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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MUSCULOSKELETAL TRANSPLANT FOUNDATION,
Petitioner,

v.

MIMEDX GROUP, INC.,
Patent Owner.

Case IPR2015-00664
Patent 8,372,437 B2

Before LORA M. GREEN, CHRISTOPHER G. PAULRAJ, and JACQUELINE T. HARLOW, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Musculoskeletal Transplant Foundation ("Petitioner") filed a Corrected Petition requesting an *inter partes* review of claims 1 and 2 of U.S. Patent No. 8,372,437 B2 (Ex. 1001, "the '437 patent"). Paper 11 ("Pet."). MiMedx Group, Inc. ("Patent Owner") filed a Corrected Preliminary Response to the Petition. Paper 10 ("Prelim. Resp."). We determined that the information presented in the Petition and the Preliminary Response demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 1 and 2 as unpatentable under 35 U.S.C. § 103(a). Pursuant to 35 U.S.C. § 314, the Board instituted trial on August 18, 2015, as to the challenged claims of the '437 patent. Paper 13 ("Institution Decision" or "Dec. Inst.").

Patent Owner filed a Response (Paper 27, "PO Resp."), but did not file a motion to amend. Petitioner subsequently filed a Reply. Paper 31 ("Reply"). An oral hearing was held on April 26, 2016, and a transcript of the hearing has been entered into the record (Paper 47). Patent Owner filed a Motion to Exclude (Paper 38), to which Patent Owner filed an Opposition (Paper 40), and Patent Owner filed a Reply (Paper 42).

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1 and 2 of the '437 patent are unpatentable.

A. Related Proceedings

Petitioner states that the '437 patent is the subject of a copending district court case, *MiMedx Group, Inc. v. Liventa Bioscience Inc. et. al.*, Case No. 1:14-CV-01178-MHC (N.D. Ga.). Pet. 1; Paper 7, 1.

Petitioner also filed a petition for *inter partes* review of U.S. Patent No. 8,323,701 B2 against Patent Owner in IPR2015-00669, in which we denied institution. IPR2015-00669, Paper 13, 30.

B. The '437 Patent (Ex. 1001)

The '437 patent issued on February 12, 2013, with John Daniel listed as the sole inventor. Ex. 1001. The '437 patent relates to tissue allografts, and more particularly "to placental membrane tissue grafts (amnion and chorion) and methods of preparing, preserving, and medical uses for the same." *Id.* at 1:15–17.

As taught by the '437 patent:

> The placenta has two primary layers of tissue including amniotic membrane and chorion. The amniotic membrane is a non-vascular tissue that is the innermost layer of the placenta, and consists of a single layer, which is attached to a basement membrane. Histological evaluation indicates that the membrane layers of the amniotic membrane consist of epithelium cells, thin reticular fibers (basement membrane), a thick compact layer, and fibroblast layer. The fibrous layer of amnion (i.e., the basement membrane) contains cell anchoring collagen types IV, V, and VII. The chorion is also considered as part of the fetal membrane; however, the amniotic layer and chorion layer are separate and separable entities.

Id. at 1:32–45. Placental membrane has been used for various types of reconstructive surgery since the early 1900s, and has also been widely used in ophthalmic procedures. *Id.* at 1:22–28. The '437 patent teaches that

"[t]ypically, such membrane is either frozen or dried for preservation and storage until need for surgery." *Id.* at 1:28–30.

According to the '437 patent, in order to prepare the implant, placental tissue is collected from a hospital. *Id.* at 4:65–66. The placenta is removed from the sterile shipment bag and transferred to a sterile processing basin preferably containing hyperisotonic saline (18% NaCl) solution at close to room temperature. *Id.* at 5:65–6:2. The placenta is gently massaged to help separate blood clots, allowed to reach room temperature to ease the separation of the amnion from the chorion, and then placed on a processing tray with the amniotic membrane layer facing down. *Id.* at 6:2–10.

With the placental tissue in the processing tray, the chorion layer is lifted gently off the amniotic membrane layer, and blood clots are removed from the layers using a blunt instrument, a finger, or a sterile, non-particulating gauze. *Id.* at 6:27–62. In particular, the '437 patent teaches:

> Care is then taken to remove blood clots and other extraneous tissue from each layer of tissue until the amniotic membrane tissue and the chorion are clean and ready for further processing. More specifically, the amnion and chorion tissues are placed on the processing tray and *blood clots* are carefully removed using a blunt instrument, a finger, or a sterile non-particulating gauze, *by gently rubbing the blood until it is free from the stromal tissue of the amnion and from the trophoblast tissue of the chorion*. The stromal layer of the amnion is the side of the amniotic membrane that faces the mother. In contrast, the basement membrane layer is the side of the amnion that faces the baby.
>
> Using a blunt instrument, a cell scraper or sterile gauze, *any residual debris or contamination is also removed*. This step must be done with adequate care, again, so as not to tear the amnion or chorion tissues. The cleaning of the amnion is complete once the amnion tissue is smooth and opaque-white in appearance. If the amnion tissue is cleaned too much, the opaque

> layer can be removed. Any areas of the amnion cleaned too aggressively and appear clear will be unacceptable and will ultimately be discarded.

Id. at 6:42–62 (emphasis added).

The tissue is chemically decontaminated, and then dehydrated on a drying fixture. *Id.* at 6:63–8:64. The drying fixture may have grooves, which may be arranged in a grid, and may also have a design in the empty spaces of the grid, such as a logo or name. *Id.* at 7:61–8:11. The drying fixture is placed in a dehydration bag, sealed, and placed into a drying oven at 35 to 50 degrees Celsius for 30 to 120 minutes. *Id.* at 8:38–8:61. The ideal drying conditions, however, appear to be at 45 degrees Celsius for 45 minutes. *Id.* at 8:51–55. Once the tissue is dehydrated, it can be cut into specific product sizes, and each cut allograft is placed into its own pouch. *Id.* at 8:65–9:8; 9:22–29.

The ’437 patent states:

> Accordingly, while the present invention has been described herein in detail in relation to preferred embodiments, it is to be understood that this disclosure is only illustrative and exemplary of the present invention and is made merely for purposes of providing a full and enabling disclosure of the invention. The foregoing disclosure is not intended nor is to be construed to limit the present invention or otherwise to exclude any such other embodiments, adaptations, variations, modifications and equivalent arrangements, the present invention being limited only by the claims appended hereto and the equivalents thereof.

Id. at 10:59–11:3.

C. Illustrative Claim

Petitioner challenges claims 1 and 2 of the ’437 patent. Claim 1 is the only independent claim and is reproduced below:

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