusion*, 40 SPINE 1311 (2015)

EX.	DESCRIPTION
1019	Robert A. Robinson and George W. Smith, *Anterolateral cervical disc removal and interbody fusion for cervical disc syndrome*, 95 BULLETIN OF THE JOHNS HOPKINS HOSPITAL 223 (1955)
1020	U.S. Patent No. 6,025,538 ("Yaccarino")

I. Introduction

RTI Surgical, Inc., petitions for *inter partes* review of claims 1-15 of U.S. Patent No. 6,458,158 ("the 158 patent"; Ex. 1002). The claims of the 158 patent are directed to a "composite" bone graft formed by pieces of cortical and cancellous bone held together by one or more bone pins.

Composite bone grafts existed before the priority date of the 158 patent. The 1987 publication "Bone Transplantation in the Area of the Vertebral Column" by Wolter et al. ("Wolter"; Ex. 1009) discloses a "composite" graft assembled by placing multiple bone pieces against one another to form alternating layers of cortical and cancellous bone. Ex. 1010, 5, Fig. 1e. One or more metal screws hold the graft together. *Id.* Wolter was not cited during prosecution of the 158 patent.

Before the alleged invention of the 158 patent, bone pins were used to hold together composite bone grafts. Prior art examples include U.S. Patent Application Publication No. 2002/0138143 A1 ("Grooms"; Ex. 1003), U.S. Patent No. 6,258,125, "Intervertebral Allograft Spacer" ("Paul"; Ex. 1006), and U.S. Patent No. 6,025,538, "Compound Bone Structure Fabricated From Allograft Tissue" ("Yaccarino"; Ex. 1020). *See, e.g.*, Ex. 1003, ¶¶48-49, Figs. 7A-B; Ex. 1006, 4:39-633, Fig. 7; Ex. 1020, 3:16-26, 5:33-35, Figs. 6, 8, 9, 15. Bone pins offered known advantages over metal screws including (1) avoiding a permanent foreign body in the patient's spine (2) providing a graft that may ultimately become the patient's

own bone, and (3) avoiding issues that may arise due to a screw becoming loose or dislodged. Thus, at the time of the alleged invention, it would have been obvious to one or ordinary skill in the art to assemble a graft by replacing the metal screw disclosed by Wolter with one or more bone pins.

U.S. Patent No. 6,123,731, "Osteoimplant and Method for its Manufacture" ("Boyce"; Ex. 1011) is a prior art patent cited during prosecution of the 158 patent. Boyce discloses forming a composite bone graft by assembling cortical and cancellous bone portions in alternating layers. Ex. 1011 at 8:16-21, Fig. 6. The bone portions are bonded to each other by demineralizing at least their surfaces to chemically cross-link them. *Id.* at 3:53-4:1. But those of ordinary skill in the art at the time of the alleged invention would have recognized (and Boyce acknowledges) that demineralizing bone weakens it. *Id.* at 4:6-16. Thus Boyce also discloses that bonding may be supplemented with mechanical fasteners, such as pins (natural or synthetic), to increase graft strength. *Id.*, 5:54-61. Because it was well known that bone pins could be used to hold bone grafts together, it would have been obvious to one of ordinary skill in the art to use bone pins to hold the graft disclosed by Boyce together without chemical cross-linking via demineralization (which would weaken the graft).

Claims 1-15 of the 158 patent describe variants of the composite grafts disclosed by Wolter and/or Boyce that would have been obvious to one of ordinary

skill in the art before the alleged invention of the 158 patent. Therefore, there is at least a reasonable likelihood that these claims are unpatentable over (1) Wolter in view of either Grooms or Paul, (2) Wolter in view of either Grooms or Paul in combination with one or more secondary references disclosing known and obvious features of spinal bone grafts; and (3) Boyce in view of either Grooms or Paul.

II. Mandatory notices

Real parties-in-interest: RTI Surgical, Inc. is the real party-in-interest.

Related matters: The 158 patent is one of two related patents, and five total patents, asserted against Petitioner in district court infringement litigation. The related patent is U.S. Patent No. 8,182,532 ("the 532 patent"; Ex. 1001). Both the 158 and the 532 patents are entitled "Composite Bone Graft, Method of Making and Using Same" and claim priority to the same U.S. patent application. Petitioner is challenging the 532 patent on similar grounds in Case IPR2019-00570. The following judicial matter would also be affected by a decision in the proceedings: *LifeNet Health v. RTI Surgical, Inc.*, Case No. 1:18-cv-00146 (N.D. Fla.), filed June 27, 2018.

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Service information: Petitioner consents to service by email at: RTI158IPR@mcandrews-ip.com.

III. Grounds for standing

The 158 patent is available for *inter partes* review and Petitioner is not barred or estopped from requesting an *inter partes* review challenging claims 1-15 of the 158 patent on the grounds identified in this Petition.

IV. Identification of challenges

Petitioner identifies the following grounds of unpatentability:

Ground 1: Claims 1-12 are obvious over Wolter et al., "Bone Transplantation in the Area of the Vertebral Column," Scientific and Clinical Aspects of Bone Transplantation, Springer Verlag 1987 ("Wolter"; Ex. 1009), which is prior art under 35 U.S.C. 102(b), in view of U.S. Patent Application Publication No. 2002/0138143 A1, "Cortical Bone Cervical Smith-Robinson

Fusion Implant" ("Grooms"), which is prior art under 35 U.S.C. 102(e) as of August 27, 1997.

Ground 2: Claims 1-2 and 11-12 are obvious over Wolter in view of U.S. Patent No. 6,258,125, "Intervertebral Allograft Spacer" ("Paul"; Ex. 1006), which is prior art under 35 U.S.C. 102(e) as of August 3, 1998.

Ground 3: Claims 3-10 are obvious over Wolter in view of Paul and further in view of U.S. Patent No. 5,989,289, "Bone Grafts" ("Coates"; Ex. 1008), which is prior art under 35 U.S.C. 102(e) as of October 9, 1997.

Ground 4: Claim 13 is obvious over Wolter in view of either (1) Grooms or (2) the combination of Paul and U.S. Patent No. 5,397,364, "Anterior Interbody Fusion Device," granted March 14, 1995 ("Kozak"; Ex. 1012), which is prior art under 35 U.S.C. 102(b).

Ground 5: Claim 14 is obvious over Wolter in view of either (1) Grooms in combination with U.S. 6,123,731, "Osteoimplant and Method for its Manufacture"

("Boyce"; Ex. 1011), which is prior art under 35 U.S.C. 102(e) as of February 6, 1998, or (2) Paul in combination with Boyce.

Ground 6: Claim 15 is obvious over Wolter in view of either (1) Grooms or (2) Paul.

Ground 7: Claims 1-2, 11-12, and 14 are obvious over Boyce in view of either (1) Grooms or (2) Paul.

V. The 158 patent

A. Subject matter of the 158 patent

The 158 patent relates generally to bone grafts used for spinal fusion. Ex. 1002, 1:11-12. Spinal fusion refers to inducing bone growth that causes adjacent vertebrae of the spine to fuse into a single bony structure. Ex. 1016, ¶ 21 (Declaration of Dr. Jeffery Fischgrund (orthopaedic surgeon and Chairman of the Department of Orthopaedic Surgery at the Oakland University William Beaumont School of Medicine)). Spinal fusion is used in surgical replacement of an intervertebral disc with an implant as treatment of an injury or disease of the spine. *Id.*, ¶23. Bone growth is induced to secure the implant to the adjacent vertebrae thereby fusing the vertebrae. *Id.* An implant formed by bone is referred to as a bone graft implant. *Id.*, ¶24. Bone grafts cause a patient's body to generate new bone that replaces the bone of the graft. *Id.*, ¶26.

Spinal fusion implants must support the load on the spine and must induce bone formation. *Id.*, ¶¶27, 28. Bone graft implants have long been made of both cortical bone and cancellous bone. *Id.*, ¶ 29. Cortical bone is the solid bone at the surface of a bone that can support large loads. *Id.*, ¶29. Cancellous bone is the porous bone inside a bone. *Id.* Cancellous bone in an implant causes new bone to form more quickly than cortical bone. *Id.*, ¶29-31.

The 158 patent is directed to composite bone grafts—grafts formed of two or more distinct bone portions. Ex. 1002, 1:12-16. According to the 158 patent, prior use of bone grafts (instead of non-bone prosthetic implants) for such procedures was "limited in part by the physical size of a cortical bone graft." Ex. 1002, 1:43-47. Bone grafts were often impractical, according to the 158 patent, because "cortical bone obtained from a cadaver source fashioned into struts is not wide enough for optimum load bearing." *Id.*, 50-53. By describing the assembly of composite bone grafts from multiple bone portions, the 158 patent claims to have "enable[d] the use of bone grafts for applications normally suited for only non-bone prosthetic implants" and to have "solve[d] the problem of graft failure by providing a composite bone graft which can be appropriately sized for any application out of for example, strong cortical bone. . . ." *Id.*, 1:65-2:4.

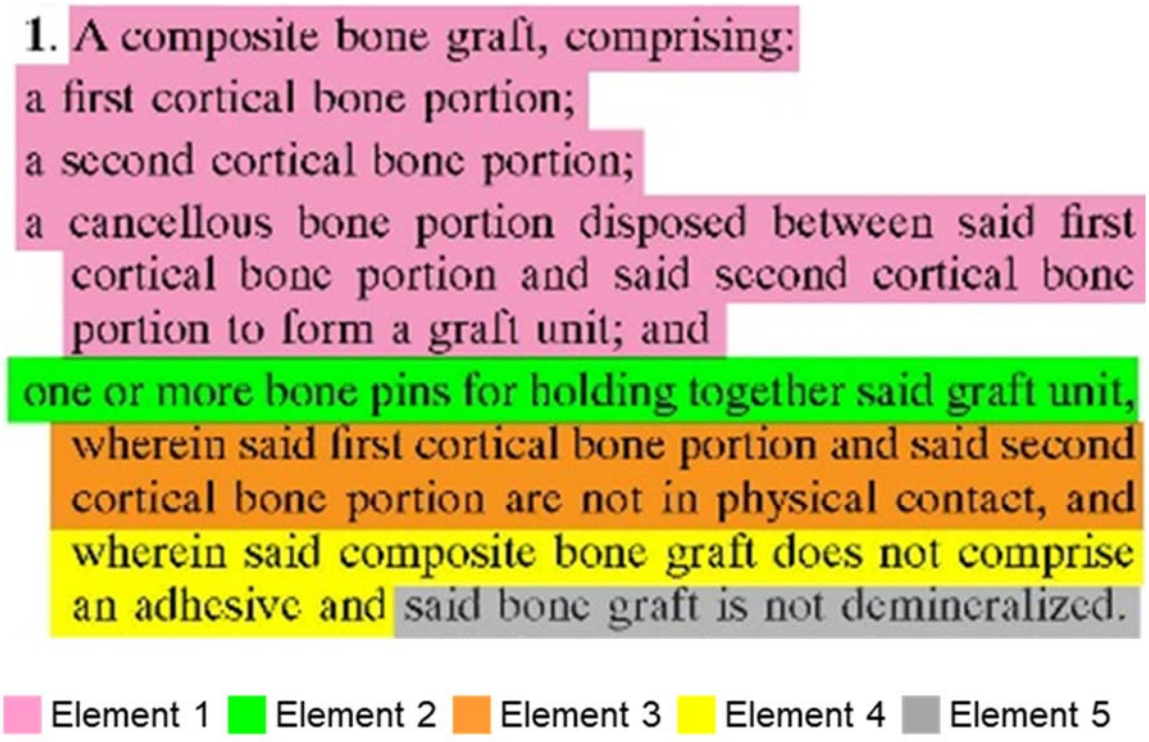
The 158 patent explains that the success of a bone graft depends on whether the graft is cellularized, *i.e.,* fused to the adjacent vertebrae. Ex. 1002, 1:55-57.

Accordingly, the grafts of the 158 patent contain one or more cancellous bone portions, which "promote[s] the ingrowth of patient bone at an implantation site." *Id.*, 2:1-7, 19:33-37.

B. Independent Claims of the 158 patent

Claim 1

Claim 1 may be considered to have five claim elements as identified by the colored highlighting of that claim below:



Those elements are:

- ***Element 1 (cortical-cancellous-cortical composite)***: a composite bone graft comprising a first cortical bone portion, a second cortical bone portion, and a

cancellous bone portion disposed between said first cortical bone portion and said second cortical bone portion to form a graft unit (Ex. 1002, 45:2-7);

- ***Element 2 (bone pins)***: one or more bone pins for holding together said graft unit (*Id.*, 45:8);
- ***Element 3 (no contact between first and second cortical portions)***: said first cortical bone portion and said second cortical bone portion are not in physical contact (*Id.*, 45:9-10);
- ***Element 4 (no adhesive)***: said composite graft does not comprise an adhesive (*Id.*, 45:11-12); and
- ***Element 5 (not demineralized)***: said bone graft is not demineralized (*Id.*, 45:12).[1]

Claim 13

Claim 13 may be considered to have five claim elements as identified by the colored highlighting of that claim below:

[1] Claim 2 is identical to claim 1, except that it (1) uses the term "consisting essentially of" instead of "comprising" and (2) lacks Element 4. *See* Ex. 1002 at 45:13-22.

13. A composite bone graft comprising two or more distinct, adjacent, bone portions comprising at least one cancellous bone portion, layered to form a graft unit; one or more bone pins provided perpendicular to an interface between adjacent bone portions; and a first chamfered edge and a second chamfered edge, said first chamfered edge provided along a length of said composite bone graft at its top edge, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge, such that the chamfered edges are diametrically opposed, wherein said composite bone graft does not comprise an adhesive, and said bone graft is not demineralized.

Element 1 Element 2 Element 3 Element 4 Element 5

Those elements are:

- ***Element 1 (layered cortical-cancellous composite)***: a composite bone graft comprising two or more distinct, adjacent, bone portions comprising at least one cancellous bone portion, layered to form a graft unit (Ex. 1002, 46:43-45);
- ***Element 2 (bone pins)*** : one or more bone pins provided perpendicular to an interface between adjacent bone portions (*Id.*, 46:45-47);
- ***Element 3 (opposed chamfered edges)***: a first chamfered edge and a second chamfered edge, said first chamfered edge provided along a length of said composite bone graft at its top edge, and said second chamfered edge

provided along a length of said composite bone graft at its bottom edge, such that the chamfered edges are diametrically opposed (*Id.*, 46:47-52);

- ***Element 4 (no adhesive)***: said composite bone graft does not comprise an adhesive (*Id.*, 46:53); and
- ***Element 5 (not demineralized)***: said bone graft is not demineralized (*Id.*, 46:54).

Claim 14

Claim 14 may be considered to have six claim elements as identified by the colored highlighting of that claim below:

14. A composite bone graft comprising:
one or more cortical bone portions layered to form a first unit;
one or more cortical bone portions layered to form a second unit;
one or more cancellous bone portions layered to form a third unit; said third unit disposed between said first and said second unit to form a graft unit and wherein one or more of said bone portions comprise a discontinuous bone portion;,
one or more bone pins for holding together said graft unit
said bone graft does not comprise an adhesive; and

one or more therapeutically beneficial substances selected from the group consisting of: an osteoinductive material selected from the group consisting of: autograft bone, allograft bone, demineraized cortical bone, demineralized cancellous bone, discontinuous demineralized cortical bone, collagen comprising one or more growth factors selected from the group consisting of: bone morphogenic protein, and transforming growth factor-β; collagen comprising demineralized bone, cancellous bone, cortical bone, and a growth factor selected from the group consisting of: bone morphogenic protein, and transforming growth factor-β; an osteoconductive substance selected from the group consisting of: demineralized cortical bone, demineralized cancellous bone, discontinuous demineralized cortical bone, discontinuous cortical bone, collagen, cancellous bone, hydrpxyapitate, polymeric matrix material, bioglass, bioceramic, resorbable biomaterial, bioabsorbable polymer, a plastic matrix, stainless steel, titanium, and cobalchromium-molybdenum alloy matrix; and a pharmaceutically active agent selected from the group consisting of: a growth factor selected from the group consisting of: bone morphogenic protein, and transforming growth factor-β, a chemotherapeutic agent, an anti-inflammatory agent, and an antibiotic, and wherein said bone portions are not demineramized.

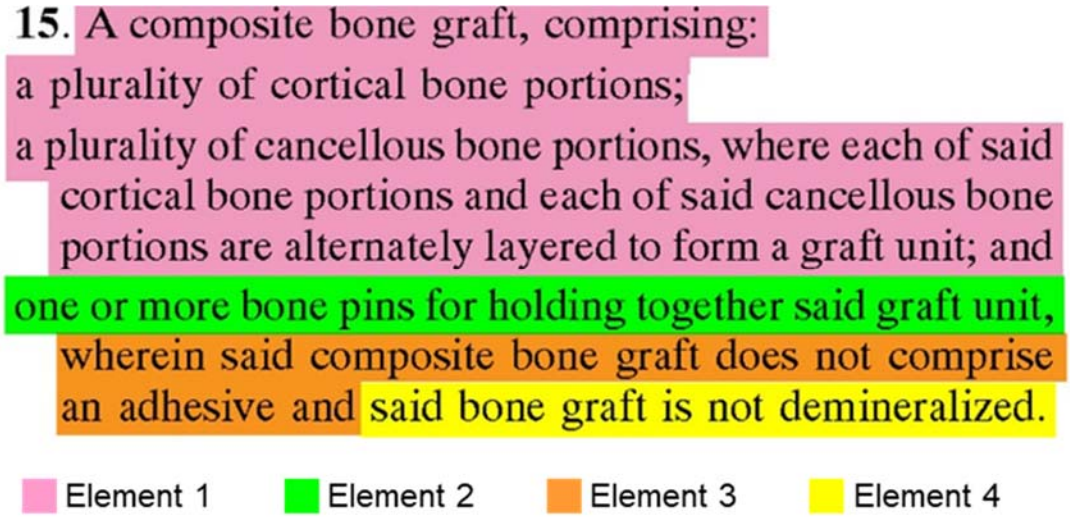
Element 1 Element 2 Element 3 Element 4 Element 5 Element 6

Those elements are:

- ***Element 1 (cortical unit-cancellous unit-cortical unit composite)***: a composite bone graft comprising one or more cortical bone portions layered to form a first unit; one or more cortical bone portions layered to form a second unit; and one or more cancellous bone portions layered to form a third unit; said third unit disposed between said first and said second unit to form a graft unit (Ex. 1002, 46:55-62);
- ***Element 2 (bone pins)***: one or more bone pins for holding together said graft unit (*Id.*, 46:65);
- ***Element 3 (discontinuous bone portion)***: one or more of said bone portions comprise a discontinuous bone portion (*Id.*, 46:63-64);
- ***Element 4 (therapeutic substance)***: [the composite bone graft comprises] one or more therapeutically beneficial substances selected from [a lengthy Markush group] (*Id.*, 47:1-48:7);
- ***Element 5 (no adhesive)***: said bone graft does not comprise an adhesive (*Id.*, 46:66); and
- ***Element 6 (not demineralized)***: said bone portions are not demineralized (*Id.*, 48:7-8).

Claim 15

Claim 15 may be considered to have four claim elements as identified by the colored highlighting of that claim below:



Those elements are:

- ***Element 1 (multilayered cortical-cancellous composite)***: a composite bone graft comprising a plurality of cortical bone portions; [and] a plurality of cancellous bone portions, where each of said cortical bone portions and each of said cancellous bone portions are alternately layered to form a graft unit (Ex. 1002, 48:9-13);
- ***Element 2 (bone pins)***: one or more bone pins for holding together said graft unit (*Id.*, 48:14);
- ***Element 3 (no adhesive)***: said composite graft does not comprise an adhesive (*Id.*, 48:15-16); and
- ***Element 4 (not demineralized)***: said bone graft is not demineralized (*Id.*, 48:16).

C. Prosecution history

The application from which the 158 patent issued was filed in October 2000, claiming priority to a number of other applications, the earliest of which was filed on January 5, 1999.[2]

The claims were initially rejected over Boyce or Boyce in combination with a secondary reference. Ex. 1014, 1-6. Patent Owner overcame those rejections by (1) amending the claims to recite that the bone graft is not demineralized and (2) arguing that Boyce failed to teach a non-demineralized bone graft because demineralization is a step in the chemical cross-linking process described by Boyce. *Id.*, 7-15. The application was then allowed. *Id.*, 16-17. There is no indication that the Examiner considered whether it would have been obvious to hold the composite graft of Boyce together using something other than the described chemical cross-linking process, which would have rendered the demineralization step unnecessary.

D. Person of ordinary skill in the art

The art relevant to the 158 patent is design of spinal bone grafts. See Ex. 1015, ¶¶16, 17 (Declaration of Michael C. Sherman). A person of ordinary skill in

[2] For purposes of this Petition, therefore, Petitioner considers January 5, 1999 to be the alleged date of invention.

the art of the 532 patent at the time of the alleged invention would typically have had at least a bachelor's degree in mechanical, biomechanical, or biomedical engineering or a closely-related discipline, as well as 5-10 years of experience designing and developing orthopedic implants and/or spinal interbody devices and/or bone graft substitutes. Alternatively, such a person would typically have had an advanced degree (master's or doctorate) in one of the above-identified fields, as well as 3 to 5 years of experience; or would be a practicing orthopedic surgeon with at least five years of experience. See Ex. 1015, ¶22.

E. Claim construction

The 158 patent provides a subsection titled "Definitions," which is described as "provid[ing] a clear and consistent understanding of the specification and claims, including the scope to be given such terms." Ex. 1002, 11:15-18. The following claim terms, the meaning of which may be relevant to this proceeding, are defined by the 158 patent:

Chamfer: "an oblique face formed at a corner of a composite bone graft, at an angle to the adjacent principal faces." Ex. 1002, 12:31-34.

Composite: "a bone graft which is made up of two or more distinct bone portions." Ex. 1002, 12:49-51.

Discontinuous bone portion: "a bone portion that contains artificially created void areas including for example, a perforated bone portion." Ex. 1002, 13:29-45.

VI. Summary of the prior art

The Grounds presented in this Petition can be divided into two groups based on the primary references on which they are based:

- Grounds 1 through 6 based on Wolter;
- Ground 7 based on Boyce.

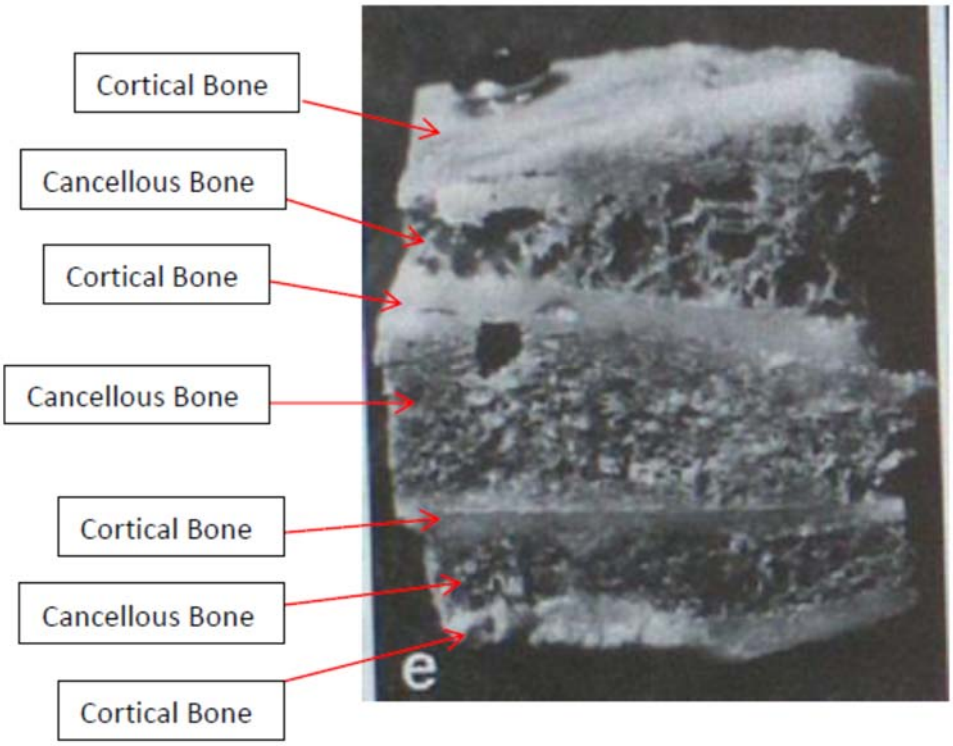
Each primary reference, as set out below, discloses (1) a composite bone graft assembled from distinct bone portions, (2) the bone portions include layered cortical and cancellous portions, and (3) the graft does not include an adhesive. The bone of the Wolter graft is not demineralized. Overviews of each primary reference and important secondary references are set out below.

A. Wolter

Wolter is a German paper titled "Bone Trasnplantation in the Area of the Vertebral Column" published in 1987. Wolter is thus prior art under 35 U.S.C. 102(b). All references to Wolter are to the English-language translation of that paper, Ex. 1010. Wolter was not cited during the prosecution of the 158 patent.

Wolter discloses a "composite corticospongial block" or "sandwich block" implant characterized by the layering of several corticospongial bone pieces united into a fixed block by one or two screws. Ex. 1010, 5. An image of such a composite block appears in Figure 1e, reproduced below.

Ex. 1010, 10. The term "corticospongial" refers to a piece of bone containing both cortical bone and spongiosa, i.e., cancellous, bone. *See* Ex. 1015, ¶45. Figure 1e shows a composite corticospongial block formed by bone pieces placed together to create a block having alternating layers of cortical and cancellous bone. Figure 1e, annotated to identify these layers, is reproduced below.



See Ex. 1015, ¶46. Wolter discloses the successful implantation of the composite block shown above in the spine of a subject. Ex. 1010, 10.

B. Grooms

Grooms is a publication of U.S. patent application 09/905,683, filed July 16, 2001, which is a continuation of U.S. patent application 09/701,933, filed August 25, 1998, and a continuation-in-part of U.S. patent application 08/920,630, filed August 30, 1997 ("the 630 application"). For the portion of its disclosure supported by the written description of the 630 application, therefore, Grooms is entitled to August 30, 1997, as a prior art date under 35 U.S.C. 102(e). *See* 35 U.S.C. 102(e) (pre-AIA). To demonstrate that the disclosure of Grooms referred to

in this Petition is entitled to the 1997 prior art date, each citation to Grooms will be to both Grooms itself (Ex. 1003) and the 630 application (Ex. 1004). Neither Grooms nor any of the applications to which it claims priority were cited during prosecution of the 158 patent.

Grooms discloses implants made of cortical bone, *i.e.*, bone grafts, for use in cervical vertebral fusion procedures commonly known in the art as Smith-Robinson procedures. Ex. 1003, Abstract; Ex. 1004, 1:6-10. Smith-Robinson procedures are anterior spinal fusions in which an implant is inserted into a space between adjacent vertebrae to provide support and induce fusion of the vertebrae. Ex. 1003, ¶5, 10; Ex. 1004, 1:14-23, 2:20-25. The implant may be either autograft or allograft.[3] Ex. 1003, ¶24, Ex. 1004, 4:1-2.

In one embodiment, an implant having an increased height may be prepared by stacking two distinct implants. Holes are drilled through the stacked implants and then pins, e.g., made from cortical bone, are pressed into the holes to form the stacked implants into a unitary body. Ex. 1003, ¶48; Ex. 1004, 16:29-17:21. An

[3] Bone obtained from the patient is referred to as autologous bone and a graft made of autologous bone is an autograft. Bone from a donor is allogenic bone and a graft of allogenic bone is an allograft. Ex. 1015, ¶ 73, Ex. 1016, ¶25.

example of a graft formed in such a manner is shown in Figures 7A and B, reproduced below.

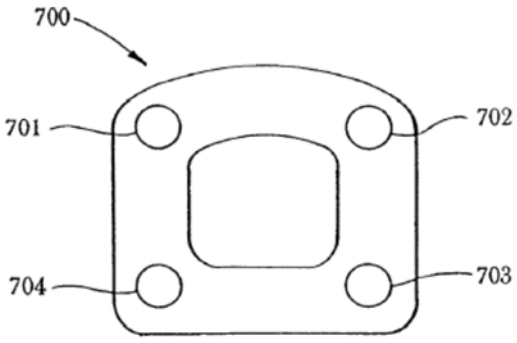


Fig. 7A

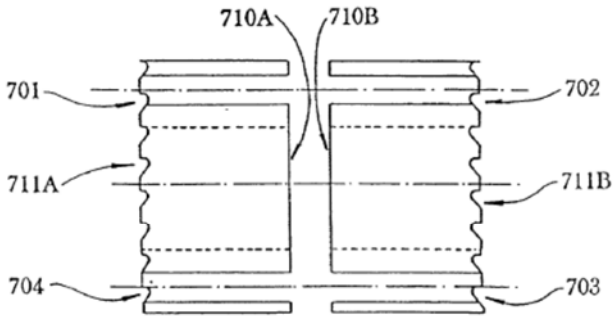


Fig. 7B

Grooms also discloses that the implants may be assembled from component parts. Ex. 1003, ¶49; Ex. 1004, 17:22-18:6. As depicted by Figures 8A and 8B (reproduced below), two halves of an implant may be procured from cortical bone and then juxtaposed to form a unitary implant. *Id.*

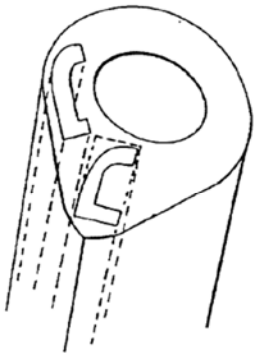


Fig. 8B

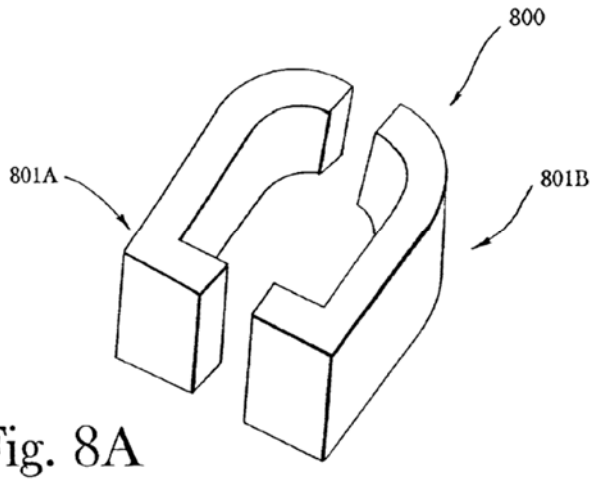


Fig. 8A

The two halves may be maintained in contact by forming holes in each half and forcing pins through those holes. *Id.*; *see also* Ex. 1003, ¶48; Ex. 1004, 17:10-12 (stating that the pins may be made of cortical bone).

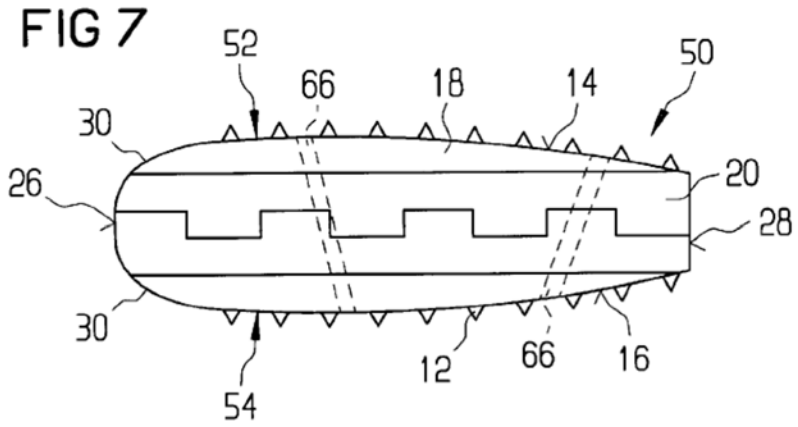
C. Paul

Paul is the U.S. patent that issued from patent application 09/363,844, filed July 30, 1999, and which claims priority to U.S. provisional application 60/095,209, filed August 3, 1998 ("the 209 application"). For disclosure supported by the written description of the 209 application, therefore, Paul is entitled to August 3, 1998, as a prior art date under 35 U.S.C. 102(e). *See* 35 U.S.C. 102(e) (pre-AIA). To demonstrate that the disclosure of Paul referred to in this Petition is entitled to the 1998 prior art date, each citation to Paul will be to both Paul itself (Ex. 1006) and the 209 application (Ex. 1007). Paul was not cited during the prosecution of the 158 patent.

Paul discloses an intervertebral implant made of allogenic bone. Ex. 1006, Abstract; Ex. 1007, 1:4-6. The implant is designed for posterior lumbar interbody fusion (PLIF), in which an implant is inserted in a space between two vertebral bodies, the implant allowing for bone growth and fusion between the vertebral bodies. Ex. 1006, 1:14-2:9; Ex. 1007, 1:9-2:24. One of ordinary skill in the art in January 1999 and earlier would have recognized that the PLIF graft implants

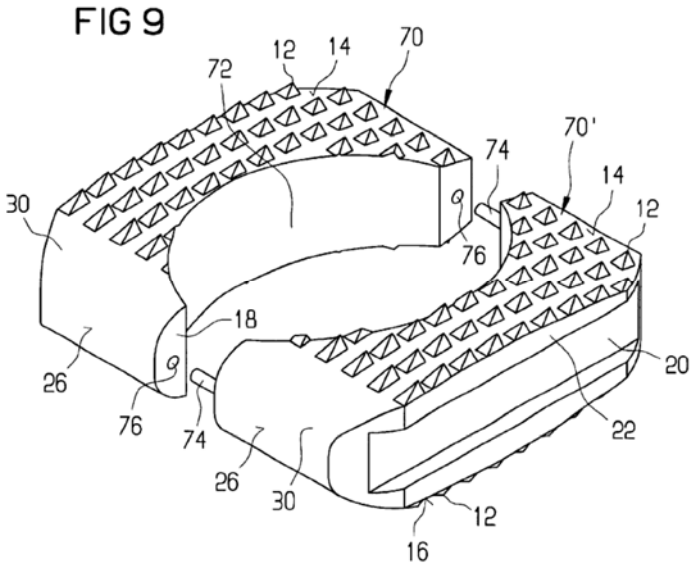
disclosed by Paul are necessarily cortical bone. Ex. 1015, ¶¶96, 97. This understanding is confirmed by the source of the bone, as disclosed by Paul, the load that the implants carry, and the shaping of parts of the graft to interlock with each other. *Id.*, ¶¶96-98.

The implant may be made of multiple sections, such as two halves. Ex. 1006, 2:30-38; Ex. 1007, 3:7-14. The two halves may be assembled together using (1) connecting surfaces which mate with one another and/or (2) aligned holes that receive a pin, such as a pin made of bone. *Id.* Figure 7, reproduced below shows one such implant:



The implant shown in Figure 7 has separate and distinct top and bottom portions joined together by surfaces that contain interlocking ridges and grooves. Ex. 1006, 4:39-63; Ex. 1007, 6:8-32. A pin, preferably of allogenic bone, passes through aligned holes in the top and bottom portions and holds the assembly together. *Id.*

Figure 9, reproduced below, shows another such implant:



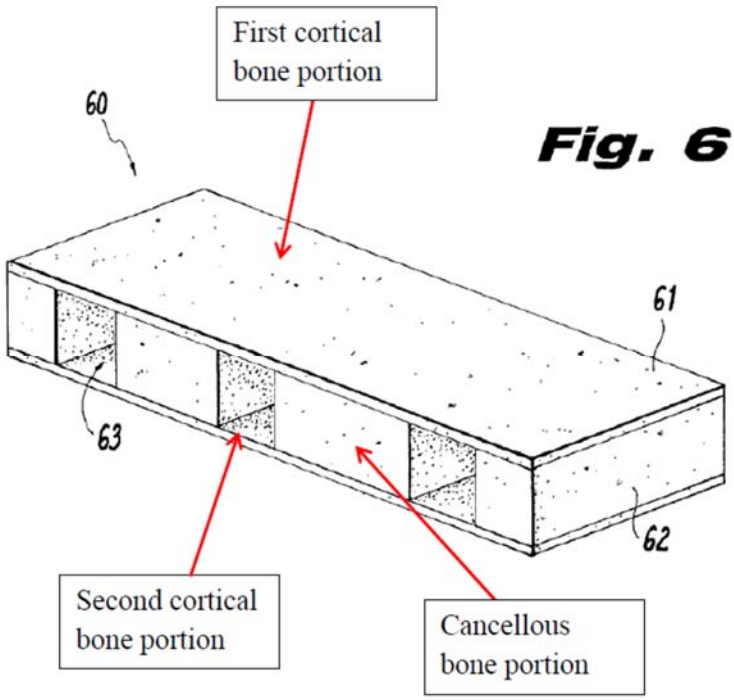
The Figure 9 implant is made of two C-shaped halves placed side-by-side to form a central cylindrical space. Ex. 1006, 5:8-23; Ex. 1007, 6:33-7:13. To assemble the implant, locking pins are inserted into apertures formed within each half and the cylindrical space is filled with an osteoconductive material. *Id.*

D. Boyce

Boyce is the U.S. patent that issued from patent application 09/020,205, filed February 6, 1998. Boyce therefore has a prior art date of February 6, 1998, under 35 U.S.C. 102(e). Boyce was cited during the prosecution of the 158 patent but, as explained in §XII.A., *infra*, the rejection based on Boyce was overcome by a claim amendment reciting that the bone graft is not demineralized. The Examiner,

however, did not consider the obviousness of preparing the graft of Boyce without demineralization.

Boyce discloses osteoimplants made from aggregates of bone-derived elements. Ex. 1011, Abstract. The bone-derived elements may include cortical and cancellous bone, preferably from allogenic sources. *Id.*, 4:2-5. In one embodiment, Boyce discloses an osteoimplant built up from cortical bone sections and cancellous bone sections arranged in alternating layers. *Id.*, 8:16-21, Fig. 6 (reproduced below and annotated)



See Ex. 1015, ¶92.

Boyce teaches bonding the bone-derived elements together by demineralizing the bone to expose collagen molecules and then forming chemical linkages between the exposed collagen molecules. Ex. 1011, 3:53-58, 6:28-43. To increase the shape-retaining and/or mechanical strength characteristics of the osteoimplant, Boyce teaches that one may also use mechanical fasteners such as pins, screws, dowels, etc. *Id.*, 5:54-61.

Boyce also discloses that the osteoimplant can possess one or more cavities which communicate with the surface of the implant through pores, apertures, perforations, or channels. Ex. 1011, 4:51-55. The cavities and associated pores, etc., can be filled with one or more medically/surgically useful substances which promote or accelerate new bone growth or bone healing. *Id.*, 4:55-5:31.

VII. Ground 1: Claims 1-12 are obvious over Wolter in view of Grooms

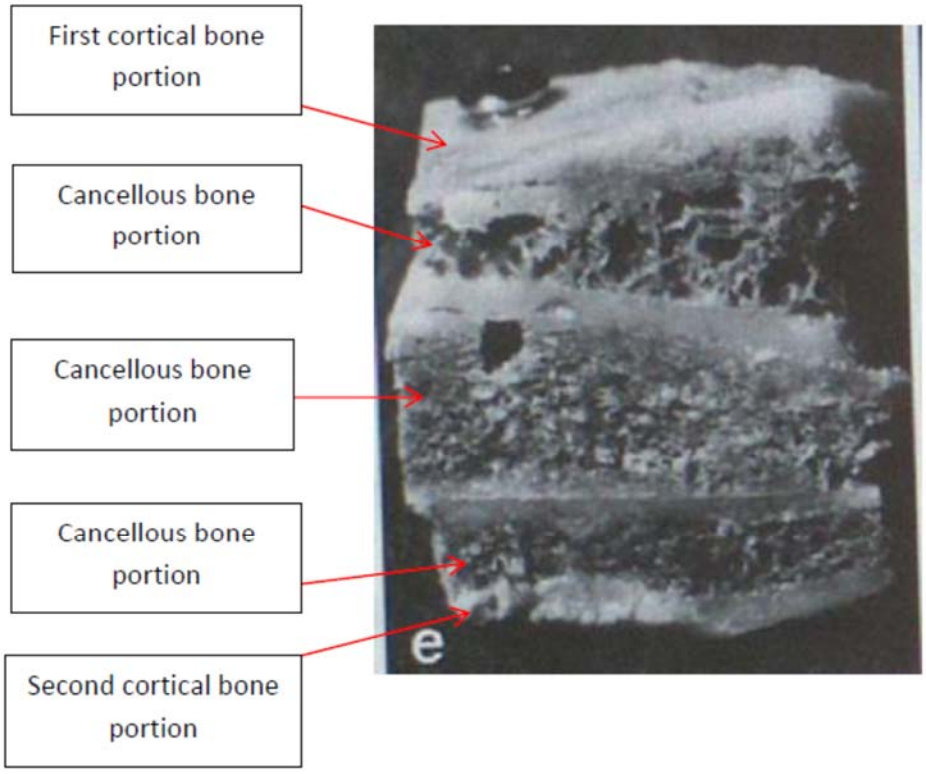
A. Claim 1

Wolter discloses most of the five elements of claim 1 (*see* §V.A, *supra*). The Wolter graft does not have the bone pin required by claim 1, but rather is held together by a metal screw. It would have been obvious to one of ordinary skill in the art to have replaced that screw with a pin made from bone, as is taught, for example, by Grooms. Ex. 1015, ¶348. That replacement would have been advantageous, as it would have both (1) eliminated the presence of a permanent foreign body (the metal screw) in the patient's spine and (2) allowed the graft to be

made entirely of bone, thereby avoiding potential complications that may arise from loosening of the bone screw during bone substitution. *Id.*, ¶300. As explained in detail below, the graft that results from that replacement satisfies every element of claim 1. Claim 1 is unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Grooms. Ex. 1015, ¶349.

Element 1 (cortical-cancellous-cortical composite)

Wolter discloses a composite bone graft made of distinct, alternating layers of cortical and cancellous bone ("the Wolter graft"). Ex. 1010, 5, Fig. 1e. A person of ordinary skill would have understood that Wolter discloses a composite bone graft comprising a first cortical bone portion, a second cortical bone portion, and a cancellous bone portion disposed between the first and second cortical bone portions, as shown below in annotated Figure 1e:



See Ex.1015, ¶¶339, 340.

Element 2 (bone pins)

Rather than using one or more bone pins to hold together portions of the graft, Wolter utilizes one or more screws. Ex. 1010, 5, Fig. 1e (showing a metal screw holding the graft together); Ex.1015, ¶45.

Grooms teaches that distinct portions of an intervertebral composite bone graft may be held together by forming holes in portions of the graft and forcing a pin through the holes to create a unitary graft. Ex. 1003, ¶¶48-49; Ex. 1004, 16:29-

18:6; *see also* Figs. 7A-B; Ex.1015, ¶¶75-79. Grooms also teaches that the pins may be made of bone. *Id.*

It would have been obvious to a person of ordinary skill in the art to have replaced the one or more metal screw(s) of Wolter with the one or more bone pins of Grooms. *See* Ex. 1015, ¶348. Such a person would have been motivated to replace the metal screws of Wolter with cortical bone pins, such as those disclosed by Grooms, in order to eliminate a foreign object—the metal screw—from being permanently present in the patient's spine. *Id.*, ¶300. Moreover, one of ordinary skill in the art would have had a reasonable expectation of successfully making such a substitution because Grooms discloses that bone pins are suitable to secure distinct portions of a composite bone graft together. *Id.*, ¶¶77- 79.

Element 3 (no contact between first and second cortical portions)

The first and second cortical bone portions in the Wolter graft are not in physical contact. As shown by the annotated Figure 1e above, there are multiple portions of both cortical bone and cancellous bone that physically separate the cortical bone portions. *See* Ex.1015, ¶341.

Element 4 (no adhesive)

Wolter discloses, in detail, the preparation of the bone graft. Yet Wolter says nothing of any adhesive, instead describing the use of one or more screws to hold the graft together. Ex. 1010, 5-6, Figs. 1a-f. Moreover, because the bone

material is harvested from the patient and the graft is prepared during the spinal surgery, *id.*, one of ordinary skill would not expect an adhesive to be used. Ex. 1015, ¶342. For both reasons, a person of ordinary skill would have understood that the Wolter graft does not include an adhesive. *Id.* Alternatively, it would have been obvious for such a person to have prepared the Wolter graft without an adhesive, as one of ordinary skill in the art would have understood that the graft is held together by mechanical connectors, *e.g.,* screws, making adhesive unnecessary. *Id.*

Element 5 (not demineralized)

Wolter discloses the preparation of the graft during surgery and says nothing of demineralization. Ex. 1010, 5-6, Figs. 1a-f. Moreover, demineralization is not done in an operating room. Ex. 1015, ¶345. Accordingly, a person of ordinary skill would have understood that the bone in the Wolter graft is not demineralized. Ex.1015, ¶346. Alternatively, it would have been obvious for such a person to have prepared the Wolter graft using non-demineralized bone, as one would have understood that the use of demineralized bone would be disfavored. *Id.*¶¶28, 346.

B. Claim 2

Claim 2 is identical to claim 1, except that (1) claim 2 uses the language "consisting essentially of" instead of "comprising" and (2) claim 2 does not contain element 4 (reciting that the graft does not include an adhesive).

The term "consisting essentially of" is used to signal a partially open claim. Specifically, "the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." *PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

Claim 1 recites a composite bone graft "comprising" limitations, one of which expressly excludes the use of adhesive. Claim 2 recites a composite bone graft "consisting essentially of" every limitation recited by claim 1 except the limitation that excludes adhesive. "Differences among claims can also be a useful guide in understanding the meaning of particular claim terms." *Philips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*). Construing claim 2 in view of claim 1, claim 2 should be construed to permit an amount of adhesive that does not materially affect the composite bone graft. The "corticospongial sandwich block" disclosed by Wolter does not include adhesive. Ex. 1015, ¶342. Claim 2 is unpatentable over Wolter in view of Grooms for the same reasons that

claim 1 is unpatentable as obvious over that combination as set out above by §VII.A.

Alternatively, looking to other materials present in the "corticospongial sandwich block" disclosed by Wolter, claim 2 recites a first cortical bone portion, a second cortical bone portion, a cancellous bone portion, and one or more bone pins. Ex. 1002, 45:13-23. However, the specification makes clear that the presence of additional cortical and/or cancellous bone portions, such as those in the Wolter graft, does not materially affect the basic properties of the invention. *See* Ex. 1002, 2:39-41, 3:9-27, 26:65-27:17, 32:55-33:3, 35:5-43, 35:53-64, 36:40-63, 48:9-16. Therefore, claim 2 is open to the presence of additional cortical and/or cancellous bone portions. *See, e.g., Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1343–44 (Fed. Cir. 2009) (interpreting "consisting essentially of" as open to the presence of materials not listed in the claim where the specification described embodiments containing those materials). Because claim 2 is open to the additional cortical and cancellous bone portions that are present in the Wolter graft, claim 2 is unpatentable as obvious over Wolter and Grooms for the reasons explained in §VII.A.

C. Claims 3, 5

Claims 3 and 5 (Ex. 1002, 45:24-41, 45:56-46:6) recite that the graft of claims 1 or 2:

- is shaped as a trapezoid wedge (claim 3) or a cervical wedge (claim 5) [*element 1*] having
- dimensions, *i.e.,* anterior and posterior height, composite width, and length, within recited ranges [*element 2*]; and
- top and bottom textured surfaces, the textured surfaces being opposing and disposed perpendicular to interfaces of the bone portions, and the top and bottom textured surfaces comprising a plurality of continuous linear protrusions defining a saw-tooth pattern [*element 3*].

Wolter does not specifically describe a graft as wedge-shaped, nor that it contains a saw-tooth pattern of continuous linear protrusions on its top and bottom surfaces. But spinal bone graft implants having a wedge shape were known prior to the 158 patent. Because it was standard practice to provide a graft having a shape and dimensions as required by a patient's anatomy, one of ordinary skill would have known that the Wolter graft would advantageously be configured with the claimed wedge shape and dimensions. *See* Ex. 1015, ¶¶363, 365; Ex. 1016, ¶¶41-46. It also would have been obvious to form the Wolter graft to have surface texturing as taught by Grooms to prevent post-operative graft expulsion. Ex. 1015, ¶¶360-362; Ex. 1016 ¶40. Claims 3 and 5 are unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Grooms. Ex. 1015, ¶368.

Element 1

The Wolter graft is a block that is not specifically disclosed to be a wedge. However, the use of wedge-shaped spinal implants was known to those of ordinary skill in the art. *See* Ex. 1015, ¶365, Ex. 1016, ¶¶45, 46. One of ordinary skill would have known that the Wolter graft would advantageously be configured as a trapezoid or cervical wedge, so that it could be used in procedures in which a wedge-shaped implant was needed. Ex. 1015, ¶365.. Such a person would have had a reasonable expectation of success because the machining of the Wolter graft to form a wedge would have been well within his or her abilities. *Id.*

Element 2

Wolter teaches that the dimensions of the graft are determined by the size of the vertebral cavity to be filled. *See* Ex. 1010, 5-6; *see also* Ex. 1015, ¶363; Ex. 1016, ¶¶41-46. Grooms discloses ranges of widths, lengths and heights of a spinal bone implant. Ex. 1003, ¶56, Ex. 1004, 18:17-20. The entire range of implant widths and the entire range of implant lengths disclosed by Grooms are within the ranges of implant widths and lengths, respectively, recited by claims 3 and 5. Ex. 1015, ¶364. It would have been obvious to one of ordinary skill in the art in January 1999 and earlier to form a spinal bone graft as taught by Wolter to have a width and a length within the ranges recited by claims 3 and 5. *Id.*

One of ordinary skill in the art would have recognized that spinal anatomy required wedge shaped implants. Ex. 1015, ¶365, Ex. 1016, ¶¶45, 46. Angles of

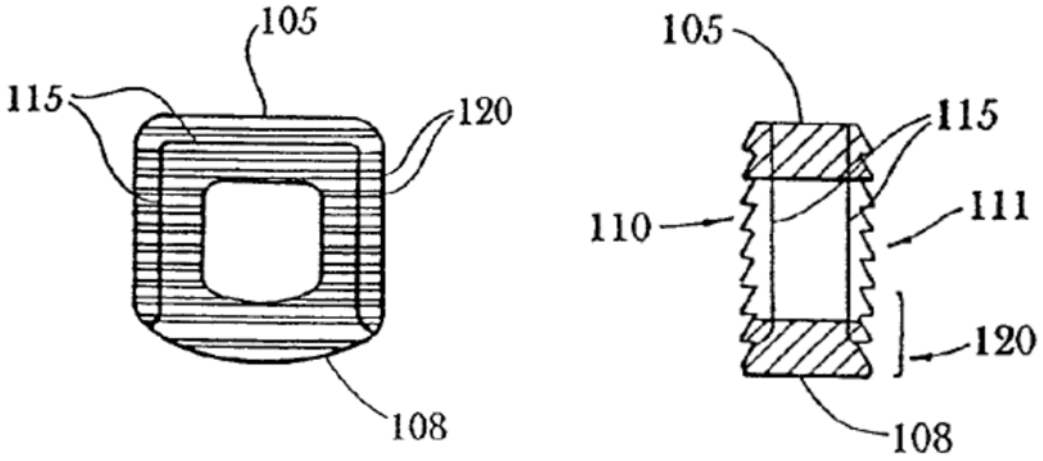
the opposing surfaces of wedge shaped implants were known as disclosed, for example, by Paul. *Id.* In view of that knowledge and the implant heights disclosed by Grooms, it would have been obvious to one of ordinary skill in the art to form an implant having anterior and posterior heights as recited by claims 3 and 5. Ex. 1015, ¶367.

Element 3

The top and bottom surfaces of the Wolter graft are opposing and disposed perpendicular to the interfaces of the bone portions. *See* Ex.1015, ¶¶50, 51, 358 (explaining that the Wolter graft is placed into a vertebral cavity such that the interfaces between the cortical and cancellous layers contact the adjacent vertebrae).

Wolter does not disclose that the top and bottom surfaces are textured to comprise a plurality of continuous linear protrusions defining a saw-tooth pattern. It was, however, well known to provide an intervertebral bone graft implant with texturing on its vertebral-engaging surfaces in order to better retain the graft within the spine. *See* Ex. 1015, ¶362; Ex. 1016, ¶40.

Grooms discloses a graft having top and bottom surfaces inscribed with a plurality of continuous linear protrusions having the profile of teeth angled toward the anterior face of the graft. Ex. 1003, ¶34; Ex. 1004, 9:13-10:6; *see also* Figs. 1C-1D, reproduced below; Ex. 1015, ¶360-361.



One of ordinary skill would have known that the Wolter graft could advantageously be configured so that its upper and lower vertebral-engaging surfaces included a plurality of continuous linear protrusions defining a saw-tooth pattern, as taught by Grooms. *See* Ex. 1015, ¶362. Such a person would have been motivated to do so in order to reduce the chances of graft migration and/or expulsion of the graft from the vertebral column as taught by Grooms. *Id.*; Ex. 1016, ¶40.

Such a person would also have had a reasonable expectation of successfully forming the continuous linear protrusions on the surfaces of the Wolter graft because the provision of such texturing to the surfaces of bone grafts was well-understood. *Id.*, ¶365. Grooms, for instance, describes at least two different procedures by which the continuous protrusions may be prepared. Ex. 1003, ¶44; Ex. 1004, 14:23-15:6.

D. Claims 4, 6

Claims 4 and 6 (Ex. 1002, 45:42-55, 46:7-21) recite that the graft of claims 1 or 2:

- is a parallel block (claim 4) or a cervical block (claim 6) [*element 1*] having
- dimensions, *i.e.,* height, composite width, and length, within recited ranges [*element 2*]; and
- top and bottom textured surfaces, the textured surfaces being opposing and disposed perpendicular to interfaces of the bone portions, and the top and bottom textured surfaces comprising a plurality of continuous linear protrusions defining a saw-tooth pattern [*element 3*].

The limitations of claims 4 and 6 differ from those of claims 3 and 5 only as to the height of the recited implant. The requirements recited by claims 4 and 6 for textured surfaces, width and length of the recited composite bone graft are the same as those recited by claims 3 and 5. *See* Ex. 1015, ¶¶354, 369, 373; Ex. 1016, ¶¶41-46. Claims 4 and 6 are unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Grooms. Ex. 1015, ¶376.

Element 1

Wolter discloses a graft having the shape of a block with parallel sides. See Ex. 1010, Figure 1e, reproduced below.

To the extent that Patent Owner may argue that imperfections in the Wolter graft prevent it from being a parallel or square block, one of ordinary skill would have known that when preparing the Wolter graft from allograft bone it would have been advantageous to have avoided those imperfections, especially given the more advanced machining possible at the time of the alleged invention. *Id.*, ¶365.

Element 2

Claims 4 and 6 recite ranges of lengths and widths identical to those recited by claims 3 and 5. As explained with respect to claims 3 and 5 (*Element 2*), it would have been obvious to one of ordinary skill in the art to form the Wolter graft to have a width and length within those ranges in view of the Grooms disclosure. Ex. 1015, ¶¶363-364. Grooms further discloses implant heights that are in the ranges of heights recited by claims 4 and 6. Ex. 1015, ¶¶375. It would therefore

have been obvious to one of ordinary skill in the art in view of Grooms to form the graft disclosed by Wolter to have a height in the range recited by claims 4 and 6. *Id.*; Ex. 1016, ¶¶41-46.

Element 3

As set out above by §VII.C (*Element 3*), it would have been obvious to one of ordinary skill in the art to provide a saw-tooth pattern of continuous linear protrusions as disclosed by Grooms on the top and bottom vertebral-engaging surfaces of the "corticospongial sandwich block" disclosed by Wolter. *See* Ex. 1015, ¶¶60-62.

E. Claims 7-10

Each of claims 7-10 recites that the plurality of continuous protrusions in the graft of one of claims 3-6 are from about 0.1 mm to about 5.0 mm high.

Grooms teaches that the teeth may be provided with a depth of 0.381 mm (0.015"), which falls squarely within the "0.1 to about 5.0 mm" recited in claims 7-10. Ex. 1003, ¶44; Ex. 1004, 15:1-3; Ex. 1015, ¶¶381, 382. Claims 7-10 are therefore unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Grooms. Ex. 1015, ¶382.

F. Claim 11

Claim 11 recites that, in the graft of claims 1 or 2, (1) one or more cortical bone planks are layered to form each of the first and second cortical bone portions

and (2) one or more cancellous bone planks are layered to form the cancellous bone portion. The Wolter graft discloses this structure as it literally is composed of layers of cortical and cancellous bone. *See* §VI.A. Alternatively, Grooms discloses that separate sections of cortical bone may be assembled and material that enhances bone fusion may be placed between them. In view of this teaching of Grooms, it would have been obvious to one of ordinary skill to form the "corticospongial sandwich block" of Wolter from separate sections of cortical and cancellous bone. *See* Ex. 1015, ¶¶385-389. Claim 11 is unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Grooms. Ex. 1015, ¶389.

G. Claim 12

Claim 12 recites that the graft of claims 1 or 2 comprises allogenic or xenogenic bone. One of ordinary skill would have known that the Wolter graft could advantageously be prepared from allograft bone, as taught by Grooms (Ex. 1003, ¶24; Ex. 1004, 4:1-2), because the advantages of allograft bone over autograft bone were well-understood before the relevant date of the 158 patent. *See* Ex. 1015, ¶¶392-397. Claim 12 is unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Grooms. Ex. 1015, ¶397.

VIII. Ground 2: Claims 1-2 and 11-12 are obvious over Wolter in view of Paul

A. Claim 1

Wolter discloses most of the five elements of claim 1 (*see* §§V.A and VII.A, *supra*). The Wolter graft is an autograft bone implant, meaning that the bone material used in the graft is harvested from the patient and the graft is prepared during the spinal surgery. Ex. 1015, ¶73. By the late 1990s, however, it was well-accepted that the preparation of spinal implants from allograft bone, i.e., bone harvested from donations, was preferred to the use of autograft bone. *See* Ex. 1015, ¶¶394-396, Ex. 1016, ¶¶36-39.

One of ordinary skill would have known that the graft disclosed (and shown to be effective) by Wolter could advantageously be prepared from allograft bone. *See* Ex. 1015, ¶¶314-320. In doing so, such a person would have applied known techniques to the preparation of such implants from allograft bone. *Id.*

While the Wolter graft is held together by a metal screw, one of ordinary skill would have known that the Wolter graft could instead be held together by a pin made from bone as is taught by Paul. Ex.1015, ¶¶321, 401, 402. That replacement would have been advantageous, as it would have both (1) eliminated the presence of a permanent foreign body (the metal screw) in the patient's spine and (2) avoided any potential complication due to screw loosening or being dislodged during bone formation and substitution. *Id.*, ¶¶402, 320. As explained

below, the graft created by that replacement satisfies every element of claim 1. Claim 1 is unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Paul. Ex. 1015, ¶403.

Element 1 (cortical-cancellous-cortical composite)

As set out above by §VII.A (Element 1), Wolter discloses a composite graft comprising a first cortical bone portion, a second cortical bone portion, and a cancellous bone portion disposed between the first and second cortical bone portions. If would have been obvious to one of ordinary skill in the art in January 1999 and earlier to form a composite bone graft having the cortical bone and cancellous bone configuration of the Wolter "corticospongial sandwich block" from allogenic bone. Ex. 1015, ¶¶315-318, 400.

Element 2 (bone pins)

Wolter discloses that bone portions that comprise the "corticospongial sandwich block" are held together by one or more screws. Ex. 1010, 5, Fig. 1e (showing a metal screw holding the graft together). Paul teaches that distinct portions of a bone graft may be secured together by pins. Ex. 1006, 2:30-38, 4:43-63; Ex. 1007, 3:7-14, 6:8-32; *see also* Figure 7. Paul also teaches that the pins may be made of allogenic bone. *Id.* It would have been obvious to a person of ordinary skill to hold together an allogenic bone graft with the one or more bone pins as disclosed by Paul. *See* Ex. 1015, ¶¶319-321, 402. Such a person would have been

motivated to replace the metal screws of Wolter with bone pins, as disclosed by Paul, in order to eliminate a foreign object—the metal screw—from being permanently present in the patient's spine. *Id.*, ¶¶320, 402. Such a person would have had a reasonable expectation of successfully making such a substitution because Paul discloses that bone pins are suitable to secure distinct portions of a composite bone graft together. *Id.*, ¶319.

Element 3 (no contact between first and second cortical portions)

The "corticospongial sandwich block" disclosed by Wolter includes first and second cortical bone portions that are not in physical contact. There are multiple portions of both cortical bone and cancellous bone that physically separate the first and second cortical bone portions. *See* Ex. 1015, ¶341.

Element 4 (no adhesive)

As set out above as §VII.A (Element 4), the "corticospongial sandwich graft" disclosed by Wolter does not include adhesive, and it would have been obvious to one of ordinary skill in the art to assemble that composite bone graft without adhesive.

Element 5 (not demineralized)

As set out above as §VII.A (Element 5), the "corticospongial sandwich graft" disclosed by Wolter is not formed by demineralized bone, and it would have been obvious to one of ordinary skill in the art to form that graft of bone that was

not demineralized. Further, Paul does not teach forming a graft of allogenic bone that is demineralized, and one of ordinary skill in the art would understand that Paul discloses the use of bone that is not demineralized. Ex. 1015, ¶99.

B. Claim 2

As set out above as §VII.B, the differences between claims 1 and 2 are not relevant to the "corticospongial sandwich block" bone graft disclosed by Wolter. Therefore, claim 2 is unpatentable as obvious over Wolter in view of Paul for the reasons, explained above, that claim 1 is unpatentable over that combination.

C. Claim 11

Claim 11 recites that, in the graft of claims 1 or 2, (1) one or more cortical bone planks are layered to form each of the first and second cortical bone portions and (2) one or more cancellous bone planks are layered to form the cancellous bone portion. The Wolter graft discloses this structure as it literally is composed of layers of cortical and cancellous bone. *See* §VI.A. As set out above by §VII.F, the "corticospongial sandwich block" disclosed by Wolter is formed by bone pieces that comprise both cortical bone and cancellous bone. Claim 11 is unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Paul. Ex. 1015, ¶413.

D. Claim 12

Claim 12 recites that the graft of claims 1 or 2 comprises allogenic or xenogenic bone. As set out above at §VIII.A, it would have been obvious to one of ordinary skill to have prepared the Wolter graft from allogenic bone as is taught by Paul. *See* Ex. 1015, ¶¶416-420. Claim 12 is unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Grooms. Ex. 1015, ¶421.

IX. Ground 3: Claims 3-10 are obvious over Wolter in view of Paul and Coates

A. Claims 3, 5

Claims 3 and 5 recite that the graft of claims 1 or 2:

- is a trapezoid wedge (claim 3) or a cervical wedge (claim 5) [*element 1*]
- has dimensions, *i.e.,* anterior and posterior height, composite width, and length, within recited ranges [*element 2*]; and
- has top and bottom textured surfaces, the textured surfaces being opposing and disposed perpendicular to interfaces of the bone portions, and the top and bottom textured surfaces comprising a plurality of continuous linear protrusions defining a saw-tooth pattern [*element 3*].

Wolter does not specifically disclose a wedge-shaped graft, nor that the graft has a saw-tooth pattern of continuous linear protrusions on its top and bottom

surfaces. Paul, however, expressly discloses that a graft may be wedge shaped. Ex. 1006, 4:6-15. It would have been obvious to one of ordinary skill in the art to form the graft disclosed by Wolter to have the dimensions recited by and be wedge shaped as recited by claims 3 and 5 in view of the Paul disclosure. *See* Ex. 1015, ¶¶433, 436; Ex. 1016, ¶¶41-46. Coates discloses a saw tooth pattern of continuous linear protrusions on the top and bottom surfaces of the graft. Coates, col. 11 lines 3-7. From Coates, it would have been obvious to one of ordinary skill in the art to form the graft disclosed by Wolter to have the continuous linear saw-tooth linear protrusions as recited by claims 3 and 5. *See* Ex. 1015, ¶¶429-431; Ex. 1016, ¶40.

Element 1

The Wolter graft is a block that is not specifically disclosed to be a wedge. However, the use of wedge-shaped spinal implants, as opposed to blocks, was known to those of ordinary skill in the art. *See* Ex. 1015, ¶434, Ex. 1016, ¶¶45, 46. One of ordinary skill would have known that the Wolter graft would advantageously be configured as a trapezoid or cervical wedge, so that it could be used in procedures in which a wedge-shaped implant was needed. *Id.* Paul teaches the use of wedge-shaped implants to help restore the natural curvature of the lumbar spine. Ex. 1006, 4:6-15; Ex. 1007, 5:12-21. Such a person would have had a reasonable expectation of success in shaping the Wolter graft into a

wedge because the machining of the Wolter graft to do so would have been well within his or her abilities. *See* Ex. 1015, ¶434.

Element 2

Paul discloses ranges of implant widths and lengths that are entirely within the ranges recited by claims 3 and 5. Paul, col. 3 lines 60-65; Ex. 1015, ¶¶432-433. Paul also discloses a range of implant heights and wedge angles of a spinal implant that form an implant having anterior and posterior heights within the ranges recited by claims 3 and 5. Paul, col. 3 lines 60-65, col. 4 lines 6-15; Ex. 1015, ¶¶432, 434, 435. It would have been obvious to one of ordinary skill in the art to form a graft as disclosed by Wolter to have the dimensions recited by claims 3 and 5. Ex. 1015, ¶¶433, 435.

Element 3

The top and bottom opposed vertebral-engaging surfaces of the Wolter graft are textured by the saw used to cut the graft to the desired form and size. *See* Ex.1015, ¶425. Providing grafts with textured surfaces to prevent movement or migration, such as the continuous protrusions disclosed by Coates, was well known to those of ordinary skill in the art in January 1999. *See* Ex. 1015, ¶427, 429; Ex. 1016, ¶40. Coates discloses continuous linear protrusions that define a saw-tooth pattern. *Id.*, ¶430. It would have been obvious to one of ordinary skill in the art in January 1999 to form the continuous linear protrusions that have a saw-tooth

pattern as disclosed by Coates on the opposed vertebral-engaging surfaces of the Wolter graft. *Id.*, ¶431. Such a person would also have had a reasonable expectation of successfully forming the continuous linear protrusions on the surfaces of the Wolter graft because the provision of such texturing to the surfaces of bone grafts was well-understood. *Id.*, ¶429; Ex. 1016, ¶40. Claims 3 and 5 are unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Paul. Ex. 1015, ¶437.

B. Claims 4, 6

Claims 4 and 6 recite that the graft of claims 1 or 2:

- is a parallel block (claim 4) or a cervical block (claim 6) [*element 1*]
- has dimensions, *i.e.,* height, composite width, and length, within recited ranges [*element 2*]; and
- has top and bottom textured surfaces, the textured surfaces being opposing and disposed perpendicular to interfaces of the bone portions, and the top and bottom textured surfaces comprising a plurality of continuous linear protrusions defining a saw-tooth pattern [*element 3*].

Element 1 of claims 4 and 6, their preambles, recite a "block" thereby differing from the preambles of claims 3 and 5 that recite a "wedge." Claims 4 and 6 recite only a height whereas, consistent with a wedge shape, claims 3 and 5 recite an

anterior height and a posterior height. The other limitations recited by claims 4 and 6 are identical to limitations recited by claims 3 and 5. Claims 4 and 6 are unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Paul. Ex. 1015, ¶445; Ex. 1016, ¶¶41-46.

Element 1

In contrast to claims 3 and 5, which recite a graft having different anterior and posterior heights, claims 4 and 6 only recite a height. Wolter discloses a graft apparently shaped as block. See Ex. 1010, Figure 1e, reproduced below.

To the extent that Patent Owner may argue that imperfections in the Wolter graft prevent it from being a parallel or square block, one of ordinary skill would have known that when preparing the Wolter graft from allograft bone it would have been advantageous to have avoided those imperfections, especially given the more advanced machining possible at the time of the alleged invention. *See Id.*, ¶365.

Element 2

A person of ordinary skill in the art would have understood that an implant must be sized based on the anatomy and needs of a patient. Ex. 1015, ¶443; Ex. 1016, ¶¶41-46. As set out above, Paul discloses implants within the ranges of lengths and widths recited by claims 3 and 5, as well as those recited by claims 4 and 6. Ex. 1015, ¶¶432, 433. Paul discloses a range of implant heights within the range of heights recited by claims 4 and 6. Paul, col. 3 lines 64-65. It would have been obvious in view of Paul for one of ordinary skill in the art to have prepared the Wolter graft to have a height, a composite width, and a length within the ranges recited by claims 4 and 6. *See id.*, ¶¶442, 444.

Element 3

As with claims 3 and 5, although Wolter does not describe continuous linear protrusions having a saw-tooth pattern on its top and bottom surfaces, such texturing was commonplace for allograft bone grafts at the time of the alleged invention. It would have been obvious to one of ordinary skill in the art to have prepared the Wolter graft from allograft bone and, in doing so, to have machined the graft to include a plurality of continuous linear protrusions defining a saw-tooth pattern, as taught by Coates, for the reasons explained in prior paragraphs. *See* §IX.A. (*Element 3*), *supra*.

C. Claims 7-10

Each of claims 7-10 recites that the plurality of continuous protrusions in the graft of one of claims 3-6 are from about 0.1 mm to about 5.0 mm high. This range extends from very small to unrealistically large for a protrusion. Ex. 1015, ¶451.

Providing protrusions on the surface of an implant that resist migration were well known to those of ordinary skill in the art in January 1999 and earlier. Ex. 1015, ¶450, Ex. 1016, ¶40. For example, Grooms discloses protrusions having a height of 0.15 inches (0.381 mm). *Id.* Similarly, Coates teaches that the Coates graft shown in Figures 15-18 has a height of about 7 millimeters, as measured between the tops of protrusions on opposing sides of the graft. Ex. 1008, 11:62-12:3, Fig. 16; *see also id.*, 4:48-55 (stating that Figs. 15-18 are different views of the same graft). This means the protrusions in Coates must fall within the about 0.1 mm to about 5.0 mm height range recited in claims 7-10. Therefore, it would have been obvious to one of ordinary skill in the art to have provided protrusions on the grafts recited by claims 3-6 having a height within the broad claimed range recited by claims 7-10. *See* Ex. 1015, ¶¶451, 452. Claims 7-10 are unpatentable as obvious to one of ordinary skill in the art over Wolter in view of Paul and Coates. Ex. 1015, ¶452.

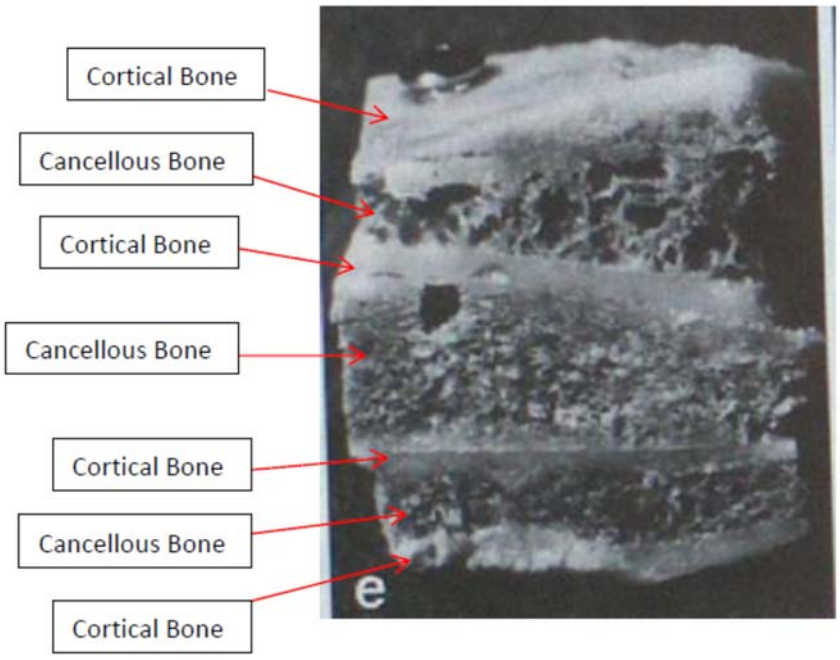
X. Ground 4: Claim 13 is obvious over Wolter in view of either (a) Grooms or (b) Paul and Kozak

Wolter discloses most of the five elements of claim 13 (*see* §V.A, *supra*). Although the Wolter graft is held together by a metal screw, it would have been obvious to one of ordinary skill in the art to have replaced that screw with a pin made from bone, as is taught by Grooms or Paul, for the same reasons discussed in §§VII and VIII.

It also would have been obvious to one of ordinary skill in the art to form a chamfer along the top and bottom edges of the Wolter graft, as is taught by Grooms or Kozak, in order to facilitate insertion of the graft into the vertebral cavity. Ex. 1015, ¶¶464, 467. Claim 13 is unpatentable as obvious to one of ordinary skill in the art over Wolter in view of either Grooms or Paul and Kozak. Ex. 1015, ¶468.

Element 1 (layered cortical-cancellous composite)

As discussed, Wolter discloses a composite bone graft comprising two or more distinct, adjacent, bone portions, layered to form a graft unit. *See* Ex. 1015, ¶¶455, 456. Specifically, Wolter discloses alternating layers of cortical and cancellous bone, as shown below.



Id., ¶455. In the event the term "distinct" as recited by claim 13 is construed to require that the bone portions be separate portions and that the cancellous bone portion be only cancellous bone, such a graft would have been obvious to one of ordinary skill in the art over Wolter in view of Grooms, and in view of Paul as set out above by §VIII.A. Ex. 1015, ¶456, 457.

Element 2 (bone pins)

As set out above at §VII.A (Element 2), it would have been obvious to one of ordinary skill in the art to substitute the bone pin taught by Grooms for the metal screw disclosed by Wolter to hold together the graft disclosed by Wolter. As set out at §VIII.A (Element 2), it would also have been obvious to one of ordinary

skill in the art to assemble the Wolter graft of allogenic bone with bone pins as taught by Paul. Ex. 1015, ¶461.

Element 3 (opposed chamfered edges)

Wolter does not disclose chamfering the top and bottom edges of the graft.

Grooms

Grooms teaches that "[i]n order to accommodate the difficulty surgeons experience in forming precise angles when forming such cavities in the spine, a beveled edge of defined radius is preferably machined into three faces of the implant, but leaving the anterior face unbeveled." Ex. 1003, ¶33; Ex. 1004, 9:4-9 (the sharp anterior edge serving to retard backing out of the graft). Grooms also refers to the teaching of U.S. Patent No. 5,397,364, *see id.*, which states that "a beveled edge around the perimeter [of such an implant] facilitates insertion between adjacent vertebrae and serves the obvious function of reducing trauma to surrounding tissue that might follow a device having sharp edges." Ex. 1012, 6:31-37. Ex. 1015, ¶463.

One of ordinary skill would have known that the Wolter graft could advantageously have been configured to have beveled edges of the top and bottom surfaces, as taught by Grooms, in order to facilitate insertion of the graft and reduce trauma to the surrounding tissue. *See* Ex. 1015, ¶464. Such beveling would have been well within his or her ability. *Id.*, ¶365. The beveling would

have produced a first chamfered edge along a length of the graft at its top edge and a second chamfered edge along a length of the graft at its bottom edge, such that the chamfered edges are diametrically opposed. *Id.*, ¶464.

Paul/Kozak

U.S. Patent No. 5,397,364 to Kozak ("Kozak") describes implants that, like Wolter, are placed into the intervertebral space left after the removal of a damaged spinal disc. Ex. 1012, 1:5-9. Kozak describes the end plate faces, *i.e.,* the top and bottom surfaces, of the implant as including a beveled edge around the perimeter. Ex. 1012, 6:31-37, Figure 1 (showing the beveled edge of the top surface). The beveled edge "facilitates insertion between adjacent vertebrae and serves the obvious function of reducing trauma to surrounding tissue that might follow a device having sharp edges." *Id.*

One of ordinary skill would have known that the Wolter graft could advantageously have been configured to have beveled edges on the top and bottom surfaces, as taught by Kozak, in order to facilitate insertion of the graft and reduce trauma to the surrounding tissue. *See* Ex. 1015, ¶465, 466. This beveling too would have been well within his or her ability. *Id.*, ¶365. The beveling would have produced a first chamfered edge along a length of the graft at its top edge and a second chamfered edge along a length of the graft at its bottom edge, such that the chamfered edges are diametrically opposed. *Id.*, ¶467.

Element 4 (no adhesive)

As explained in detail with respect to this same element of claim 1, *see* §§VII.A and VIII.A (*Element 4*), *supra*, a person of ordinary skill in the art would have understood that the Wolter graft does not comprise an adhesive and that it would have been obvious to prepare the Wolter graft (as modified above) without the use of an adhesive, since the graft would be held together with one or more bone pins.

Element 5 (not demineralized)

As explained in detail with respect to this same element of claim 1, see §§VII.A and VIII.A (*Element 5*), *supra*, a person of ordinary skill in the art would have understood that the bone portions of the Wolter graft are not demineralized and that it would have been obvious to prepare the Wolter graft with non-demineralized bone for the reasons previously discussed.

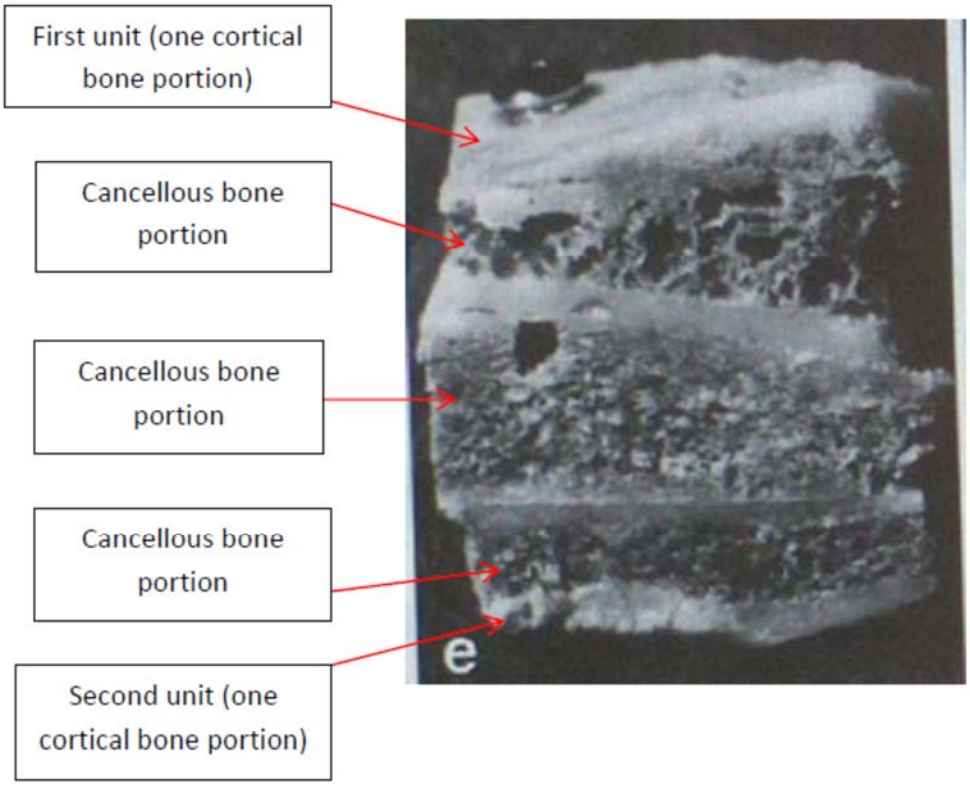
XI. Ground 5: Claim 14 is obvious over Wolter in view of either (a) Grooms and Boyce or (b) Paul and Boyce

Wolter discloses most of the six elements of claim 14 (*see* §V.A, *supra*). Although the Wolter graft is held together by a metal screw, one of ordinary skill would have known that the Wolter graft could advantageously have been assembled by replacing that screw with a pin made from bone, as taught by Grooms or Paul, for the same reasons discussed in §§VII and VIII.

Moreover, although the Wolter graft does not include a discontinuous bone portion containing a therapeutically beneficial substance, it would have been obvious to have included such a portion, as taught by Boyce, in order to further facilitate bone ingrowth and successful spinal fusion. Ex. 1015, ¶478. Claim 13 is unpatentable as obvious to one of ordinary skill in the art over Wolter in view of either Grooms and Boyce, or Paul and Boyce. Ex. 1015, ¶486.

Element 1 (cortical unit-cancellous unit-cortical unit composite)

Wolter discloses a composite bone graft comprising one or more cortical bone portions layered to form a first unit, one or more cortical bone portions layered to form a second unit, and one or more cancellous bone portions layered to form a third unit disposed between the first and second units. See Ex. 1009, Fig. 1e, reproduced and annotated below.



In the event that the term "cortical bone portion" be construed to require separate portions and that each portion comprise only the recited bone, such a graft would have been obvious to one of ordinary skill in the art in view of Grooms or Paul. Ex. 1015, ¶¶472-474.

Element 2 (bone pins)

As set out above at §VII.A (Element 2), it would have been obvious to one of ordinary skill in the art to substitute the bone pin taught by Grooms for the metal screw disclosed by Wolter to hold together the graft disclosed by Wolter. As set out by §VIII.A (Element 2), it would have been obvious to one of ordinary skill in the art to provide the bone pin taught by Paul to hold together a graft constructed

of allogenic bone to have the structure of the graft disclosed by Wolter. Ex. 1015, ¶481.

Element 3 (discontinuous bone portion)

Wolter does not disclose that the graft contain a "discontinuous bone portion" as that term is defined by the 158 patent.

Boyce, however, discloses osteoimplants fabricated from a solid aggregate of bone-derived elements, i.e., composite bone grafts. Ex. 1011, Abstract. Boyce describes the grafts as possessing cavities communicating with the surface of the graft through pores, apertures, perforations, or channels. Those perforations, channels, etc., can have diameters of from a few microns to several millimeters and may be filled with medically useful substances which promote or accelerate new bone growth. *Id.*, 4:51-60.

In one embodiment, for instance, Boyce describes a graft built from sheets of cortical bone and cubes of cancellous bone arranged in alternating layers. Ex. 1010, 8:16-26, Fig. 6. The cancellous cubes are arranged to create a pattern of channels, which Boyce describes as permitting vascular bone ingrowth and/or diffusion of one or more medically useful substances therefrom. *Id.* Figure 6 of Boyce is reproduced below.

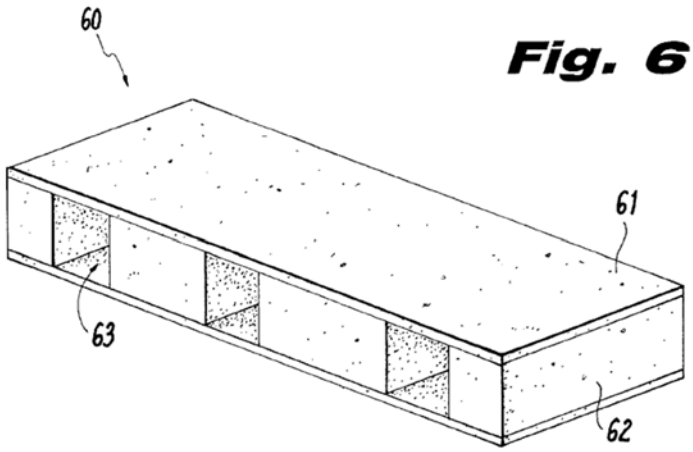


Fig. 6

One of ordinary skill would have known that the Wolter graft could advantageously have included channels, perforations, or other artificially created void areas within one or more of the bone portions in order to facilitate bone ingrowth, including by the diffusion of medically useful, *i.e.* bone-growth inducing, substances contained therein, as is disclosed by Boyce. Ex. 1015, ¶478. The machining of such void areas would have been well within the technical ability of such a person. *Id.*, ¶365.

Element 4 (therapeutic substance)

Boyce also discloses that the channels, perforations, etc., may be filled with one or more medically useful substances which promote or accelerate new bone growth or bone healing. Ex. 1011, 4:51-60. Among the useful substances disclosed are collagen, bone, demineralized bone, bone morphogenic proteins (BMPs), transforming growth factor (TGF-beta), and antibiotics. *Id.*, 4:61-5:30. Each of these substances is included in the Markush group of therapeutically

beneficial substances recited in claim 14. Ex. 1002, 47:1-48:7. One of ordinary skill would have known that the Wolter graft could advantageously have been assembled by filling the void areas with one or more of those substances in order to promote or accelerate new bone growth. *See* Ex. 1015, ¶482-484.

Element 5 (no adhesive)

As explained in detail with respect to this element of claim 1, *see* §§VII.A and VIII.A (*Element 4*) *supra*, a person of ordinary skill would have understood that the Wolter graft does not comprise an adhesive and that it could advantageously be assembled without using an adhesive, since the graft would be held together with one or more bone pins.

Element 6 (not demineralized)

As explained in detail with respect to this same element of claim 1, *see* §§VII.A and VIII.A (*Element 5*) *supra*, a person of ordinary skill would have understood that the Wolter graft is not formed of demineralized bone and that it would have been obvious to prepare the Wolter graft with non-demineralized bone.

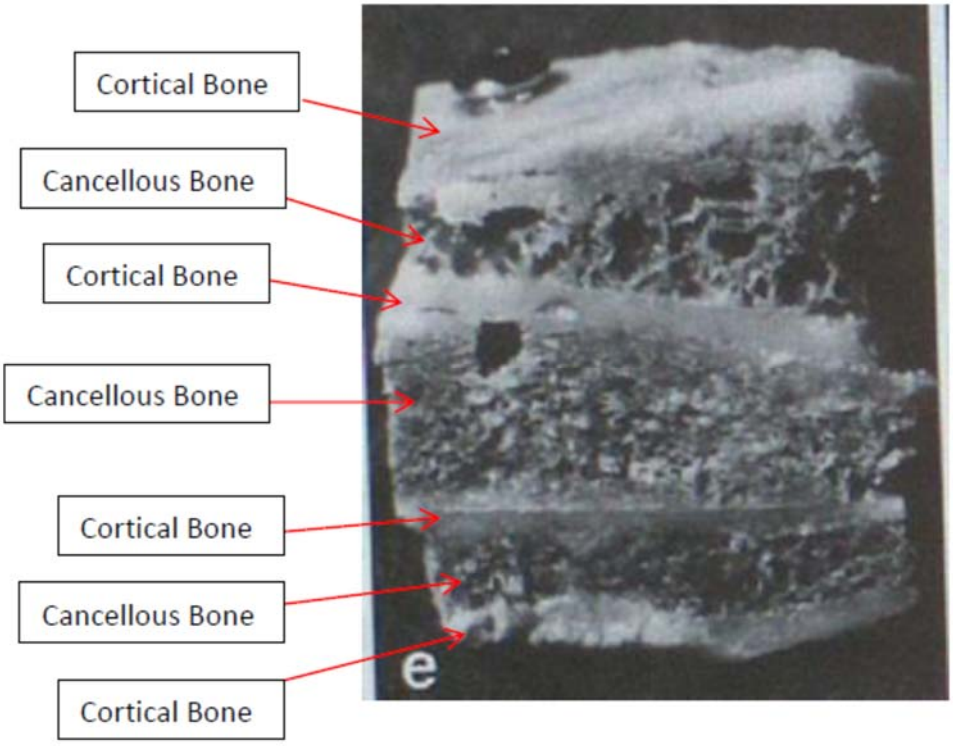
XII. Ground 6: Claim 15 is obvious over Wolter in view of either (a) Grooms or (b) Paul

Wolter discloses most of the four elements of claim 15 (*see* §V.A, *supra*). Although the Wolter graft is held together by a metal screw, it would have been obvious to one of ordinary skill in the art to have replaced that screw with a pin

made from bone, as taught by Grooms or Paul, for the same reasons discussed in §§VII and VIII. Claim 15 is unpatentable as obvious to one of ordinary skill in the art over Wolter in view of either Grooms or Paul. Ex. 1015, ¶491.

Element 1 (multilayered cortical-cancellous composite)

The Wolter graft is a composite comprising alternating layers of cortical bone portions and cancellous bone portions. *See* Ex. 1010, Fig. 1e, reproduced and annotated below.



Ex. 1015, ¶490.

Element 2 (bone pins)

Rather than using one or more bone pins to hold together portions of the graft, Wolter utilizes one or more screws. Ex. 1010, 5, Fig. 1e.

As set out above at §VII.A (Element 2) Grooms teaches that distinct portions of an intervertebral composite bone graft may be held together by forming holes in each portion and forcing a pin through the holes. Ex. 1003, ¶¶48-49; Ex. 1004, 16:29-18:6; *see also* Figs. 7A-B. Grooms also teaches that the pins may be made of bone. *Id.* Similarly, as set out above at §VIII.A (Element 2), Paul teaches that distinct portions of a bone graft may be secured together by pins. Ex. 1006, 2:30-38, 4:43-63; Ex. 1007, 3:7-14, 6:8-32; *see also* Figure 7. Paul also teaches that the pins may be made of bone. *Id.* As also set out above at sections VII.A (Element 2) and VIII.A (Element 2), it would have been obvious to one of ordinary skill to secure the Wolter graft together by substituting, as taught by Grooms or Paul, a bone pin for the metal screws disclosed by Wolter.

Element 3 (no adhesive)

As explained in detail with respect to this element of claim 1, *see* §§VII.A and VIII.A (*Element 4*) *supra*, a person of ordinary skill would have understood that the Wolter graft does not comprise an adhesive and that it could have been advantageously assembled without the use of an adhesive, since the graft would be held together, as taught by Grooms or Paul, with one or more bone pins.

Element 4 (not demineralized)

As explained in detail with respect to this same element of claim 1, *see* §§VII.A and VIII.A (*Element 5*) *supra*, a person of ordinary skill in the art would have understood that the bone portions of the Wolter graft are not demineralized and that it would have been advantageous to prepare the Wolter graft of allogenic bone with non-demineralized bone.

XIII. Ground 7: Claims 1-2, 11-12, and 14 are obvious over Boyce in view of either (a) Grooms or (b) Paul

A. 35 U.S.C. §325(d)

Although the Examiner cited Boyce during examination, the Examiner did not consider the combinations set forth in this Ground, Boyce in view of Grooms or Paul, because neither Grooms nor Paul was before the Examiner. Thus, this Ground does not "present the same or substantially the same *prior art or arguments* previously [] presented to the Office." 35 U.S.C. §325(d) (emphasis added).

The *Becton* factors further confirm that this Ground warrants institution. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, slip op. at 17–28 (PTAB Dec. 15, 2017) (Paper 8) (informative). With respect to the asserted art (1) it is different than that on which the Examiner relied, (2) it is not cumulative, (3) the Examiner was not presented with and therefore did not consider

Grooms or Paul, (4) there is no "overlap" between the arguments made during examination and the arguments made here, and (5) the Examiner did not consider additional evidence, such as expert testimony, during prosecution (*see Becton* factors a-d, and f).

During prosecution, the Examiner rejected the claims over Boyce or Boyce in view of U.S. Patent No. 6,241,771 ("Gresser"). *See* Ex. 1014, 3-6.[4] Patent Owner overcame these rejections by (1) amending each claim to recite that the bone graft is "not demineralized" and (2) pointing out that Boyce discloses demineralizing its bone portions to form chemical linkages that secure the portions together. *Id.* at 7-15. However, Grooms and Paul disclosed other methods (i.e. bone pins) to secure bone portions together without requiring demineralization. But the Examiner not consider those references. Nor did the Examiner consider any argument (or expert testimony) that it would have been obvious to use such methods in order to avoid demineralizing the graft—a process that was well-known to weaken bone and thus the graft. Accordingly, the issues raised and presented in this Ground differ significantly from any at issue during examination. *See, e.g.*, *Google LLC v. Cywee Group Ltd.*, IPR2018-01258, 2018 WL 6566980, at *14

[4] The Examiner cited Gresser for its teaching of "serrations 16 to aid in anchoring the device to surrounding bone." Ex. 1014, 4-5.

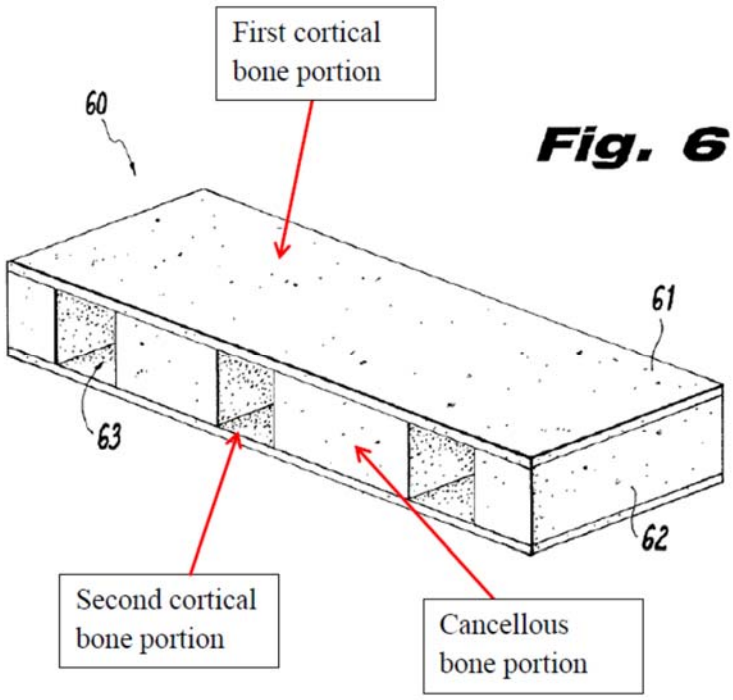
(P.T.A.B. Dec. 11, 2018) (specific combination not considered by examiner); *10x Genomics, Inc. v. Univ. of Chicago*, IPR2015–01157, 2015 WL 7304561 (P.T.A.B. Nov. 16, 2015) (expert declaration not before examiner).

B. Claim 1

Boyce discloses most of the five elements of claim 1 (*see* §§V.A, VI.D, *supra*). Boyce describes the assembly of a composite graft using a chemical cross-linking process to hold the graft together, and discloses that pins may also be used increase the graft strength. It would have been obvious to have used mechanical connectors, such as the bone pins described by Grooms or Paul, to hold the graft together instead of the chemical cross-linking process disclosed by Boyce. Ex. 1015, ¶¶499, 500. That replacement would have been viewed as advantageous because it avoids demineralization of the bone, a step in the cross-linking process of Boyce which was known to weaken the bone, thus creating a stronger graft. *Id.*, ¶500. The graft that results from such a replacement satisfies every element of claim 1.

Element 1 (cortical-cancellous-cortical composite)

Boyce discloses a composite bone graft comprising a first cortical bone portion, a second cortical bone portion, and a cancellous bone portion disposed between the first and second cortical portions, as shown in Figure 6.



Ex. 1015, ¶92. Specifically, Boyce describes the graft shown in Figure 6 as built from sheet sections of cortical bone (reference number 61) and cube sections of cancellous bone (reference number 62) arranged in alternating layers. Ex. 1011 at 8:16-21.

Element 2 (bone pins)

Boyce discloses that the portions of the composite graft are held together by a process that produces chemical linkages between adjacent surface-exposed collagen. Ex. 1011, 8:21-22, Abstract. This chemical cross-linking process is the asserted invention of Boyce. *See id.*, 9:57-10:29 (independent claims 1-4). Boyce teaches that increasing the shape-retaining and/or mechanical strength characteristics of the graft by adding mechanical fasteners such as pins, screws,

dowels, etc., which can be fabricated from natural or synthetic materials and bioabsorbable as well as nonbioabsorbable materials. *Id.*, 5:54-67. One of ordinary skill would have known, as Boyce disclosed, that the Boyce graft could advantageously have been assembled by using bone pins because it would have produced a stronger graft than that prepared using the chemical cross-linking process disclosed by Boyce. Ex.1015, ¶499.

It would have been obvious to one of ordinary skill in the art in January 1999 and earlier to provide bone pins for holding the graft disclosed by Boyce together without also bonding the graft together by surface exposed collagen. Grooms teaches that distinct portions of a bone graft may be held together *solely* by forming holes in each portion and forcing pins through the holes. Ex. 1003, ¶¶48-49; Ex. 1004, 16:29-18:6; *see also* Figs. 7A-B. Similarly, Paul teaches that distinct portions of a bone graft may be secured together *solely* by pins. Ex. 1006, 2:30-38, 4:43-63; Ex. 1007, 3:7-14, 6:8-32; *see also* Figure 7. Grooms and Paul disclose composite bone graft implants held together as a unitary implant by cortical bone pins. *See* §§VI.B, VI.C, Ex. 1015, ¶¶75, 101, 102, 104. Neither discloses the need for chemical cross-linking or any other adhesive material or process to hold the graft together. Accordingly, a person of ordinary skill in the art would have understood from Grooms or Paul that the graft of Boyce could be held together solely through the use of bone pins. *Id.*, ¶500.

A person of ordinary skill in the art would be motivated to assemble the Boyce composite using bone pins to avoid the disadvantages of demineralization otherwise needed to provide surface exposed collagen. Ex. 1011, 3:53-58. Demineralization of the bone that makes up a graft is generally disfavored because demineralization is known to weaken bone, thereby creating a weaker graft. Ex. 1015, ¶28. Boyce itself recognizes this drawback, teaching one to preserve the strength of the graft by limiting the amount of bone demineralized to that necessary to achieve cross-linking between the bone portions. Ex. 1011, 4:6-16. Other advantages that would have been recognized are improved consistency of strength of the connection between graft pieces and avoidance of the cost and difficulty of demineralization. Ex. 1015, ¶505.

Element 3 (no contact between first and second cortical portions)

The first and second cortical bone portions of the graft shown in Figure 6 of Boyce are not in physical contact. *See* Ex. 1015, ¶¶493, 494.

Element 4 (no adhesive)

The bone portions of Boyce are bonded together by chemical linkages between exposed collagen on the surfaces of the bone portions. Ex. 1011, 6:28-43. And the 158 patent makes a distinction between adhesives and surface modifications. Ex. 1002, 27:57-67, 12:58-61. Thus, the Boyce graft does not comprise an adhesive. Regardless of that distinction, it would have been obvious

to have replaced the surface modification of Boyce with one or more bone pins (as described above), which one of skill in the art would have understood would be done without an adhesive. Ex. 1015, ¶¶495-498.

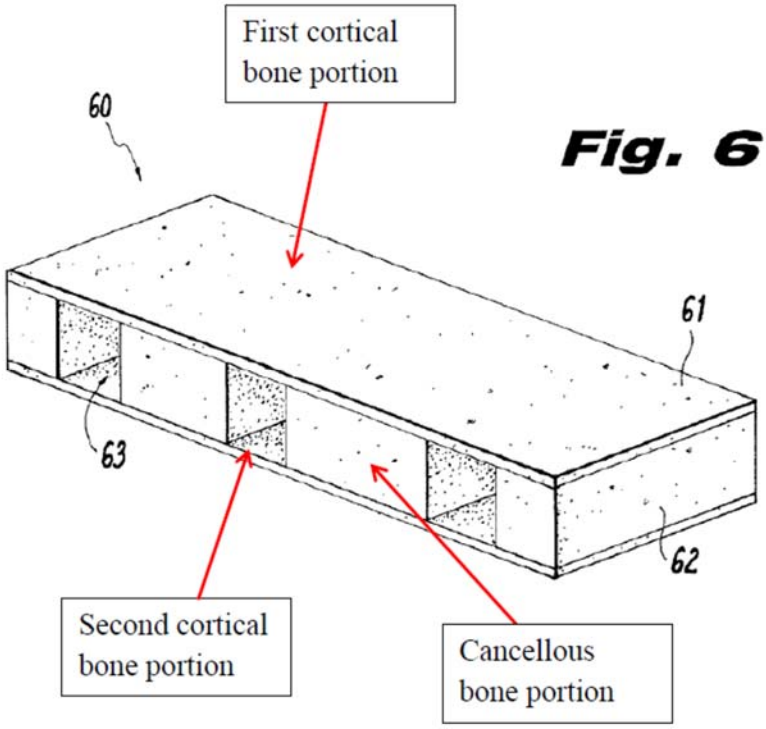
Element 5 (not demineralized)

As explained above, it would have been obvious to a person of ordinary skill to have used one or more bone pins in place of the chemical crosslinking process described by Boyce. In doing so, there would have been no reason to demineralize, and thus weaken, the bone portions that make up the graft. Accordingly, it would have been obvious to such a person to have prepared the Boyce graft with non-demineralized bone. Ex. 1015, ¶¶501-505.

C. Claim 2

As set out above by §VII.B, Claim 2 differs from claim 1 because claim 2 (1) uses the language "consisting essentially of" instead of "comprising" and (2) does not contain element 4 (reciting that the graft does not include an adhesive). As noted, claim 2 limits additional material that may be present. For the bone graft disclosed by Boyce and depicted by Figure 6, only surface demineralization and the bonding by surface exposed collagen that results from demineralization are embodied by that graft but are not recited by claim 2. That demineralization and bonding are specifically excluded by the combination set out by §XIII.B above for claim 1. The Boyce graft shown in Figure 6, modified (as described above with

respect to claim 1) to be held together by one or more bone pins instead of by chemical cross-linking by collagen that demineralization exposed, is a graft that consists essentially of a first cortical bone portion, a second cortical bone portion, a cancellous bone portion disposed between the first and second cortical bone portions, one or more bone pins, and the bone graft is not demineralized. *See* Ex. 1011, Fig. 6, reproduced and annotated below:



Ex.1015, ¶¶506-509. The modified Boyce graft satisfies the other elements of claim 2 for the reasons recited in §XIII.B.

D. Claim 11

Claim 11recites that, in the graft of claims 1 or 2, one or more cortical bone planks are layered to form each of the first and second cortical bone portions and one or more cancellous bone planks are layered to form the cancellous bone portion. In the Boyce graft, one cortical bone plank forms each of the first and second cortical bone portions and one cancellous plank (a discontinuous one) forms the cancellous bone portion. *See* Ex. 1011, Fig. 6; Ex. 1015, ¶¶510-515.

E. Claim 12

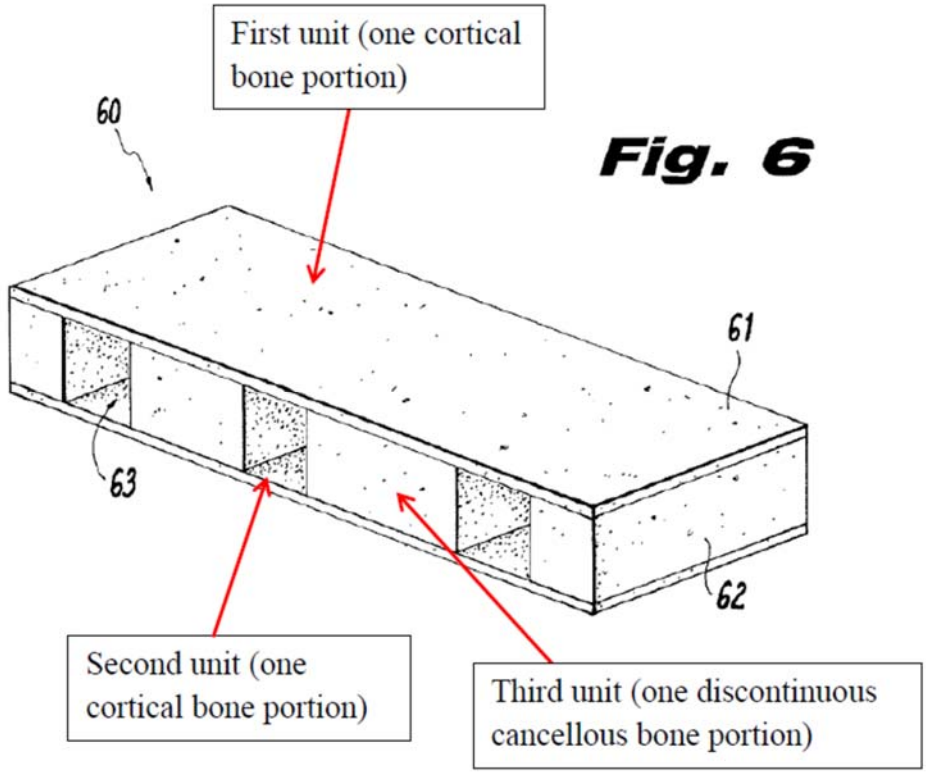
Claim 12 recites that the graft of claims 1 or 2 comprises allogenic or xenogenic bone. Boyce discloses that the bone elements used to prepare the graft are preferably allogenic bone, and can also include xenogenic bone. Ex. 1011, 4:2-5; Ex. 1015, ¶¶516-519.

F. Claim 14

Boyce discloses most of the six elements of claim 14 (*see* §V.A, *supra*). Although Boyce describes forming a composite graft using chemical cross-linking, one of ordinary skill would have known that the graft could advantageously be assembled by simply using mechanical connectors, such as the bone pins described by Grooms or Paul, for the same reasons described above with respect to claim 1.

Element 1 (cortical unit-cancellous unit-cortical unit composite)

Boyce discloses a composite bone graft comprising one or more cortical bone portions layered to form a first unit, one or more cortical bone portions layered to form a second unit, and one or more cancellous bone portions layered to form a third unit disposed between the first and second units. *See* Ex. 1011, Fig. 6, reproduced and annotated below:



Ex. 1015, ¶¶521, 523.

Element 2 (bone pins)

As explained in detail above, one of ordinary skill would have known that the Boyce graft could advantageously be assembled using one or more bone pins,

as taught by either Grooms or Paul, rather than by the described chemical cross-linking. *See* §XII.B (*Element 3*).

Element 3 (discontinuous bone portion)

Because the cancellous bone portion of the Boyce graft contains a plurality of channels, it is a discontinuous bone portion. Ex. 1011, 8:16-27, Fig. 6; Ex. 1015, ¶¶522; *see also* Ex. 1002, 13:29-45 (defining discontinuous bone portion).

Element 4 (therapeutic substance)

Boyce teaches that the channels in the cancellous bone portion may be filled with one or more medically/surgically useful substances. Ex. 1011, 8:22-26. Included are substances which promote or accelerate new bone growth, such as collagen, bone, demineralized bone, bone morphogenic proteins (BMPs), transforming growth factor (TGF-beta), and antibiotics. *Id.*, 4:51-5:30. Each is included in the Markush group of therapeutically beneficial substances recited in claim 14. Ex. 1002, 47:1-48:7. Thus, one of ordinary skill would have known that the Boyce graft could advantageously have been assembled by filling the channels of the graft with one or more of the "therapeutically beneficial substances" recited in claim 14. Ex. 1015, ¶¶481, 482, 522.

Element 5 (no adhesive)

The bone portions of Boyce are bonded together by chemical linkages between exposed collagen on the surfaces of the bone portions, which is a surface

modification and not an adhesive. Ex. 1011, 6:28-43; *see also* Ex. 1002, 27:57-67, 12:58-61. One of ordinary skill would have known that the Boyce graft could advantageously be assembled using one or more bone pins (as described above), which such a person would have understood would be done without the presence of an adhesive. Ex. 1015, ¶¶495-498, 521.

Element 6 (not demineralized)

As described in detail above (§XIII.B (*Element 3*), *supra*), it would have been obvious to a person of ordinary skill in the art to have used one or more bone pins to hold the bone portions of the Boyce graft together instead of the disclosed chemical crosslinking process. In doing so, there would have been no reason to demineralize, and thus weaken, the bone portions that make up the graft. Accordingly, it would have been obvious to such a person to have assembled the Boyce graft with non-demineralized bone. Ex. 1015, ¶¶501-505, 521.

XIV. Conclusion

Petitioner has established a reasonable likelihood of prevailing as to each of claims 1-15 of the 158 patent, and therefore respectfully requests that the Board institute *inter partes* review of those claims.

Respectfully submitted,

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Dated: February 19, 2019

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CERTIFICATE OF WORD COUNT

I certify under 37 CFR § 42.24 that this **PETITION FOR INTER PARTES REVIEW** contains fewer than 13,822 words, as determined by Microsoft Word.

Dated: February 19, 2019

By: /Herbert D. Hart III/
Herbert D. Hart III *for Petitioner RTI Surgical, Inc.*

CERTIFICATE OF SERVICE

Under 37 C.F.R. §§ 42.6(e)(4) and 42.105, the undersigned certifies on this date, a true and correct copy of this Federal Express to the Patent Owner at the following correspondence address of record for U.S. Patent No. 6,458,158:

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