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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ARLEN D. HANSEN and DAVID LEWALLEN

Appeal 2018-001527
Application 14/278,916
Technology Center 3700

Before ERIC B. GRIMES, FRANCISCO C. PRATS, and
JENNIFER MEYER CHAGNON, *Administrative Patent Judges*.

CHAGNON, *Administrative Patent Judge*.

DECISION ON APPEAL¹

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant² appeals from the Examiner's decision to reject claims 2–29. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

¹ In this Decision, we refer to the Specification filed May 15, 2014 (“Spec.”); Non-Final Office Action dated April 4, 2017 (“Non-Final Act.”); Appeal Brief filed August 18, 2017 (“Appeal Br.”); Examiner’s Answer dated October 3, 2017 (“Ans.”); and Appellant’s Reply Brief filed November 28, 2017 (“Reply Br.”).

² We use the word Appellant to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as Zimmer, Inc. Appeal Br. 2.

CLAIMED SUBJECT MATTER

Appellant's disclosure relates to "prosthetic devices for implantation within a bone, and more particularly to support structures that are affixed to a bone and that support prosthetic implants." Spec. ¶ 3. Claim 2, reproduced below, is illustrative of the claimed subject matter:

2. An acetabular system implantable in an acetabular cavity in a patient, comprising:
 - an acetabular cup implant; and
 - a support component for occupying an area in the acetabular cavity, the support component connected to the acetabular cup implant for supporting the acetabular cup implant in the acetabular cavity, the support component including an outer surface for facing an inner surface of the acetabular cavity and an interior into which only part of the acetabular cup implant is received, the support component being formed separately from the acetabular cup implant for subsequent connection to the acetabular cup implant, the support component capable of being impacted, by itself, into the acetabular cavity for obtaining a press fit of the support component in the acetabular cavity, *the support component being formed with a porous metal material that is a bone ingrowth-receptive material with a porous structure for allowing bone of the patient to grow into and throughout the support component for restoring lost bone stock in the acetabular cavity in the area occupied by the support component when the support component is implanted in the acetabular cavity.*

Appeal Br. 76 (emphasis added).

REFERENCES

The prior art relied upon by the Examiner is:

| Name | Reference | Date |
|----------|-----------------------|----------------|
| Kampner | U.S. Patent 4,840,632 | June 20, 1989 |
| Grimes | U.S. Patent 5,176,711 | Jan. 5, 1993 |
| Christie | U.S. Patent 5,192,329 | Mar. 9, 1993 |
| Tullos | U.S. Patent 5,658,338 | Aug. 19, 1997 |
| Draenert | U.S. Patent 5,958,314 | Sept. 28, 1999 |

REJECTIONS

The Examiner maintains the following rejections on appeal:

1. Claims 2–29 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Non-Final Act. 2–4.
2. Claims 2, 8–12, 14–19, 21–24, 26, and 27 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Grimes and Draenert. *Id.* at 4–5.
3. Claims 4, 5, 13, 20, and 25 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Grimes, Draenert, and Christie. *Id.* at 5–6.
4. Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Grimes, Draenert, and Tullos. *Id.* at 6–7.
5. Claims 3, 28, and 29 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Grimes, Draenert, and Kampner. *Id.* at 7.

OPINION

We have reviewed the Examiner’s rejections in light of Appellant’s contentions that the Examiner has erred. Further, we have reviewed the Examiner’s response to Appellant’s arguments. We are persuaded by

Appellant's arguments that the Examiner erred in rejecting the claims based on the grounds of rejection set forth above.

Written Description

Claims 2–29 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Non-Final Act. 2–4. In particular, the Examiner contends that the claim language “a porous structure for allowing bone of the patient to grow into and throughout the support component”, as recited in claim 2, with similar language in the other independent claims, “lacks clear original support.” *Id.* at 3.

Appellant contends there is direct support in the Specification for “(i) forming the support component from a *porous* metal material; and (ii) having the *entire structure* of the support component be porous (and thus capable of receiving bone ingrowth),” and there is, thus, “support for the support component being formed with a porous metal material and for the support component’s ability to allow bone of the patient to grow into and throughout itself for restoring lost bone stock in the acetabular cavity, as claimed.” Appeal Br. 9–10; *see also id.* at 8–18 (expanding upon this contention). We agree.

The Specification describes that “[o]ne problem commonly encountered by surgeons replacing joints is the loss of strong bone stock near the joint being replaced.” Spec. ¶ 4. As such, “there is a need for a prosthetic implant system . . . that encourages bone ingrowth and attachment over as large a surface area as possible.” *Id.* ¶ 10. According to the Specification, the present invention solves this problem. *See id.* ¶¶ 19, 97.

Appellant presents testimony that a porous structure that is receptive to bone ingrowth has the ability to restore lost bone stock in an area occupied by the porous structure. *See* Lewallen Decl.³ ¶ 6.

In the Answer, the Examiner contends that “restoring lost bone stock does not necessarily means [sic] that the implant must be porous throughout only that the implant must be capable [of] replacing the bone from a purely structural standpoint. It does not require that the implant be porous throughout.” Ans. 2. We agree with Appellant, however, that in combination with the figures, e.g., Figure 8, the disclosures of at least paragraphs 13, 55, 58, and 60 of the Specification support claims directed to the support component being formed entirely with a porous metal material, even if this is not *required* in all of the Specification’s embodiments. *See* Reply Br. 12–14; *see also* Appeal Br. 22 (Appellant arguing that “Appellant’s disclosure is not limited to embodiments where only the very outer surface is porous and available for bone ingrowth. It also includes embodiments where a support component is porous throughout.”).

Written description requires that the Specification demonstrates Appellant had possession of the claimed invention at the time the application was filed. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Based on at least the foregoing disclosures of the Specification and the testimony presented in the Lewallen Declaration, we are persuaded that Appellant had possession of the support component being formed entirely with porous metal material. We further agree with Appellant that, based on the disclosures above and those cited by Appellant,

³ Declaration of David G. Lewallen under 37 C.F.R. § 1.132, executed March 16, 2017 (“Lewallen Decl.”).

a person of ordinary skill in the art would have understood that such a porous support structure “allow[s] bone of the patient to grow into and throughout the support component,” as claimed. We therefore reverse the rejection under 35 U.S.C. § 112, first paragraph, for lack of adequate written description.

Claims 3, 28, and 29 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Non-Final Act. 2–3. Claims 3 and 29 recite that the “support component . . . is capable of being impacted and wedged, by itself, into the acetabular cavity for obtaining a press fit . . . in the acetabular cavity.”⁴ Appeal Br. 77, 83–84. In particular, the Examiner contends the claimed “‘wedged’ acetabular support component lacks original support.” Non-Final Act. 3. According to the Examiner, “the relevant prior art . . . refers to ‘wedged’ as relevant to angled surfaces that can separate or push surfaces apart,” and does not apply to acetabular cups. *Id.* at 8.

We agree with Appellant, however, that in the claim, the term “wedged” is used as a verb, rather than as a noun or adjective as used by the Examiner. Appeal Br. 29. The Specification notes that “[p]ress fit . . . techniques can be employed in conjunction with the . . . prosthetic systems according to the invention.” Spec. ¶ 47. In discussing embodiments of the invention, the Specification describes support components being “impacted into” the bone, so as to be “firmly wedged” therein. *See id.* ¶¶ 12, 49, 52, 57, 60, 64. The embodiments specifically directed to an acetabular cup implant also discuss the support structure being “impacted into” the bone.

⁴ Claim 28, also subject to this rejection, depends from claim 3. Appeal Br. 83.

See id. ¶¶ 70, 74, 77, 81, 84, 88, 91, 94. Based on at least the foregoing disclosures of the Specification, we are persuaded that Appellant had possession of the support component being “impacted and wedged, by itself, into the acetabular cavity for obtaining a press fit.”

We therefore reverse the rejection under 35 U.S.C. § 112, first paragraph, for lack of adequate written description.

Obviousness

Claims 2, 8–12, 14–19, 21–24, 26, and 27 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Grimes and Draenert. Non-Final Act. 4–5. Claims 4, 5, 13, 20, and 25 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Grimes, Draenert, and Christie. *Id.* at 5–6. Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Grimes, Draenert, and Tullos. *Id.* at 6–7. Claims 3, 28, and 29 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Grimes, Draenert, and Kampner. *Id.* at 7. We address these rejections together as the same issue is dispositive to all rejections.

The Examiner relies on acetabular shell 14 and augmentation piece 16 of Grimes as teaching the claimed acetabular cup and support structure, respectively. *See* Non-Final Act. 4; Grimes 3:51–4:2, Figs. 2–5d, 7j. As acknowledged by the Examiner, Grimes “does not disclose having the porous material extending throughout the entire support structure.” Non-Final Act. 4. For this feature of the claim, the Examiner points further to Draenert. *Id.* According to the Examiner, Draenert “teaches that it was known to make similar implants out of porous materials where the pores extend throughout the entire piece.” *Id.* (citing Draenert 5:62–6:56). The Examiner, thus, asserts that “it would have been considered clearly obvious

to an ordinary artisan to utilize porous material, as taught by Draenert in making the piece (16) of Grimes for the same reasons that Draenert utilizes the same or for the reason that it would have been a mere substitution of one known material for another to yield a predictable result.” *Id.* at 5 (citing MPEP 2143).

Appellant argues Draenert does not teach anything about acetabular support components for connecting components in a patient’s body. Appeal Br. 34. Appellant further contends that the “overwhelming majority of component (16) in Grimes is completely non-porous and thus overwhelmingly not receptive to bone ingrowth” and “Grimes fails to shed any light on how having bone growth throughout component (16) would affect the efficacy of that particular component and/or things connected to it in the body . . . over time.” *Id.* at 35. According to Appellant, a person of ordinary skill in the art would not have modified Grimes in view of Draenert, as proposed by the Examiner. *Id.* at 34–36.

We agree that a preponderance of the evidence does not support the Examiner’s findings that the skilled artisan would have been motivated to combine Grimes and Draenert. A prima facie case for obviousness “requires a suggestion of all limitations in a claim,” *CFMT, Inc. v. Yieldup International Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003), and “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does,” *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

As acknowledged by the Examiner (Non-Final Act. 4), Grimes discloses a porous coating on the surface of augmentation piece 16. Grimes 3:51–4:2. The Examiner has not identified any other teaching in Grimes

regarding the porous coating, such as a reason that the coating material would not need to be a different substance from that of the remainder of the augmentation piece, as Grimes discloses.

Draenert teaches a process

for producing a positive-material with a skeleton made of shell-like structures and an interconnecting pore system designed between the skeleton structures. Also disclosed is a process for producing a negative-material made of shaped bodies interconnected by bridges[,] a process for producing a positive/negative-material, materials produced by this process and their use as bone replacement materials, implants, filters and drug delivery systems. According to this process deformable shaped bodies in bulk are poured into a mold that forms a negative model of the material.

Draenert Abstract. Along with the Abstract, the Examiner points to Draenert's Figures 1–10, which depict porous substances made by the processes described above. *See* Non-Final Act. 4.

Upon review of the disclosures identified by the Examiner, we are not persuaded that a person of ordinary skill in the art would have found it obvious to use the porous materials taught by Draenert to make the augmentation piece of Grimes, as reasoned by the Examiner. The Examiner has not identified a teaching that would have prompted the artisan to combine the elements in the way the claimed new invention does. *KSR*, 550 U.S. at 418.

The Examiner also contends that Grimes has porous structures because it includes holes that “can function for ingrowth even though they are disclosed as providing visualization of the bone or screw attachments.” Non-Final Act. 10; Ans. 8. Appellant counters that “[s]uch large holes would never be interpreted by a person of ordinary skill in the art as ‘pores’

for receiving bone ingrowth” because “they are much, much too large.” Appeal Br. 37; *see also id.* at 38 (discussing that pores suitable for bone growth are often in the range of about 100–600 μm , which is much smaller than the large holes in Grimes that are provided for receiving screws). Appellant argues that, in any case, “the overwhelming majority of component (16) in Grimes remains completely solid/non-porous and thus overwhelmingly not receptive to bone ingrowth.” *Id.* at 37–38. The Examiner responds that it was known in the art “to have large holes for bone ingrowth.” Ans. 8–9. Even if we were to agree with the Examiner that the large screw holes would be understood by a person of ordinary skill in the art to be receptive to bone ingrowth, we still are not persuaded that their presence in Grimes is a suggestion to have porous material extend through the entire augmentation piece of Grimes. Further, even if a wholly porous support component were desired, the Examiner has not pointed us to teachings in Draenert that suggest the artisan would have reasonably believed that the proposed “substitution of one known material for another to yield a predictable result” (Non-Final Act. 5) would be successful, particularly as the materials disclosed by Draenert are not the same size or shape as the augmentation piece 16 of Grimes.

Appellant also submits extensive evidence of secondary considerations (*see* Appeal Br. 39–69; Reply Br. 2–7), which the Examiner contends lacks probative weight (Non-Final Act. 11–13; Ans. 9–11). However, given that we conclude the references do not suggest the claimed subject matter, we find that a preponderance of the evidence does not support the Examiner’s conclusion that the rejected claims are obvious. Because all of the rejections are based on the Examiner’s finding that a

person of ordinary skill in the art would have found it obvious to use the porous materials taught by Draenert such that the augmentation piece 16 of Grimes is porous throughout, we reverse all of the rejection under 35 U.S.C. § 103.

CONCLUSION

The Examiner's rejections are reversed.

DECISION SUMMARY

In summary:

| Claims Rejected | 35 U.S.C. § | Reference(s)/Basis | Affirmed | Reversed |
|-------------------------------|----------------------|----------------------------|-----------------|-------------------------------|
| 2-29 | 112, first paragraph | | | 2-29 |
| 2, 8-12, 14-19, 21-24, 26, 27 | 103(a) | Grimes, Draenert | | 2, 8-12, 14-19, 21-24, 26, 27 |
| 4, 5, 13, 20, 25 | 103(a) | Grimes, Draenert, Christie | | 4, 5, 13, 20, 25 |
| 6, 7 | 103(a) | Grimes, Draenert, Tullos | | 6, 7 |
| 3, 28, 29 | 103(a) | Grimes, Draenert, Kampner | | 3, 28, 29 |
| Overall Outcome | | | | 2-29 |

REVERSED