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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHN M. ARMACOST, RYAN C. KEEFER, and JEFFREY A. McANELLY

Appeal 2018-000010
Application 14/548,370
Technology Center 3700

Before ADRIENE LEPIANE HANLON, JAMES C. HOUSEL, and SHELDON M. MCGEE, *Administrative Patent Judges.*

Opinion for the Board filed by *Administrative Patent Judge* HOUSEL.

Opinion Dissenting filed by *Administrative Patent Judge* MCGEE.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to finally reject claims 1–6 under 35 U.S.C. § 103(a) as unpatentable over Andersen (CA 2354065 A1, pub. Nov. 18, 1999) in view of Dickerson (US 2012/0010720 A1, pub. Jan. 12, 2012) or Vargas (US

[1] 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 DePuy Synthes Products, Inc. Appeal Brief ("Appeal Br.") filed May 18, 2017, p. 2.

2012/0125896 A1, pub. May 24, 2012). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.[2]

CLAIMED SUBJECT MATTER

The claims are directed to a method of making an orthopaedic prostheses, particularly a dual modulus hip stem for use in hip replacement surgery. Spec. Title and ¶ 2.

Claim 1, reproduced below from the Claims Appendix to the Appeal Brief, is illustrative of the claimed subject matter:

> 1. A method of manufacturing an orthopaedic prosthesis for a patient, comprising:
>
> producing a shell from a metallic foam material having a first elastic modulus,
>
> producing a stem core from a metallic material having a second elastic modulus greater than the first elastic modulus, the stem core including a neck configured to receive a femoral head component and a stem body that extends from the neck to a distal tip, and
>
> securing the shell to the stem body such that (i) the shell is positioned over a proximal segment of the stem body, and (ii) a cover layer of the shell is positioned distal of the neck and extends along a lateral surface of a distal segment of the stem body, wherein the distal segment of the stem body includes the distal tip.

[2] Our Decision additionally refers to the Specification ("Spec.") filed Nov. 20, 2014, the Examiner's Answer ("Ans.") dated July 27, 2017, and Appellant's Reply Brief ("Reply Br.") filed Sept. 27, 2017. We note that each of the pages of the Answer are labeled as "Page 1." For purposes of our Decision, we refer to the pages of the Answer consecutively with the Grounds of Rejection appearing on page 2.

OPINION

After review of the Examiner's and Appellant's opposing positions and the appeal record before us, we determine that Appellant's arguments are insufficient to identify reversible error in the Examiner's obviousness rejection. *In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011). Accordingly, we affirm the stated rejection for substantially the fact findings and the reasons set forth by the Examiner in the Examiner's Answer and the Final Office Action. We offer the following for emphasis only.

Claim 1

The Examiner found that Andersen discloses a method of manufacturing an orthopaedic prostheses substantially as recited in claim 1, except for forming layer 250 as a sleeve that is secured to stem core 220.[3] Ans. 2–3. However, the Examiner found that it was known to form biocompatible layers such as Andersen's as a sleeve that is subsequently secured to a stem core as taught by Dickerson and Vargas. *Id.* at 3. The Examiner, therefore, concluded that it would have been obvious to have formed Andersen's layer 250 as a sleeve that is secured to stem core 220 in light of the teachings of Dickerson and Vargas "as a matter of obvious design choice." *Id.*

The Examiner further found that Andersen's shell layer 250 is a metallic foam material because it may be a sintered porous titanium material. Ans. 2, 5. The Examiner provided a definition for "foam"—"a

[3] Although the Examiner refers to Andersen's element 260 as the stem core, Andersen refers to the stem core as distal portion 220 of the hip joint prostheses, whereas Andersen refers to the distal segment as distal stem 260. Accordingly, we refer to the stem core using numeral 220 here and thereafter.

material in a lightweight cellular form resulting from introduction of gas bubbles during manufacturing" (*id.* at 5)—in support of the Examiner's interpretation of Andersen's sintered porous metallic material as a metallic foam material.

In addition, the Examiner found that Andersen's shell layer 250 includes a shell body that is positioned over a proximal segment of stem core 220 and a cover layer positioned distal of neck 240 and extending along a lateral surface of a distal segment of stem core 220, wherein the distal segment includes the distal tip. Ans. 2–3. According to the Examiner, Andersen's proximal segment is the portion of stem core 220 extending from the neck and covered by the shell body, whereas the distal segment is the portion of stem core 220 extending from the distal tip, a portion of which is covered along a lateral surface thereof by a cover layer extending from the shell body. *Id.* at 6–8.

Appellant argues that the Examiner failed to sufficiently support the finding that Andersen's porous sintered metal material is necessarily or inherently a metallic foam material. Appeal Br. 3–4. Appellant urges that the Examiner's inherency position "is effectively that all porous metallic structures with a plurality of holes are metallic foams." Reply Br. 2. Appellant cites three porous metal structures, e.g., a wire mesh, a metal grate, and a cheese grater, as examples that would not be understood to be metallic foams. *Id.* Appellant contends that neither the Examiner's definition nor Andersen satisfy the standard for inherency. Appeal Br. 5. Appellant also contends that it is not clear whether Andersen's partially sintered porous structure becomes part of Andersen's implant. *Id.*

Although Appellant correctly notes that the Examiner bears the initial burden of establishing inherency, Appellant makes no attempt in this argument to direct us to any reversible error in the Examiner's finding that the "porous sintered metal" described in Andersen is encompassed by the claimed "metallic foam." Indeed, Appellant does not advance any definition of a "metallic foam" that excludes Anderson's porous sintered metal, nor direct us to any disclosure in the Specification demonstrating that the claimed metallic foam is produced from a process that would have been expected to yield a physically different product from Anderson's porous sintered metal.

With regard to the three examples of porous metallic structures that Appellant provides as an indication that not all porous metallic structures are metallic foams, we note that each of these examples is generally a two-dimensional metallic grid with holes or openings therethrough. Appellant does not contend that Andersen's porous sintered metallic layer is equivalent to such structures. Further, the ordinary artisan would generally understand such porous sintered metallic layer to have a three dimensional network of holes, just as expected for Appellant's metallic foam material.

Moreover, as the Examiner found (Ans. 5), Andersen teaches that the shell may be sintered by forming a layer of a mixture of metal particles, binder, and a sacrificial binder, wherein it was known in the art that, during sintering, the sacrificial binder evaporates, thereby resulting in the porous structure. Thus, the sintered porous layer becomes a part of the prosthetic structure. Accordingly, Appellant has not identified any error in the Examiner's treatment of Andersen's porous sintered metal as covering the recited metallic foam material of the claims.

Appellant next argues that the Examiner failed to establish that the combination of Andersen, Dickerson, and Vargas produces the claimed shell and cover layer. Appeal Br. 6. In particular, Appellant contends that Andersen fails to disclose manufacturing a prosthesis with a shell positioned over a proximal segment of the stem body, and (ii) a cover layer of the shell is positioned distal of the neck and extends along a lateral surface of a distal segment of the stem body, wherein the distal segment of the stem body includes the distal tip. *Id.* at 7. In this regard, Appellant contends that the Examiner applies an unreasonably broad interpretation of "distal" and "proximal" which does not comport with the understanding of a person of ordinary skill in the art and is nonsensical. *Id.* at 8. Appellant urges that a person of ordinary skill in the art would understand that Andersen's tissue fixation surface (shell) 250 is positioned on only a proximal segment of Andersen's stem. *Id.* Appellant further contends that neither Dickerson nor Vargas remedy this deficiency in Andersen. *Id.* at 8–11.

Appellant's argument depends on a claim interpretation that requires the cover layer extend over the distal segment so as to include (and cover) the distal tip. However, claim 1 merely requires that the distal segment includes the distal tip and that the cover layer "is positioned distal of the neck and extends along a lateral surface of the distal segment." Claim 1 does not require that the cover layer extend any particular amount or length of the distal segment nor that the cover layer extends to the distal tip. Nor does claim 1 define how far the proximal segment extends from the neck or how far the distal segment extends from the distal tip.

Moreover, although Appellant argues that the Examiner applied an unreasonably broad interpretation to the terms "distal" and "proximal" in the

claims, Appellant makes no attempt to provide any meaning for these terms that clearly delineate where the proximal segment ends and the distal segment begins. Indeed, a skilled artisan would understand that the term "proximal," as used in the claims and Specification, refers to a portion of the stem extending from the neck toward the distal tip, whereas the term "distal" refers to a portion of the stem that is spaced from the neck and includes the distal tip. However, no clear delineation is established for the proximal and distal segments except that the shell is positioned over the proximal segment and the cover layer is positioned distal of the neck, i.e., spaced from the neck, extending along a lateral surface of the distal segment. Thus, the neck and shell define the position of the proximal segment, and the neck, distal tip, and cover layer define the position of the distal segment.

Applying this interpretation of claim 1 to Andersen, as the Examiner found (Ans. 7, annotated figure), Andersen's proximal segment extends from the neck of the prosthesis to the beginning of the cover layer, whereas the distal segment extends from the distal tip to the point where the cover layer joins the shell body. Thus, contrary to Appellant's argument, Andersen's prosthesis has a shell positioned over a proximal segment of the stem body and a cover layer distal of the neck and extending along a lateral surface of the distal segment of the stem body. Accordingly, Appellant has not identified any error in the Examiner's interpretation of claim 1 and finding that Andersen teaches a prosthesis having a shell and cover layer positioned as required in the claim. Because we find no error in the Examiner's interpretation of either claim 1 or Andersen, we need not address the Examiner's alternative position that it would have been obvious to modify the shape or configuration of Andersen's prosthesis.

We note that, in the view of the dissent, the Examiner fails to provide sufficient evidence or technical rationale supporting the finding that Andersen's "porous, sintered metal" is, in fact, a "metallic foam material," and as such improperly shifts the burden to Appellant. This view not only advances arguments Appellant has not made, but also applies an incorrect approach to our appellate review procedure. While the Examiner bears the initial burden of presenting a prima facie case of obviousness during examination (*In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992)), on appeal, the initial burden is on Appellant to identify reversible error. *Shinseki v. Sanders*, 129 S.Ct. 1696, 1706 (2009) (citations omitted) ("Lower court cases make clear that courts have correlated review of ordinary administrative proceedings to appellate review of civil cases in this respect. . . . [T]he party seeking reversal normally must explain why the erroneous ruling caused harm.") Appellant's burden on appeal is not met simply by expressing disagreement with an Examiner's finding of fact, but by persuasively pointing to where the error is in that finding. *See In re Lovin*, 652 F.3d 1349, 1356–57 (Fed. Cir. 2011).

The Examiner's finding that Andersen teaches a porous, sintered metal material is undisputed. Further, although the dissent acknowledges that the Examiner provided a definition for the term "foam," the dissent argues, *unlike Appellant*, that the Examiner fails to adequately explain—or provide evidence to support—how that extrinsic definition applies to the specifics of this case. However, the Examiner found, *and Appellant did not dispute*, that one of ordinary skill in the art would have understood that Andersen's sacrificial filler would evaporate during sintering, presumably creating air bubbles or air pockets that form the porous, sintered structure.

The dissent emphasizes that the Office may show that two products are identical or substantially the same by showing that they are produced by identical or substantially identical processes. *We note again that Appellant did not make this argument, nor did Appellant disclose any process for making the recited metallic foam.* We reiterate that Appellant did not even attempt to structurally define or explain how a "metallic foam" is structurally distinct from Andersen's porous, sintered metallic material.

Accordingly, a preponderance of the evidence supports the Examiner's conclusion of obviousness of claim 1. Appellant does not argue claims 2 and 3 separately from claim 1. Given this record, therefore, we sustain the Examiner's obviousness rejection of claims 1–3.

Claims 4–6

Claim 4 depends from claim 1 and further requires that the step of securing the shell to the core includes sintering.

Claim 5 depends from claim 1 and further requires that the shell is produced by compressing the metallic foam material around the stem core, and machining the metallic foam material to form the shell.

Claim 6 depends from claim 1 and further requires that the shell is produced by compressing the metallic foam material to form the outer geometry of the shell, and machining a channel in the metallic foam material sized to receive the stem core.

For each of these claims, the Examiner found that the recited manufacturing steps were old and well known in the art and that the skilled artisan would have found it obvious to use such a process to produce the shell and secure it to the stem body. Ans. 4–5. The Examiner stated that the "Examiner took Official Notice that the limitations of claims 4–6 were

known in the art." *Id.* at 9. In addition, the Examiner found that Andersen teaches sintering the metallic foam material to the stem core. *Id.* at 4.

Appellant argues because Andersen does not teach a "metallic foam material," Andersen cannot teach sintering a metallic foam material to the stem core as recited in claim 4, or compressing and machining a metallic foam material as recited in claims 5 and 6. Appeal Br. 14; Reply Br. 6. However, as discussed above, we are not persuaded that the Examiner erred in finding that Andersen teaches a metallic foam material. We, therefore, are not persuaded of reversible error in the Examiner's finding that Andersen teaches sintering the metallic foam material to the stem core, or that it would have been obvious to compress and machine a metallic foam material to produce Andersen's shell given that such steps were old and well known in the art.

As to claims 5 and 6, Appellant further argues that the Examiner fails to cite a single reference teaching the compressing and machining steps of these claims. Appeal Br. 14, 15. However, Appellant failed to challenge the Examiner's Official Notice that such compressing and machining steps were old and well known in the art. It is well settled that there are situations in which it is permissible to "take notice of facts beyond the record which, while not generally notorious, are capable of such instant and unquestionable demonstration as to defy dispute." *In re Ahlert*, 424 F.2d 1088, 1091–92 (CCPA 1970). According to MPEP § 2144.03(C) (8th ed., Rev. 9, Aug. 2012), "[t]o adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art." To the contrary, it appears that

Appellant concedes the Examiner's Official Notice. *See* Reply Br. 6–7 ("regardless of whether it was generally known to compress and machine metallic foam"). Therefore, we are not persuaded of reversible error in the Examiner's obviousness conclusion as to claims 5 and 6.

Accordingly, we sustain the Examiner's obviousness rejection of claims 4–6.

CONCLUSION

Upon consideration of the record, and for the reasons given above and in the Examiner's Answer, the decision of the Examiner rejecting claims 1–6 under 35 U.S.C. § 103(a) as unpatentable over Andersen in view of Dickerson or Vargas is *affirmed*.

DECISION SUMMARY

In summary:

Claims Rejected	**35 U.S.C. §**	**References**	**Affirmed**	**Reversed**
1–6	103(a)	Andersen, Dickerson, Vargas	1–6	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

McGEE, *Administrative Patent Judge*, dissenting.

I respectfully dissent from my colleagues' affirmance of the Examiner's obviousness rejection.

The propriety of shifting the burden of proof to a patent applicant is governed by the circumstances of a given case. Relevant to this appeal, the Examiner finds that Andersen discloses a "metallic foam material" because Andersen teaches a "porous, sintered metal."[4] I agree with Appellant, however, that the Examiner fails to provide sufficient evidence or technical rationale supporting the finding that Andersen's "porous, sintered metal" is, in fact, a "metallic foam material" as recited in sole independent claim 1. Appeal Br. 4–5; Reply Br. 2–3.

Although the Examiner provides a dictionary definition of a "foam," the Examiner fails to adequately explain—or provide evidence to support—how that extrinsic definition applies to the specifics of this case. Ans. 5. For example, the Examiner states that a "foam" is defined as "a material in lightweight cellular form resulting from introduction of gas bubbles during manufacturing." *Id.* The Examiner, however, neither asserts, nor establishes with evidence, that gas bubbles are actually introduced during the manufacture of Andersen's sintered structures. Rather, the Examiner at best implies that gas bubbles would be present in Andersen's process due to evaporation of a sacrificial binder.[5] The Examiner furthermore fails to

[4] *See* Notice of Panel Decision from Pre-Appeal Brief Review dated April 18, 2017, p. 2.

[5] The Examiner fails to provide evidence to support the assertion that "[i]t is known in the art that the 'sacrificial binder' evaporates during the sintering process and escapes from the structure" which results in a porous structure.

address, much less explain, how Andersen's sintered structure meets the "material in a lightweight cellular form" portion of the proffered definition.

When "the claimed and prior art products are identical or substantially identical, *or are produced by identical or substantially identical processes*, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (emphasis added). In my view, the Examiner has not shown that is the case here. Without a further developed record on this point, I do not agree with my colleagues that Appellant has the burden of proving the differences between the claimed and prior art materials. Maj. Op. 5, 9.

As I see it, the only burden Appellant has with respect to this particular finding is to identify it as reversible error on the part of the Examiner, which—contrary to the majority's view—Appellant repeatedly satisfied. Appeal Br. 4–5 (asserting three times how the Examiner failed to put forth sufficient evidence or analysis to support this finding); Reply Br. 2–3 (asserting three times how sufficient evidence and analysis is lacking); *see In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011) ("it has long been the Board's practice to require an applicant to identify the alleged error in the examiner's rejections").

Ans. 5. Although Appellant does not directly contest the Examiner's assertion regarding evaporation, the Examiner does not establish that such evaporation of a sacrificial filler or binder necessarily generates "gas bubbles." Moreover, Appellant points out, again, that the Examiner's resulting conclusion—that porous sintered metals are inherently metallic foam—is unsupported by sufficient evidence or analysis. Reply Br. 2.

I do not view Appellant's repeated arguments regarding the Examiner's lack of evidence and analysis as "simply . . . expressing disagreement with an Examiner's finding of fact." Maj. Op. 8. Rather, Appellant's multiple assertions on this point are, to me, more than sufficient to identify the alleged error as harmful and, as such, ripe for our review. Appeal Br. 4–5; Reply Br. 2–3. Indeed, in the *Shinseki* case the majority cites, the Supreme Court explained that "showing an error was harmful" is not "a particularly onerous requirement." *Shinseki*, 129 S.Ct. at 1706. "Often the circumstances of the case will make clear . . . that the ruling, if erroneous, was harmful and nothing further need be said." *Id.* "[I]f not, then the party seeking reversal normally must explain why the erroneous ruling caused harm." *Id.*

Here, by pointing out the lack of evidence and analysis that it is incumbent on the Examiner to provide in the first instance, Appellant has satisfied its obligation to identify reversible error in the rejection, and need not provide the additional information the majority faults it for not producing. Maj. Op. 5, 9.

Therefore, under the circumstances of this particular case, I disagree with my colleagues that more is legally required of Appellant, and would reverse the rejection as lacking evidentiary support. *See In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967) (explaining that "[t]he Patent Office has the initial duty of supplying the factual basis for its rejection" and "[w]here the legal conclusion [of obviousness] is not supported by facts it cannot stand").

For these reasons, I dissent, with respect.