

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVITA MEDICAL LIMITED,
Petitioner,

v.

RENOVACARE SCIENCES CORP.,
Patent Owner.

Case IPR2017-01243
Patent 9,610,430 B2

Before BART A. GERSTENBLITH, JAMES A. WORTH, and
ROBERT L. KINDER, *Administrative Patent Judges*.

GERSTENBLITH, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review
35 U.S.C. § 325(d); 37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Avita Medical Limited (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting institution of *inter partes* review of claims 1–11 of U.S. Patent No. 9,610,430 B2 (Ex. 1001, “the ’430 patent”). RenovaCare Science Corp. (“Patent Owner”) filed a Preliminary Response (Paper 10, “Prelim. Resp.”). Based on the particular circumstances of this proceeding, we exercise our discretion under 35 U.S.C. § 325(d) and do not institute an *inter partes* review of the challenged claims.

B. Related Proceedings

The parties indicate that the ’430 patent is not the subject of any other proceeding. Pet. 2; Paper 4, 2–3.

C. Real Parties in Interest

The Petition identifies “Avita Medical Limited” and “Avita Medical Americas LLC” as the real parties in interest. Pet. 1. Patent Owner identifies itself as the sole real party in interest. Paper 4, 2.

D. The References

Petitioner relies on the following references:

U.S. Patent Application Publication No. US 2002/0106353 A1, published Aug. 8, 2002 (Ex. 1002, “Wood”);

F. A. Navarro, MD et al., *Sprayed Keratinocyte Suspensions Accelerate Epidermal Coverage in a Porcine Microwound Model*, JOURNAL OF BURN CARE & REHABILITATION, Nov./Dec. 2000, 21(6): 513–18 (Ex. 1003, “Navarro”);

U.S. Patent Application Publication No. US 2004/0219133 A1, published Nov. 4, 2004 (Ex. 1004, “Lyles”);

U.S. Patent No. 7,833,522 B2, issued Nov. 16, 2010 (Ex. 1005, “Dixon”); and

U.S. Patent No. 6,479,052 B1, issued Nov. 12, 2002 (Ex. 1006, “Marshall”).

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–11 of the ’430 patent on the following grounds:

Reference(s)	Basis	Claims challenged
Wood	§ 103(a)	1–11
Wood and Lyles	§ 103(a)	1–11
Wood and Navarro	§ 103(a)	1–11
Wood and Dixon	§ 103(a)	1–11
Wood and Marshall	§ 103(a)	1–11

Petitioner supports its challenge with a Declaration by Jeffrey W. Shupp, MD, dated April 4, 2017 (Ex. 1007).

Patent Owner supports its arguments set forth in the Preliminary Response with a Declaration by Gary D. Shipley, Ph.D., dated September 18, 2017 (Ex. 2001).

F. The ’430 Patent

The ’430 patent generally relates to “the grafting of cells” and, particularly, “to a method of inducing epidermal growth and a device for spraying a cell suspension from a tissue sample obtained from a donor site and distributing that cell suspension to a recipient site, and its method of use thereof.” Ex. 1001, 1:16–21. The ’430 patent explains the following:

Using individually-sprayed cells through an embodiment of the device disclosed here, rather than confluent grown

keratinocyte sheets as in the prior art, results in the need for fewer cells and application to a larger treatment surface. Blister formation is avoided by the use of single cells without forming a closed sheet. Reducing the cell number speeds up application time by avoiding an in vitro cell expansion. Avoiding in vitro cell expansion, in turn, reduces in vitro differentiation and therefore better preserves basal keratinocyte progenitor cells in the cell suspension.

Id. at 4:41–50. Other advantages of the invention include: reducing the size of the skin cell donor sites, improving the rate of healing of small burns, and improving scar quality. *Id.* at 4:51–60.

G. Illustrative Claim

Claim 1, the sole independent claim of the '430 patent, is illustrative of the claimed subject matter and is reproduced below:

1. A method to treat a wounded area of skin on a human subject, comprising:

providing a single cell-suspension of cells comprising progenitor skin cells in a serum-free physiological solution in a sterilizable container, wherein the cells are obtained from the subject's normal skin tissue that has been treated with enzymes so as to release the cells from the dermal-epithelial cell junction, wherein the skin cells have not been subjected to ex vivo or in vitro expansion;

contacting the single-cell suspension of cells with a gas flow at an outlet of the container to create droplets of the suspension at a flow-controlled spray head; and

spraying the droplets onto the wounded area of skin without forming a closed cell sheet so that the single cells are distributed directly and evenly and the cells regenerate normal skin by in situ multiplication to heal the wounded area in the absence of applying a pre-formed skin graft.

Id. at 9:28–10:9.

II. CLAIM CONSTRUCTION

Although Petitioner and Patent Owner present proposed constructions for several claim terms, no terms require express construction for purposes of this Decision. Pet. 6–15; Prelim. Resp. 12–26.

III. ANALYSIS

In determining whether to institute *inter partes* review, we may “deny some or all grounds for unpatentability for some or all of the challenged claims.” 37 C.F.R. § 42.108(b); see 35 U.S.C. § 314(a). Our discretionary determination of whether to institute review is guided, in part, by 35 U.S.C. § 325(d), which states, in relevant part:

MULTIPLE PROCEEDINGS-- . . . In determining whether to institute or order a proceeding under this chapter . . . the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

35 U.S.C. § 325(d).

Our discretion pursuant to § 325(d) involves a balance between several competing interests. “On the one hand, there are the interests in conserving the resources of the Office and granting patent owners repose on issues and prior art that have been considered previously.” *Fox Factory, Inc. v. SRAM, LLC*, Case IPR2016-01876, slip op. at 7 (PTAB Apr. 3, 2017) (Paper 8). “On the other hand, are the interests of giving petitioner the opportunity to be heard and correcting any errors by the Office in allowing a patent—in the case of an *inter partes* review—over prior art patents and printed publications.” *Id.*

Under the circumstances of this case, we exercise our discretion pursuant to § 325(d) and decline to institute an *inter partes* review based on

each ground asserted in the Petition because the Petition presents “the same or substantially the same prior art” as was presented previously to the Office during prosecution of the ’430 patent. 35 U.S.C. § 325(d).

To begin, during prosecution, the Examiner rejected the then-pending claims based on anticipation by Lyles, obviousness over Lyles, and obviousness over Lyles in combination with Wood. *See, e.g.*, Ex. 1009, 145–53 (Non-Final Office Action, dated Aug. 25, 2015), 101–11 (Final Office Action, dated June 1, 2016). Patent Owner overcame the Examiner’s rejections by amending then-numbered claim 15, which issued as claim 1. *Id.* at 84; *see id.* at 62 (Notice of Allowability, Reasons for Allowance).

In each of the grounds raised in the Petition, Petitioner asserts that claims 1–11 would have been obvious over either Wood as the sole reference or Wood in combination with another reference. In particular, Petitioner’s first ground is based on Wood alone. Petitioner’s second ground is based upon Wood in combination with Lyles, and relies upon Lyles for its teaching of an “air-jet sprayer” to deliver the cell suspension of Wood to the wound site. Pet. 40. Petitioner contends that the combination of Wood and Lyles meets the following step of claim 1: “contacting the single-cell suspension of cells with a gas flow at an outlet of the container to create droplets of the suspension at a flow-controlled spray head.” *Id.* Petitioner’s additional grounds rely upon Wood in combination with one of Navarro, Dixon, and Marshall. For each of these grounds, Petitioner relies upon the secondary reference as meeting the same limitation of claim 1 for which Petitioner relies upon Lyles in the second ground. *See* Pet. 47 (relying upon Navarro for its teaching of “spray devices”), 54 (relying upon Dixon for its

teaching of a “cell spray apparatus”), 61 (relying upon Marshall for its teaching of “Spraying Devices”).

As reflected above, Wood and Lyles were before the Office and considered expressly by the Examiner in rejecting the pending claims. Additionally, for the purposes employed by Petitioner, the disclosures in Navarro, Dixon, and Marshall regarding spray devices are substantially the same as the disclosure in Lyles regarding its air-jet sprayer. *See* Pet. 40, 47, 54, 61 (discussing the spray devices of each of Lyles, Navarro, Dixon, and Marshall). Accordingly, we determine that Wood and Lyles previously were presented to and substantively considered by the Office and that Navarro, Dixon, and Marshall are substantially the same as Lyles.¹

Accordingly, under the facts and circumstances presented here, we exercise our discretion pursuant to 35 U.S.C. § 325(d) and decline to institute an *inter partes* review.

IV. CONCLUSION

For the foregoing reasons, we exercise our discretion and decline to institute *inter partes* review of claims 1–11 of the ’430 patent on the grounds presented in the Petition. *See* 35 U.S.C. §§ 314(a), 325(d); 37 C.F.R. § 42.108.

¹ Petitioner does not provide an analysis of § 325(d) or explain why we should not exercise our discretion pursuant to § 325(d) to decline to institute *inter partes*.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied*, and no *inter partes* review is instituted.

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