



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/619,190	09/14/2012	Arlen D. Hanssen	4394.374US9	3286
104326	7590	01/02/2020	EXAMINER	
Schwegman Lundberg & Woessner / Zimmer			PREBILIC, PAUL B	
P.O. Box 2938			ART UNIT	PAPER NUMBER
Minneapolis, MN 55402			3774	
			NOTIFICATION DATE	DELIVERY MODE
			01/02/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SLW@blackhillsip.com
USPTO@slwip.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ARLEN D. HANSEN and DAVID LEWALLEN

Appeal 2018-001559
Application 13/619,190
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 2–7, 23–31, and 34–55. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

¹ In this Decision, we refer to the Specification filed September 14, 2012 (“Spec.”); Final Office Action dated April 27, 2017 (“Final Act.”); Appeal Brief filed August 9, 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. A prosthetic system implantable in a cavity in an end of a bone, the prosthetic system comprising:
 - a prosthetic implant including a stem component;
 - a hollow sleeve for occupying an area in a cavity in an end of a bone, the hollow sleeve securable to an inner surface of the cavity, said hollow sleeve including an axial channel that extends through the length of the hollow sleeve for accommodating said stem component, wherein said hollow sleeve is formed separately from said stem component for subsequent connection to said stem component, said hollow sleeve capable of being positioned, by itself, in the cavity in the end of the bone and capable of being impacted and wedged, by itself, into the cavity in the end of the bone for obtaining a press fit of the hollow sleeve in the cavity prior to connecting the hollow sleeve to the stem component, wherein *said hollow sleeve consists essentially of a porous metal material that is a bone ingrowth-receptive material with a porous structure for encouraging bone ingrowth and attachment throughout the hollow sleeve for restoring lost bone stock in the cavity in the end of the bone in the area occupied by the hollow sleeve when the hollow sleeve is implanted in the cavity in the end of the bone;* and
 - an adhesive deliverable to said axial channel for interdigitation into said porous structure for securing said stem component in said channel.

Appeal Br. 72–73 (emphasis added).

REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Davidson	U.S. Patent 4,735,625	Apr. 5, 1988
Noiles	U.S. Patent 4,790,852	Dec. 13, 1988
Kelman	U.S. Patent 5,591,233	Jan. 7, 1997
Draenert	U.S. Patent 5,958,314	Sept. 28, 1999

REJECTIONS ON APPEAL

The Examiner maintains the following rejections on appeal:

1. Claims 2, 3, 5–11, 14–17, 23–27, 30, 31, and 34–55 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Final Act. 2–4.
2. Claims 7, 8, 10, 11, 14–17, 23, 24, 26, 27, 30, 31, 37–42, 44–52, 54, and 55 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Noiles. *Id.* at 4–5.
3. Claims 7, 8, 10, 11, 14–17, 23, 24, 26, 27, 30, 31, 37–42, 44–52, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Noiles and Draenert. *Id.* at 4–6.
4. Claims 2, 3, 6, 9, 25, 34–36, 43, and 53 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Noiles, Draenert, and Kelman. *Id.* at 6–7.
5. Claim 5 stands rejected under 35 U.S.C. § 103(a) as having been obvious over Noiles, Draenert, Kelman, and Davidson. *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, 3, 5–11, 14–17, 23–27, 30, 31, and 34–55 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Final Act. 2–4. In particular, the Examiner contends that the claim language “said hollow sleeve consists essentially of a porous metal material”³, as recited in claim 2, with similar language in the other independent claims, “lacks clear original support.” *Id.* at 3. According to the Examiner, “it is not clear from the original specification what is essential to the invention or what is the basic and novel characteristic is of the invention.” *Id.* (citing MPEP 2111.03). Regarding dependent claims 43, 44, and 47, the Examiner further contends that the claim language “the hollow sleeve is formed entirely with said porous metal material”⁴ “lacks clear original support.” *See id.* at 4.

Appellant contends there is direct support in the Specification for “(i) forming the sleeve from a *porous* metal material; and (ii) having the *entire structure* of the sleeve be porous (and thus capable of receiving bone ingrowth),” and there is, thus, “support for the sleeve being formed entirely with a porous metal material and for the sleeve’s ability to encourage bone ingrowth and attachment throughout itself for restoring lost bone stock in the

³ We note that the Final Office Action refers to “claim language requiring the hemispherical support structure ‘consisting essentially of’ a porous material,” which appears to be a clerical error, as that particular language is not present in the rejected claims. *See* Final Act. 3.

⁴ Again, the Final Office Action recites “support structure” instead of “hollow sleeve,” which appears to be a clerical error. *See* Final Act. 4.

ordinary skill in the art also would understand the Specification's language "into the porous structure of the sleeve" means the entire sleeve has a porous structure. Appeal Br. 17 (citing Spec. ¶ 60, emphasis added by Appellant).

The Specification further describes an embodiment in which "[a]ll surfaces against host bone . . . are available for bone ingrowth into porous materials used for the components." Spec. ¶ 14. 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.⁵ ¶ 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 hollow sleeve being formed entirely with a porous metal material, even if this is not *required* in all of the Specification's embodiments. See Reply Br. 6–8; see also Appeal Br. 30 (Appellant arguing that "[w]hile it is true that Appellant's disclosure includes embodiments where a support structure includes a porous outer coating but is not porous throughout, it is also true that Appellant's disclosure includes embodiments where the entire support structure has a porous structure. The fact that our specification discloses the former embodiment does not make any less valid our inventions involving

⁵ Declaration of David G. Lewallen under 37 C.F.R. § 1.132, executed March 16, 2017 ("Lewallen Decl.").

the latter embodiment—or the reality that implanting a hollow sleeve that encourages bone ingrowth and attachment throughout itself provides many advantages over prior art sleeve products that are overwhelmingly non-porous—not the least of which is the ability to actually grow new bone in areas where it once existed rather than just filling those areas with solid/non-porous metal.”).

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 hollow sleeve being formed entirely with porous metal material. We further agree with Appellant that, based on the disclosures above and those cited by Appellant, a person of ordinary skill in the art would have understood the “consisting essentially of” claim language to include a metal material hollow sleeve that is porous throughout the structure. *See Ariad*, 598 F.3d at 1351. We therefore reverse the rejection under 35 U.S.C. § 112, first paragraph, for lack of adequate written description.

Anticipation

Claims 7, 8, 10, 11, 14–17, 23, 24, 26, 27, 30, 31, 37–42, 44–52, 54, and 55 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Noiles. Final Act. 4–5. We select claim 7 as representative of the claims subject to this ground of rejection.

“To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating

subject matter.” *PPG Indus. Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996). The Examiner relies on Noiles’s teaching of sleeve 13 having a porous structure on the outside thereof as disclosing the claimed hollow sleeve that “consists essentially of a porous metal material.” *See* Final Act. 4–5; Noiles 7:33–43, Fig. 2. As discussed above, we agree with Appellant that a person of ordinary skill in the art would have understood “consisting essentially of a porous metal material,” read in light of the Specification, to require a metal material hollow sleeve that is porous throughout the structure. As acknowledged by the Examiner (Final Act. 5), Noiles does not disclose this claim element because it does not disclose porous material extending throughout the entire structure. Because Noiles does not disclose every element of claim 7, we reverse the rejection. As the other challenged claims similarly recite a hollow sleeve “consisting essentially of a porous metal material,” we likewise reverse the rejection of those claims.

Obviousness

Claims 7, 8, 10, 11, 14–17, 23, 24, 26, 27, 30, 31, 37–42, 44–52, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Noiles and Draenert. Final Act. 4–6. Claims 2, 3, 6, 9, 25, 34–36, 43, and 53 stand rejected under 35 U.S.C. § 103(a) as having been obvious over Noiles, Draenert, and Kelman. *Id.* at 6–7. Claim 5 stands rejected under 35 U.S.C. § 103(a) as having been obvious over Noiles, Draenert, Kelman, and Davidson. *Id.* at 7. We address these rejections together as the same issue is dispositive to all rejections.

The Examiner relies on sleeve 13 of Noiles, which has a porous coating on the outside thereof, as teaching the claimed hollow sleeve. *See*

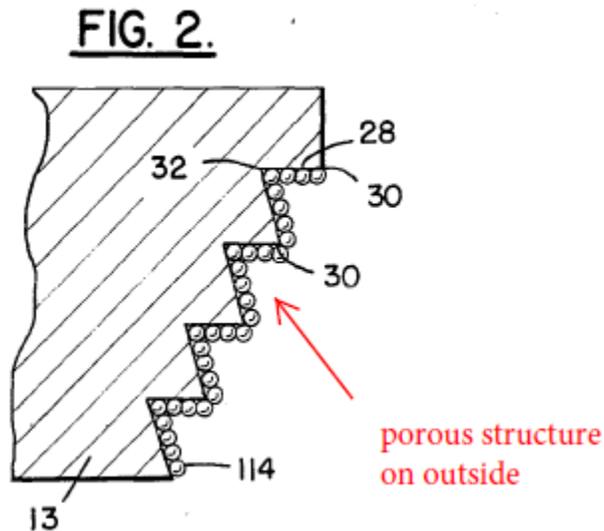
Final Act. 5; Noiles 7:33–43, Fig. 2. In the instance where the claims are interpreted to require porous material throughout the hollow sleeve (as here), the Examiner points further to Draenert. Final Act. 5. According to the Examiner, Draenert “teaches that it was known to make similar implants out of porous metal materials where the pores extend throughout the entire piece.” *Id.* (citing Draenert, Abstract, 6:3–20, Figures). The Examiner, thus, asserts that “it would have been considered at least clearly obvious to an ordinary artisan to utilize porous material, as taught by Draenert, to make the components of Noiles porous throughout 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 5–6 (citing MPEP 2143). Each of the rejections under 35 U.S.C. § 103(a) relies upon this reasoning for disclosure of a hollow sleeve “consisting essentially of a porous metal material.” *See id.* at 5–7.

Appellant argues Draenert does not disclose the use of a sleeve or use of an implant with a sleeve to connect components in a patient’s body. Appeal Br. 42. Appellant further contends that the “overwhelming majority of the sleeve in Noiles is completely non-porous and thus overwhelmingly not receptive to bone ingrowth” and “Noiles fails to shed any light on how having bone growth throughout sleeve (13) would affect the efficacy of that particular component and/or things connected to it in the body . . . over time.” *Id.* According to Appellant, a person of ordinary skill in the art would not have modified Noiles in view of Draenert, as proposed by the Examiner. *Id.* at 42–43.

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 Noiles 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 (Final Act. 5), Noiles discloses a porous coating on the surface of the sleeve as shown in Figure 2, reproduced below, with annotation of the porous coating identified by the Examiner:



Annotated Figure 2 “is a magnified view of a section through the outside surface of the sleeve of [Noiles’s] invention.” Noiles 3:37–38. Regarding this sleeve structure, Noiles discloses:

As also shown in FIG. 2, to further enhance bone ingrowth, the outer surface of the sleeve can be porous coated using small balls 114 composed of the same metal as that used to form sleeve 13, e.g., a surgically implantable alloy such as a titanium alloy containing 6% aluminum and 4% vanadium or chemically pure titanium (see ASTM Spec. Nos. F136-79 and F67-83). *By using a single layer of balls (see FIG. 2), the*

benefits of bone ingrowth can be achieved without sacrificing the benefits resulting from terracing and undercutting the outer surface of the sleeve.

Noiles 7:33–43 (emphasis added).

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* Final Act. 5.

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 such that the sleeve of Noiles is porous throughout, as reasoned by the Examiner. In particular, we find that Noiles's disclosure that by using "a single layer of balls, the benefits of bone ingrowth can be achieved without sacrificing the benefits resulting from terracing and undercutting the outer surface of the sleeve" teaches that full porosity is unnecessary and possibly detrimental to the sleeve structure. We find that this disclosure would not have motivated the artisan to make a wholly porous sleeve. And even if a wholly porous sleeve 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” (Final Act. 5–6) would be successful.

Appellant also submits extensive evidence of secondary considerations (*see* Appeal Br. 46–67; Reply Br. 2–4), which the Examiner contends lacks probative weight (Final Act. 12–14; Ans. 6–8). 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 sleeve of Noiles is porous throughout, we reverse all of the rejections 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, 3, 5–11, 14–17, 23–27, 30, 31, 34–55	112, first paragraph	Written description		2, 3, 5–11, 14–17, 23–27, 30, 31, 34–55
7, 8, 10, 11, 14–17, 23, 24, 26, 27, 30, 31, 37–42, 44–52, 54, 55	102(b)	Noiles		7, 8, 10, 11, 14–17, 23, 24, 26, 27, 30, 31, 37–42, 44–52, 54, 55

Appeal 2018-001559
 Application 13/619,190

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
7, 8, 10, 11, 14–17, 23, 24, 26, 27, 30, 31, 37–42, 44–52, 54, 55	103(a)	Noiles, Draenert		7, 8, 10, 11, 14–17, 23, 24, 26, 27, 30, 31, 37–42, 44–52, 54, 55
2, 3, 6, 9, 25, 34–36, 43, 53	103(a)	Noiles, Draenert, Kelman		2, 3, 6, 9, 25, 34–36, 43, 53
5	103(a)	Noiles, Draenert, Kelman, Davidson		5
Overall Outcome				2–7, 23–31, 34–55

REVERSED