UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

Biomet Inc., Plaintiff, v. Bonutti Skeletal Innovations LLC, Defendant.	Case No. 3:13-CV-176 JVB

OPINION AND ORDER

A. Introduction

On March 8, 2013, Plaintiff Biomet, Inc. ("Biomet"), filed a Declaratory Action regarding fifteen patents against Defendant, Bonutti Skeletal Innovations LLC ("Bonutti"). The parties have resolved the dispute as to five of the fifteen patents. Among the remaining patents, the parties initially disagreed on eleven terms in six patents. One day before the claim construction hearing, the parties reached a stipulation on two disputed term. They further agreed not to present arguments on one of the asserted patents. As a result, claim construction is narrowed down to seven terms in five patents: U.S. Patent Nos.: 7,708,740 ("the '740 patent"), 7,806,896 ("the '896 patent"), 7,828,852 ("the '852 patent"), 7,931,690 ("the '690 patent"), and 8,133,229 ("the '229 patent"). The five patents can be grouped into two categories: three patents (the '896, '740, and '229 patents) relate to knee replacement surgery ("Knee Surgery Patents") and two patents (the '852 and '690 patents) relate to using bone growth materials to artificially stimulate bone growth around surgical implants ("Bone Growth Patents"). The seven terms in

dispute include two terms in the Knee Surgery Patents and five terms in the Bone Growth Patents. The Court, having reviewed the evidence, and having considered the arguments of the parties, now makes its claim construction ruling.

B. Standard of Review

Claim Construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). Words of a claim are generally given their ordinary and customary meaning. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal citation omitted). The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. *Id*. at 1313. In many cases, however, the meaning of a claim term as understood by persons skilled in the art is often not immediately apparent. *Id*. As a result, the Court looks to a number of sources to ascertain the meaning. Those sources include: "the words of the claims themselves, the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id*. at 1314 (internal citation omitted).

To begin with, the Court looks at the claims themselves. There are several principles guiding the usage of claim language in claim construction. First, the Court looks at the use of a term within the asserted claim. *Id*. In addition, other claims of the patent in question, both asserted and unasserted, can be valuable sources as to the meaning of a claim term. *Id*. For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim. *Id*. at 1315.

Furthermore, it is presumed that claim terms are normally used consistently throughout the patent. *Id*. at 1314.

The claims, however, do not stand alone. Rather, they must be construed so as to be consistent with the specification. *Id.* at 1316 (internal citation omitted). In some cases, the patentee has provided a special definition to a claim term. In other cases, the patentee has intentionally disclaimed a claim's scope. Those instances are regarded dispositive in claim construction. *Id*.

Besides the specification, the Court also considers the patent's prosecution history. *Id*. at 1317. Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent. *Id*. Yet, because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes. *Id*. Nonetheless, the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be. *Id*.

In addition to the patent and prosecution history, the Court is allowed to use extrinsic evidence including expert and inventor testimony, dictionaries, and learned treatises. *Id*. Within the class of extrinsic evidence, dictionaries, especially technical dictionaries, may be proper tools to assist the court in determining the meaning of particular terminology to those of skill in the art of the invention. *Id* at 1318. Expert evidence can also be useful to a court for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent

with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field. *Id*. However, expert testimonies should be discounted when they are conclusory assertions on the definition of a claim term, or when they are at odds with the patent and prosecution history. *Id*. In general, the Federal Circuit has viewed extrinsic evidence as less reliable than the patent and its prosecution history in determining how to read claim terms. *Id*. Nonetheless, because extrinsic evidence can help educate the Court regarding the field of the invention and can help the Court determine what a person of ordinary skill in the art would understand claim terms to mean, it is permissible for the Court in its sound discretion to admit and use such evidence. *Id*. at 1319.

C. Terms in Dispute

(1) *The Knee Surgery Patents*

The three Knee Surgery Patents (the ‘896, ‘740, and ‘229 patents) are continuations from U.S. Pat. 7,104,996. The patents teach various aspects of surgical methods and techniques for a partial or total knee replacement surgery. Generally, in a knee replacement surgery, surgeons first make an incision on the knee. After exposing the knee, the surgeons move or evert the patella and make several cuts on the end of the femur using femoral cutting guides. The cutting guides have traditionally been intramedullary rod and extramedullary rod. After the cuts on femur, surgeons cut the top of the tibia using tibial cutting guide. Subsequently, the surgeons resurface the back of the patella and implant the joint components. As part of the process, ligament balancing is also checked to ensure proper function of the knee.

To improve this surgical process, the ‘740 patent teaches a method of ligaments balancing during the knee surgery. The ‘229 patent claims a method of sliding the patella to the

side which helps to reduce the size of the incision. Lastly, the ‘896 patent discloses using side cutting guide, hologram, and robot in addition to intramedullary rod to assist femoral cutting.

Terms in dispute for Knee Surgery Patents are: “computer navigation system” and “side surface.” The term “computer navigation system” appears in the ‘896 patent while the term “side surface” appears in all three Knee Surgery Patents.

(a) *“Computer navigation system”*

This term appears in claim 3 of the ‘896 patent. Biomet construes the term as: “a computer system having locating devices attached to the femur and tibia.” Bonutti, on the other hand, proposes the term’s definition as “a computer system used to control the course, position, or alignment of joint replacement components.” The parties’ dispute centers on whether the “computer navigation system” must include locating devices, and if it does require locating devices, whether such locating devices must be attached to femur and tibia.

Claim 3 of the ‘896 patent teaches: “[t]he method of claim 1 wherein a computer navigation system is used in the determining step.” This claim is dependent from claim 1 of the same patent. Claim 1’s determining step states: “determining a position of a cutting guide using references derived independently from an intramedullary device.” Claims 1 and 3 taken together show that the “computer navigation system” is an alternative to intramedullary device and is used to determine the positions of a cutting guide. Unfortunately, neither these two claims nor other claims in the patent shed more lights on what the “computer navigation system” actually is.

With the claims in mind, the analysis turns to the patent’s specification. One of the key paragraphs discussing “computer navigation system” shows that the locating devices are a part of

the "computer navigation systems" but such locating devices are not required to be attached to femur and tibia. Specifically, the paragraph states:

> It is contemplated that emitters, receivers, and/or reflectors **of** computer navigation systems **could be** pinned or otherwise attached onto the femur 126 and tibia 214 to provide cutting positions and to facilitate ligament balancing through relatively small incisions.

('896 patent, col. 36, lns. 55 – 62 (emphasis added).)

Plain meaning of the word "of" shows that emitters, receivers, and/or reflectors are components of the computer navigation system. The parties have not disputed that locating devices are not "emitters, receivers, and/or reflectors." In addition, other sections of the specification are consistent with the interpretation that locating devices are a part of the computer navigation system. (*See id*. col. 42, lns. 8 – 18 ("[I]t is contemplated that a computer navigation system may be used with the robot 370 to guide movement of a cutting tool, such as a saw or milling cutter, relative to the tibia and femur in the leg 70 of the patient. Two or more locating devices are connected with the distal end portion 124 of the femur 126. In addition, two or more locating devices are connected to the proximal end portion of the tibia 214. The locating devices cooperate with motors and computer controls 386 for the robot 370 to provide the robot with information as to the position of the mounting section 396 and cutting tool relative to the femur 126 and tibia 214."); *see also id.* Col. 42, lns. 48 – 51 ("computer controls which respond to the locating devices provide information to the surgeon about cutting tools and/or other instruments being moved by the articulate arms.")

Biomet further argued that the locating devices must be pinned to femur and tibia. This argument, however, imports improper limitation into the claim. The written description has explicitly stated that the locating devices "could be pinned or otherwise attached onto the femur

126 and tibia 214." The use of the phrase "could be" shows that it is not mandatory for the locating devices to be attached to femur and tibia.

Bonutti also urged the Court not to adopt Biomet's construction because the paragraphs cited above are merely examples. Specifically, Bonutti quotes the following language in the Generation of Images and Robotic Device section:

> The above-described image guided surgery system is merely intended to be representative of the type of system that can be used with the present invention. However, it should be understood that other known image guided surgery systems, both in conjunction and independent of robotic systems, could be utilized if desired. Examples of commercially available systems include systems the Z-KAT (Hollywood, Fla.) suites, the MEDIVISION system (Oberdorf, Switzerland), the STEALTH NAVIGATOR system (Louisville, Colo.), and the ORTHOPILOT System (Tuttlingen, Gemany).

(*Id*. col. 42, lns. 30 – 39.)

The quoted disclaimer only applies to "the above-described image guided surgery system" which is the system described in the Generation of Images and Robotic Device section of the patent. It does not apply to every paragraph describing computer navigation system. For example, the paragraph in col. 36, lns. 55 – 62 (quoted before) provides general statements on the usage, functionalities, and components of the computer navigation system. It is in a separate section of the patent; and thus does not fall within the scope of the quoted disclaimer. In addition, the prosecution history has cited this paragraph to distinguish prior art because the present invention "provides attachment of a cutting guide to a femur without first resecting the femur, and without connection to an EM or IM rod." ('896 patent file history, 10/9/2007 Response to Office Action at 11.) This further shows that the paragraph in col. 36, lns. 55 – 62 is not merely intended as an example.

For the above-mentioned reasons, the Court construes "computer navigation system" as "a computer system having locating devices and such system is used to control the course, position, or alignment of joint replacement components."

(b) *"Side surface"*

The parties agree that the definition of the term "side surface" includes lateral (outside) and medial (inside) surface of a knee. However, Bonutti argues that the definition should also incorporate posterior (back) and anterior (front) surfaces. Figures 1 – 3[1] below illustrate major anatomical structures of a knee.

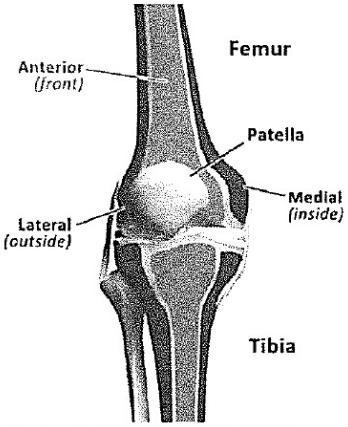

Fig.1 *(Front view of the right knee)*

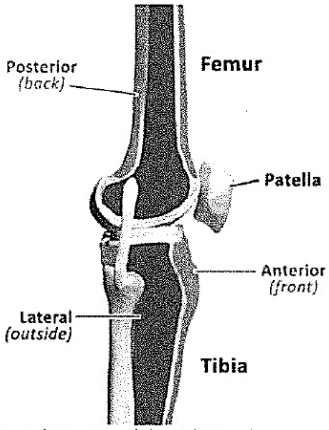

Fig.2 *(Side view of the right knee)*

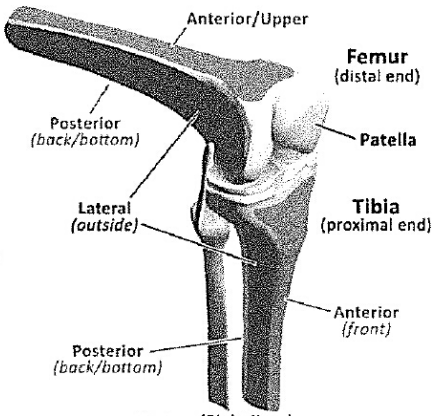

Fig.3 *(Right Knee)*

The disputed term appears in multiple dependent claims including claim 4 of the '896 patent, claim 33 of the '229 patent, and claims 23 and 24 of the '740 patent.

Claim 4 of the '896 patent discloses: "the method of claim 1 wherein the positioning step includes removably attaching the cutting guide to **the side surface** of the distal end portion of the femur." (Emphasis added.) Claim 4 is a dependent claim of claim 1. Claim 1's positioning step states: "positioning a cutting guide using the determined position, passing the cutting guide

[1] Biomet Opening Br. at 6 (DE 71).

through the incision and on **a surface** of a distal end portion of an unresected femur, the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod." (Emphasis added.) Although claim 4 uses "the side surface", claims 1 – 3 don't have the phrase "a side surface." This lack of antecedent basis for the term "the side surface" is not fatal, however, if the meaning of the claim would reasonably be understood by persons of ordinary skill when read in light of the patent. *See Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 1370 (Fed. Cir. 2006).

Because claim 4 is a dependent claim of claim 1, the doctrine of claim differentiation creates a presumption that the scope of claim 4 is narrower than that of claim 1. *See Phillips*, 415 F.3d at 1315 ("[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim."). Because claim 1 teaches attaching the cutting guide to a surface of the femur and claim 4 discusses attaching the cutting guide to a side surface, presumable side surface is narrower than any surface of the femur.

Claim 23 of the '740 patent also provides insights into the meanings of "side surface." The claim states: "the method according to claim 20, wherein the primary incision is located on a side surface of the knee joint, the side surface being one of medial and lateral relative to the centerline of the patient." Bonutti argues that restricting "side surface" to medial and lateral sides would render the sentence "the side surface being one of medial and lateral relative to the centerline of the patient" superfluous. The Court disagrees. Even if "side surface" means only medial and lateral surfaces, the phrase "a side surface" itself is ambiguous as to which specific surface the claim is referring. The quoted sentence above merely clarifies the side surface could be either medial or lateral surface. Bonutti also uses claim 14 of the '896 patent to support the

same argument. However, claim 14, a dependent claim, narrows the definition of side surface to "the medial or lateral side of **the end portion of the first bone**." (Emphasis added.) Even if "side surface" is interpreted as medial or lateral surface, the phrase "the end portion of the first bone" still prevents claim 14 from being superfluous because it shows that claim 14 is only related to a specific bone instead of providing a narrower example of side surface.

In addition, the specification of the Knee Surgery Patents has consistently shown that the side surface is the medial or lateral surface. Figure 54 illustrates the manner in which "a femoral cutting guide may be mounted on a side surface of a femur in a patient's leg." ('896 patent, col. 8, lns. 31 – 33.) In explaining Figure 54, the specification states:

> A femoral cutting guide 800 is illustrated in FIG. 54 as being mounted on a lateral surface 802 of the femur 126. However, the femoral cutting guide 800 could be mounted on the medial surface of the femur 126 if desired. When the cutting guide 800 is mounted on the lateral surface 802 of the femur 126, the incision 114 (FIG. 6) is laterally offset.

(*Id*. col. 70, lns. 18 – 22.) In addition, Figure 55 also shows that side surface 802 is on the medial or lateral side. Nevertheless, Bonutti argues that the description of Figure 55 supports its broad construction by pointing to the following two sentences:

> In the embodiment illustrated in FIG. 55, the image 850 is projected onto **a side surface** 802 of the femur 26. If desired, a three dimensional image may be projected onto **all sides** of the distal end portion 124 of the femur 126.

(*Id*. col. 73, lns. 43 – 46 (emphasis added).) Reading the two cited sentences as a whole, the Court finds that the terms "side surface" and "all sides" are not interchangeable. The second sentence merely discusses another way of projecting image. It does not inform the meaning of "side surface" one way or the other. In another word, an image may be projected onto all sides of the femur, regardless of whether a side surface means one of two surfaces or one of the four surfaces.

Lastly, in the prosecution history, Dr. Bonutti has distinguished the prior art reference by stating that the prior art does not have a cutting guide "positioned on a side surface of an end portion of a bone." Rather, the prior art "discloses anterior and posterior gauges extending from the block and interlocking within the block." ('896 patent file history, 4/30/2007 Response to Office Action at 12.) By distinguish "side surface" from the anterior and posterior surface in the prior art, it shows that Bonutti does not intend "side surface" to incorporate posterior and anterior surfaces.

For these reasons, the Court construes "side surface" as "medial or lateral surface."

(2) ***Bone Growth Patents***

The Bone Growth Patents (the '852 and '690 patents) share similar specifications. They generally relate to an implant inlaid in a recess created in a bone. Such implant may contain materials that promote bone growth so as to cause fixation between the implant and the bone. The growth is possible because bone tissue has the ability to regenerate completely if there are spaces and materials facilitating bone growth. A bone growth material can provide a scaffold to guide new bone growth. It can also include substances that induce and accelerate bone growth. The bone growth process may be facilitated by a combination of scaffold and growth promoting substances or by scaffold alone.

Terms in dispute for Bone Growth Patents include ——

- "inner surface including a bone growth promoting material /substance";
- "growth promoting body supporting said surface";
- "growth promoting body including a material that promotes tissue ingrowth thereinto / growth promoting body is operative to promote tissue growth into a surface thereof"; and

- "growth promoting body that includes a material that promotes osteoinduction."

(a) *Bone Growth Terms*

The Bone Growth Patents discuss bone growth terms in three contexts: "growth promoting body," "growth promoting material/substance," and "material that promotes tissue ingrowth." The main dispute is whether the definitions of bone growth terms must include biological substances. Biomet takes the position that scaffold alone is not enough: the claim terms should be construed to include both scaffold and additional biological materials. Bonutti, on the other hand, argues that the terms should be construed as a material or substance known for promoting bone growth.

Terms concerning "growth promoting body" appear in claims 34, 36, 37, 58, 59 of the '852 patent. Claim 34 of the '852 patent describes the structure and content of the growth promoting body as the following:

> a growth promoting body supporting said surface, and positionable between said surface replacement and bone of the joint, **said growth promoting body including a material that promotes tissue ingrowth thereinto**, wherein a load applied to the surface replacement is transferrable to bone of the joint through said growth promoting material.

(Emphasis added.) The plain meaning of the phrase "material that promotes tissue ingrowth" does not suggest that the growth promoting body must include both the scaffold and the biological materials. In addition, the dependent claims of the '852 patent discloses that the growth promoting body can contain either osteoinductive materials or ceramic materials. ('852 patent, claims 34 and 46.) Because ceramic materials are not biological substance, the "growth promoting body" is not required to contain biological substance.

The term "growth promoting materials" appears in the context of promoting tissue ingrowth. Claim 34 of the '852 patent recites: "said growth promoting body including a material that promotes tissue ingrowth thereinto." Claim 56, a dependent claim of claim 34, further states: "[t]he implant of claim 34, wherein said material that promotes tissue ingrowth promotes bony tissue ingrowth into said growth promoting body." The plain language of claims does not suggest that the growth promoting materials should incorporate both the scaffold and biological substance.

Furthermore, the specification shows that the material promoting tissue ingrowth does not have to contain biological materials. Specifically, the specification of the '852 patent discloses:

> It may also be advantageous to include some type of known tissue in-growth promoting features on at least a portion of body 1404. Such features include a porous or textured surface, a porous body (for example so-called "foam metals"), and osteoinductive or osteoconductive materials or factors.

('852 patent, col. 106, lns. 34 – 39.) The plain reading of the cited paragraph shows that the material promoting tissue in-growth can be a textured surface or osteoconductive materials, which are not necessarily biological substance.

Biomet argues that claim 34 of the '852 patent provides two components. The first component is the "growth promoting body" which provides a scaffold for bone growth while the second component is a "material" to stimulate bone growth. The Court agrees that "growth promoting body" and material promoting issue ingrowth refer to slightly different things. Nevertheless, as mentioned above, both phrases do not have a built-in requirement for biological substances.

The parties also dispute the meaning of the term "growth promoting material/substance" in claims 18 and 44 of the '852 patent as well as claim 32 of the '690 patent. Claim 18 of the

‘852 patent is directed to a multi-layered implant, which has an outer layer and a base layer. The claim describes the layered implant with growth promoting substance as the following:

> An implant for implantation in a recess created in a portion of a single articular surface on a bone, the implant comprising: … a base layer, supporting the outer layer, and having an inner surface configured and dimensioned to engage bone tissue when inserted in the recess, **the inner surface further including a bone growth promoting substance**.

(Emphasis added.)

Claim 44 of the ‘852 patent depends from claim 43 which further depends from claim 34. Claim 34 discusses placing a bone growth promoting materials inside the growth promoting body. It recites:

> A growth promoting body supporting said surface, and positionable between said surface replacement and bone of the joint, said growth promoting body including a material that promotes tissue ingrowth thereinto, wherein a load applied to the surface replacement is transferrable to bone of the joint through said growth promoting material.

Referring to the implant in claim 34, claim 43 recites: “The implant of claim 34, wherein the articulating load bearing surface replacement includes a smooth metallic surface.” Claim 44 further recites: “the implant of claim 43, wherein the foam metal material incorporates a bone growth promoting material or a healing agent.” Claim 32 of the ‘690 patent also uses similar language and structure. The plain language of these claims does not require bone growth to be based on the biological properties of the material. Additionally, specification consistently states that the bone growth materials are not limited to biological materials. For example, the Layered Implant Section of the ‘852 patent describes the composition of base layer as follows:

> The inner layer 678 may be formed of bone growth promoting materials which promote migration of bone cells from the bone 674 to the base layer 678. New bone growth into the base layer 678 will interconnect the base layer and the bone 674. The base layer 678 may contain cortical cancellous bone power or chips and/or demineralized bone matrix, bone morphogenic protein, anti-inflammatories and/or immuno suppressants may be disposed in the base layer 678. An antibiotic,

> hydroxyapatiate, tricalcium phosphate and/or polymers and copolymers may also be included in the base layer 678.

('852 Patent, col. 59, lns. 60 – col. 60, lns. 3.) Furthermore, the '852 patent's specification also teaches the use of bone fragments as a material inducing bone growth:

> The scaffold holds bone growth inducing materials and may include bone fragments to which tri-calcium phosphate, an antibiotic, hydroxyapatiate, allografts, autografts, and/or any other polymeric has been added. It is believed that it will be particularly advantageous to provide a bone growth morphogenetics protein in the implant 626 to promote the growth of bone into the implant. The scaffold may hold cultured and/or noncultured cells which promote biological resurfacing.

(*Id*., col. 55, lns. 62 – col. 56, lns. 3.) Similar paragraphs also appear in other parts of the patent. (*See id.*, at col. 58, lns. 42 – 65.)

As shown in the cited paragraphs, although the implant may contain biological materials such as bone growth morphogenetics proteins, it does not have to incorporate biological substance. For example, tricalcium phosphate, polymers, or bone chips may be included in the implant.

For all these reasons, the Court construes bone growth terms according to their ordinary and customary meaning. Accordingly:

- "Inner surface including a bone growth promoting material/substance" in claims 18, 44 of the '852 patent, and claim 32 of the '690 patent in construed as a [material/substance] that encourages bone tissue to grow.
- "Growth promoting body supporting said surface" in claims 34, 36, 37, 58, 59 of the '852 patent is construed as body that encourages tissue to grow.
- "Growth promoting body including a material that promotes tissue ingrowth thereinto" in claim 34 of the '852 patent and "material that promotes tissue ingrowth promotes bony tissue ingrowth into said growth promoting body" in claim 56 of the '852 patent are

construed as growth promoting body including a material that encourages tissue to grow into the growth promoting body.

- "Growth promoting body is operative to promote tissue growth into a surface thereof" in claim 59 of the '852 patent is construed as growth promoting body is operative to encourage tissue to grow into a surface of the growth promoting body.

(b) *"Growth promoting body that includes a material that promotes osteoinduction"*

Parties dispute the meaning of the phrase "growth promoting body that includes a material that promotes osteoinduction" in claim 35 of the '852 patent and claim 24 of the '690 patent. At the heart of the dispute is the definition of "osteoinduction." The parties agree that "osteoinduction" is a well-known term in the medical field. The parties, however, cannot agree on the commonly known definition. Without finding much support in the intrinsic evidence, Bonutti relies on dictionary and expert testimony arguing that the term means stimulating development and formation of a bone. Meanwhile, Biomet mainly uses an article from a European medical journal and proposes the definition to be "the portion of the implant underlying the surface having a substance that stimulates bone tissue to grow by causing undifferentiated cells to become bone forming cells based on biological properties of the substance." Having construed the term "growth promoting body," the Court will focus its analysis on "osteoinduction" alone.

Claim 35 of the '852 patent is a dependent claim of claim 34. Claim 35 requires "growth promoting body" in claim 34 to promote osteoinduction. Presumably, the scope of claim 35 is narrower than claim 34. *See Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) ("The presence of a dependent claim that adds a particular limitation raises a presumption

that the limitation in question is not found in the independent claim."). As the Court discussed in the previous section, the "growth promoting body" is construed as "body that encourages tissue to grow." If Bonutti's construction is adopted, the scope of claim 35 would be as broad as claim 34, where both claims disclose a "growth promoting body" which includes a material that facilitates bone growth. This violates the basic principle of claim differentiation mentioned above. The same analysis also applies to "osteoinduction" in claim 24 of the '690 patent.

Specification also suggests that the scope of "osteoinduction" is narrower than "stimulates development and formation of bone." For example, the specification distinguishes osteoinductive materials from form metals and osteoconductive materials. Specifically, the specification of the '852 patent states:

> It may also be advantageous to include some type of known tissue in-growth promoting features on at least a portion of body 1404. Such features include a porous or textured surface, **a porous body (for example so-called "foam metals"), and osteoinductive or osteoconductive materials or factors.**

('852 patent, col. 106, lns. 36 – 39 (emphasis added).) The bold phrase separately lists "osteoinductive materials" and "foam metals" suggesting that they are different kinds of materials. Similarly, the conjunction "or" shows that osteoinductive and osteoconductive materials are not of the same type.[2] However, under Bonutti's construction, "osteoinduction" would cover "form metal"[3] as well as osteoconductive materials. This construction is not consistent with the specification.

Although the definition of "osteoinduction" remains unclear after examining the intrinsic evidence, the intrinsic evidence does suggest that the term is narrower than "stimulates development and formation of bone." With this in mind, the Court turns to the extrinsic evidence. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996)

[2] *See also*, '852 patent, col. 57, lns. 5 – 18 and col. 58, lns. 50 – 68.
[3] Hr'g Tr. vol. 2, 64:2 - 10, Sept. 24, 2014.

(reliance on extrinsic evidence to interpret claims is proper only when the claim language remains genuinely ambiguous after considering the intrinsic evidence).

As discussed earlier, Bonutti's dictionary definition is inconsistent with the patent's claims and specification. Therefore, the Court will not adopt Bonutti's proposed construction. *See id* (extrinsic evidence that contradicts intrinsic evidence is accorded no weight). The article proffered by Biomet, discusses osteoinduction and osteoconduction process, among other things. Specifically, the article distinguishes osteoinduction from osteoconduction. It describes osteoinduction as a process where primitive, undifferentiated cells (such as a mesenchymal cell) are transformed into preosteoblast cells. Osteoconduction, on the other hand, represents the process where bones grow onto a surface. (Biomet Ex. 25, Albrektsson at S96 – 97 (DE 72).) In addition, the Court's own search in databases has found other scientific articles published around the same time of the disputed patents. These articles have similar understanding as Biomet regarding the meaning of osteoinduction. For example, one article describes osteoinduction as involving "the recruitment of mesenchymal stem cells to become osteoblasts." Lyndon F. Cooper, *Biologic Determinants of Bone Formation for Osseointegration: Clues for Future Clinical Improvements,* Journal of Prosthetic Dentistry 80(4): 442 (1998). Similarly, another article describes osteoinductive stimuli as factors or signals that cause osteoblastic differentiation. James E. Fleming Jr. et al, *Bone Cells and Matrices in Orthopedic Tissue Engineering*, Orthopedic Clinics of North America 31(3): 358 (2000). The articles taken together with the intrinsic evidence show that the ordinary meaning of "osteoinduction" at the time of the invention means causing undifferentiated cells to become bone forming cells. Accordingly, the Court construes "growth promoting body includes a material that promotes osteoinduction" as

growth promoting body includes a material that stimulates bone tissue to grow by causing undifferentiated cells to become bone forming cells.

D. Conclusion

The claims, terms, and phrases of the patent at issue are thereby construed and set forth in this Order.

Date: April 10, 2015

s/ Joseph S. Van Bokkelen
JOSEPH S. VAN BOKKELEN
UNITED STATES DISTRICT JUDGE