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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PETER F. ULLRICH JR., KEVIN W. GEMAS,
CHAD J. PATTERSON, and JENNIFER M. SCHNEIDER

Appeal 2018-008637
Application 13/784,144
Technology Center 3700

Before STEFAN STAICOVICI, ANNETTE R. REIMERS, and
JEREMY M. PLENZLER, *Administrative Patent Judges*.

PLENZLER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 1, 3–8, and 25–37. An oral hearing was held on July 29, 2020. A transcript of that hearing is included in the record. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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 Titan Spine, Inc. Appeal Br. 3.

CLAIMED SUBJECT MATTER

The claims are directed to a spinal implant. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. An interbody spinal implant, comprising:

a titanium or titanium alloy body having a top surface, a bottom surface, sides, and at least one aperture extending from the top surface to the bottom surface; and

internal surfaces having a roughened, irregular surface topography lacking symmetry, facilitating osseointegration and cellular attachment and osteoblast maturation, and including (a) macro-scale structural features having a maximum peak-to-valley height of about 40 microns to about 500 microns, (b) micro-scale structural features having a maximum peak-to-valley height of about 2 microns to about 40 microns, and (c) nano-scale structural features having a maximum peak-to-valley height of about 0.05 microns to about 5 microns, the three types of structural features overlapping.

REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Garcia Saban	US 2010/0218854 A1	Sept. 2, 2010
Ullrich	US 2011/0282454 A1	Nov. 17, 2011
Mayfield	US 2013/0248487 A1	Sept. 26, 2013

REJECTION

Claims 1, 3–8, and 25–37 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Ullrich, Garcia Saban, and Mayfield.

OPINION

Claims 1 and 32 are the only independent claims pending. The Examiner finds that “Ullrich discloses internal surfaces with a roughened topography” as required by the claims, but not the specific features of the

internal surfaces that are required by the claims, which the Examiner finds are taught by Garcia Saban and Mayfield. *See, e.g.*, Ans. 4, 6 (“Mayfield teaches details of a roughened surface comprising three structural features that overlap to increase the osseointegration process” and “Garcia has been provided as a teaching of lacking symmetry, and Ulrich discloses the internal surfaces.”).

Appellant responds that the combination of the recited features on the internal surfaces of the implant of the subject invention “provide an unexpected functional advantage: both osseointegration and spontaneous bone growth on the interior of the implant,” which “is also recited in claim 1 as a functional limitation.” Appeal Br. 27 (emphasis omitted). During prosecution, Appellant provided two declarations under 37 C.F.R. § 1.132 to support its arguments regarding unexpected results.² Appellant explains that “[o]steointegration (or osseointegration) normally requires a connection to existing bone,” and “[i]n the absence of this existing bone, no bone growth or osteointegration would be expected to occur.” Appeal Br. 30. Appellant further explains, for example, that it “presented data (Ullrich Declaration) and supporting publications (Exhibits A and B to the Ullrich Declaration) . . . that confirm the lack of osteointegration in the absence of the roughened, irregular surface topography and in the absence of a bone graft material.” *Id.* Appellant explains that “[i]n contrast, osteoinduction, which the claimed implants promote on the internal surfaces of the implant, achieves fusion, in part, by inducing mesenchymal stem cells to differentiate into bone cells and

² The Ullrich Declaration (entered January 26, 2016) and the Schneider Declaration (entered October 7, 2016).

osteoblasts to synthesize new bone growth out from the implant surfaces.”
Id.; *see also* Ans. 6.

The Examiner does not dispute the veracity of Appellant’s contentions regarding unexpected results. Rather, the Examiner concludes that “spontaneous bone growth has not been claimed and is therefore moot.” Ans. 9 (emphasis omitted). That is, the Examiner completely disregards Appellant’s evidence of unexpected results. Initially, we note that the MPEP counsels against such treatment of Appellant’s evidence. *See* MPEP § 716.01(B) (“Evidence traversing rejections, when timely presented, must be considered by the examiner whenever present,” and “[g]eneral statements such as . . . ‘the evidence is not commensurate with the scope of the claims’ without an explanation supporting such findings are insufficient.”).

Obviousness “is a question of law based on underlying findings of fact.” *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). Those underlying findings of fact include: (1) “the scope and content of the prior art,” (2) “differences between the prior art and the claims at issue,” (3) “the level of ordinary skill in the pertinent art,” and (4) the presence of evidence of secondary considerations, such “as commercial success, long felt but unsolved needs, failure of others,” and unexpected results. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966). Evidence of secondary considerations, when present, must always be considered in determining obviousness. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983).

Contrary to the Examiner’s conclusion, Appellant’s evidence is related to the claimed features. As Appellant explains, the recited internal surface feature recited in the claims produce the unexpected results. *See*

Appeal Br. 27–37 (discussing the Ullrich Declaration and the Schneider Declaration). The Examiner’s conclusion to the contrary is unsupported by any reasoned explanation and fails to consider Appellant’s evidence. The Examiner errs by failing to consider Appellant’s evidence of unexpected results.

Appellant further contends that the Examiner relies on impermissible hindsight in the rationale for combining the exterior surface features from Garcia Saban with the internal surface of Ullrich. Appeal Br. 37–40 (explaining that in view of the evidence of unexpected results, one skilled in the art would not have combined the teachings as proposed without impermissible hindsight). The Examiner responds that “the combination has been formed with TSM motivation from the cited prior art, i.e. not hindsight.” Ans. 13. The Examiner acknowledges that Garcia Saban and Mayfield relate to external implant surfaces, not internal surfaces. *See id.* at 4, 6. As noted above, the Examiner does not dispute Appellant’s evidence regarding unexpected results. Based on the record before us, Appellant has the better position (i.e., that one skilled in the art would not have found it obvious to include the external surfaces features from Garcia Saban and Mayfield on the internal surface of Ullrich’s implant where one skilled in the art would not have expected osteointegration to occur due to the lack of contact with bone). *See* Appeal Brief. 33 (“Without the benefit of the applicant’s data, the skilled artisan would not have understood that the roughened, irregular surface would be osteoinductive in the absence of a bone graft material or in the absence of a connection with adjacent bone.”).

CONCLUSION

The Examiner’s rejection is reversed.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 3-8, 25-37	103(a)	Ullrich, Garcia Saban, Mayfield		1, 3-8, 25-37

REVERSED