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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JEROME CONNOR

Appeal 2019-006165
Application 13/483,674
Technology Center 1600

Before ERIC B. GRIMES, MICHAEL A. VALEK, and
JAMIE T. WISZ, *Administrative Patent Judges*.

WISZ, *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, 6, 9–16, and 56–59. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

CLAIMED SUBJECT MATTER

The Specification describes methods for producing tissue products such as adipose tissue. Spec. ¶4. The “methods include selecting an adipose tissue; mechanically processing the adipose tissue to reduce the tissue size; and treating the mechanically processed tissue to remove substantially all cellular material from the tissue.” *Id.* According to the Specification, “[t]he processed tissue is suspended in a solution and cross-linked to produce a stable three-dimensional structure.” *Id.*

Claim 1, the only independent claim, is illustrative of the claimed subject matter and is reproduced below:

1. A method for producing a porcine tissue product, comprising:
 - selecting porcine-derived adipose tissue;
 - mechanically processing the adipose tissue to reduce the tissue size and washing the tissue to remove lipids;
 - treating the tissue to remove substantially all cellular material from the tissue;
 - suspending the tissue in a liquid to form a suspension;

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as LifeCell Corporation, a subsidiary of Allergan plc. Appeal Br. 1.

freezing and drying the tissue in the suspension to form a porous sponge; and

stabilizing the sponge after freezing and drying the tissue by heating the tissue to produce a stable three-dimensional structure, wherein washing the tissue to remove lipids and treating the tissue to remove cellular material are performed by a process consisting of mechanically processing the tissue, diluting the mechanically processed tissue with water, mechanically removing freed lipids from the tissue, and treating the tissue with a detergent.

Appeal Br. 23 (Claims App.).

REJECTIONS

The Examiner rejected claims 1, 6, 10–13, and 57–59 under 35 U.S.C. § 103(a) as obvious over Nahas.²

The Examiner rejected claims 1, 6, 9–13, and 56–59 under 35 U.S.C. § 103(a) as obvious over Nahas and further in view of Hassingboe.³

The Examiner rejected claims 1, 6, 10–14, and 57–59 under 35 U.S.C. § 103(a) as obvious over Nahas and further in view of Ksander.⁴

The Examiner rejected claims 1, 6, 10–13, 15, 16, and 57–59 under 35 U.S.C. § 103(a) as obvious over Nahas and further in view of Brown.⁵

² Nahas et al., WO 2011/019822 A2, published Feb. 17, 2011 (“Nahas”).

³ Hassingboe et al., US 2009/0220579 A1, published Sept. 3, 2009 (“Hassingboe”).

⁴ Ksander et al., US 4,950,483, issued Aug. 21, 1990 (“Ksander”).

⁵ Brown et al., US 2006/0153816 A1, published July 13, 2006 (“Brown”).

ISSUES AND ANALYSIS

Rejection of Claims 1, 6, 10–13, and 57–59 under 35 U.S.C. § 103(a) as obvious over Nahas

According to the Examiner, Nahas discloses compositions and methods for implantation of processed adipose tissue products, including porcine adipose tissue. Final Act. 2, 4 (citing Nahas, title, 4). The Examiner also finds that, in Example 2 of Nahas:

acellular biomaterial / processed human adipose tissue (PhAT) is prepared by isolating subcutaneous fat (i.e., selecting an adipose tissue) from a tissue sample by scraping, homogenizing the scraped adipose tissue in a blender or with a press or mincing by forcing through a die while rinsing with water to remove lipid (i.e., mechanically processing the adipose tissue to reduce the tissue size and mechanically removing freed lipids from the tissue), washing with water to remove lipid and cellular debris (i.e., treating the mechanically processed tissue to remove substantially all cellular material from the tissue), treating with TRITON X-100 (i.e., detergent), and solubilizing (i.e., forming a solution, wherein a “solution” encompasses a “suspension” per [Nahas] page 19 line 13) using weak acid and water with shaking to promote chemical decellularization (Example 2) (i.e., suspending the tissue in a solution to form a suspension).

Id. at 2–3. According to the Examiner, the material is then optionally lyophilized (i.e., freeze dried), which would form a sponge, prior to storage.

Id. at 3 (citing Nahas, 43:18–44:20). The Examiner also finds that “[t]he processed adipose material is then made into particles for injection with or without a biopolymer scaffold and cross-linking agents (Example 2), wherein a biopolymer scaffold provides a three dimensional framework.”

Id. (citing Nahas, 25:1–5). Furthermore, the Examiner finds that “[a]n external mold can be applied to shape an injected solution, the injected implant can be molded like one would mold clay, or the mixture can be

injected into a mold (i.e., producing a desired shape), then the biomaterial allowed to harden (i.e., cross-linked), then the material implanted.” *Id.* (citing Nahas, 36:11–15).

The Examiner acknowledges that Nahas does not disclose an example combining all the elements above but concludes it would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to combine all such elements with a reasonable expectation of success given that Nahas suggests these elements and arrangements thereof. Final Act. 4. The Examiner also finds that, although Example 2 of Nahas “discloses use of acid such as solubilizing using weak acid and water with shaking to promote chemical decellularization,” it would have been obvious to a person of ordinary skill in the art to substitute a non-ionic detergent for such acid with a reasonable expectation of success because Nahas “discloses that the agent to promote decellularization may comprise an agent selected from an acid or a non-ionic detergent such as TRITON X-100” and Example 2 also includes treatment with TRITON X-100. *Id.* at 4–5 (citing Nahas, claims 29, 32, 33).

Appellant argues that the Examiner fails to consider the prior art and the invention as a whole and that “(i) the prior art does not disclose, teach or suggest removal of lipids and cellular material from an adipose tissue material without the use of acid” and “(ii) the prior art teaches away from producing a porous sponge having a stable three-dimensional structure.” Appeal Br. 6.

First, Appellant asserts that “Nahas does not enable washing tissue to remove lipids and treating the tissue to remove cellular materials, wherein the washing and treating consists only of the steps recited in claim 1.”

Appeal Br. 8. According to Appellant, claim 1 is closed to the inclusion of elements not recited in the washing and treating steps because the claim recites that these steps “are performed by a process *consisting of*,” wherein the list that follows does not include any step of treating the tissue with an acid. *Id.* at 8–9 (emphasis added). Appellant cites to *Vehicular Techs. Corp. v. Titan Wheel Int’l, Inc.*, 212 F.3d 1377, 1383 (Fed. Cir. 2000) and *Promega Corp. v. Life Techs. Corp.*, 2011 WL 13209364, at *7 (W.D. Wis. Nov. 29, 2011) in support of its argument that claim 1 cannot include any additional washing or treating steps. *Id.*

Appellant also asserts that Nahas does not enable a processing step using a detergent, without an acid, to remove lipid and cellular material from its tissue product. Appeal Br. 9. According to Appellant, “Nahas does not provide a single detailed instruction regarding the use of a detergent, or any other composition, to remove lipid and cellular material from the adipose tissue product in the absence of acid” in contrast to the enabling disclosure provided with respect to removing cellular material and lipids using acids or the use of non-ionic detergents in conjunction with acids. *Id.* at 10–11.

We are not persuaded by Appellant’s arguments. First, we agree with the Examiner that claim 1 is open to steps not explicitly recited therein because the preamble includes the transitional phrase “comprising” which is open-ended and does not exclude additional, unrecited steps. “The transition ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.” *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003). The “consisting of” limitation appears in the wherein clause of claim 1 and only modifies the steps of “washing the tissue to remove lipids” and “treating the tissue to remove cellular material.”

Thus, while those steps exclude additional elements, the overall method recited in claim 1 does not exclude additional unrecited steps such as “an additional step of treating the tissue with acid for solubilization . . . or for some other purpose,” as referenced by the Examiner. Ans. 3.

This claim construction is not inconsistent with the *Vehicular* and *Promega* cases cited by Appellant. In *Vehicular*, the court explained that the phrase “‘consisting of’ is a term of art in patent law signifying restriction and exclusion” and “‘comprising’ indicates an open-ended construction.” *Vehicular Techs.*, 212 F.3d at 1382. Based on this understanding, the court held that a claimed spring assembly only included two springs due to the use of the phrase “consisting of” to describe the assembly components in a product claim. *Id.* *Vehicular* did not deal with the question of whether additional, unrecited steps could be included in a method claim reciting the word “comprising” in the preamble.

In contrast, in *Promega*, the court found that when the phrase “consisting of” was used in one step of a method claim, it *did not* exclude the presence of other loci that were not explicitly recited in that step because the preamble of the claim included the word “comprising.” *See Promega*, 2011 WL 13209364, at *6–7.⁶ Thus, neither *Promega* nor *Vehicular* is inconsistent with the claim interpretation here wherein the “comprising” language used in the preamble opens the claim up to other unrecited steps. Indeed, our interpretation is consistent with the court’s construction of the

⁶ In contrast, the court in *Promega* found that the claims to a kit “consisting of” certain components did exclude additional loci. *Id.* at *7. Appellant’s claim 1, however, is distinguished by the fact that it is a method claim and, therefore, the use of “comprising” in the preamble allows for additional unrecited steps.

method claim in *Promega*. Furthermore, “during examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.” *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000).

We further agree with the Examiner that, even if claim 1 were interpreted to exclude the use of acid in any step, Nahas discloses removing lipids and cellular material without the use of acid. *See* Ans. 3–4. For example, claim 29 of Nahas recites a method for preparing a processed adipose tissue by decellularizing or extracting lipid from adipose, in which the agent to promote decellularization comprises an agent selected from “a weak acid, a weak organic acid, a *non-ionic detergent*, and a bile acid.” Nahas 56 (emphasis added). Furthermore, claims 32 and 33 of Nahas specifically recite use of a non-ionic detergent for decellularizing the adipose or extracting lipid from the adipose. *Id.* at 57.

With regard to Appellant’s argument that Nahas fails to enable the removal of lipids and cellular material without using an acid, we are unpersuaded for multiple reasons. First, we agree with the Examiner that Nahas discloses different detergent concentrations for serial washes and discloses removal of lipids by treatment with 1% TRITON X-100 overnight at 37° C. Ans. 4 (citing Nahas, 25:26–29, 44:4–5). Although these serial washes are disclosed as following acid washes, the rejection here is for obviousness, not anticipation. Therefore, the fact that the process in Nahas differs from Appellant’s in this respect, does not distinguish claim 1 because, even accepting Appellant’s non-enablement argument, Nahas is still prior art for all that it teaches. *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991) (“a non-enabling reference may qualify as prior art for the purpose of determining obviousness under § 103”); *see also Beckman*

Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (“[e]ven if a reference discloses an inoperative device, it is prior art for all that it teaches”). Here, we agree with the Examiner that Nahas’ disclosure of concentrations, temperature, time, and repetitions of detergent treatments would have provided ample direction for a person of ordinary skill in the art to practice the invention without the use of an acid, especially because Nahas discloses that the agent to promote decellularization can be an acid *or* a detergent. *See* Ans. 4–5.

Second, we agree with the Examiner that the substitution of known equivalents for the same purpose supports obviousness and Appellant has not presented persuasive evidence or arguments as to why the disclosure provided in Nahas would not enable one of skill to make or use the claimed invention nor has Appellant presented any evidence of unexpected results when detergent is used alone. Although Nahas does not include a specific example of using only detergent for decellularization, a “specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation.” *In re Borkowski*, 422 F.2d 904, 908 (CCPA 1970). We find that Nahas includes sufficient disclosure in this regard.

Appellant further contends that Nahas teaches away from a porous sponge having a stable three-dimensional structure. Appeal Br. 13–14. Specifically, Appellant asserts that Nahas is directed toward an injectable composition and “limits steps to effect molding or supplemental crosslinking of the graft, if any, to those performed post-implantation of its product into a tissue.” *Id.* at 13. According to Appellant, Nahas “teaches steps to create a

product with viscoelastic rheological properties but not steps to form the stable three-dimensional structure” and “does not teach forming a porous product, a sponge, or a product capable of acting as a manifold for transmission of fluid.” *Id.* Appellant concedes that “Nahas does disclose a pre-formed product in one sentence” but asserts that Nahas does not enable this disclosure. *Id.* at 14 (citing Nahas, 36:14–15).

We are not persuaded by Appellant’s argument. Nahas explicitly teaches that the composition can be injected into a mold, the biomaterial allowed to harden, and then the material can be implanted. Nahas, 36:14–15. We agree with the Examiner that such “hardened implant would have a stable three-dimensional structure.” Ans. 5. Appellant asserts that Nahas does not enable this disclosure but provides no specific arguments or evidence as to why this is the case. “[A] prior art printed publication cited by an examiner is presumptively enabling barring any showing to the contrary by a patent applicant or patentee.” *In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012). Thus, the Examiner had a reasonable basis to find that Nahas provides an enabling disclosure of an implant that has a three-dimensional structure. Appellant does not provide adequate evidence or arguments that the Examiner’s reasoning is improper or defective, and we find the Examiner is supported by the evidence of record.

With regard to porosity, we also agree with the Examiner that Nahas specifically discloses that its matrix, when viewed by Scanning Electron Microscopy (“SEM”) was found to be “porous in nature, facilitating cell migration and nutrient diffusion.” Nahas, 48:11–12. Appellant argues that it is unknown what Nahas means by the term “porous” and Nahas does not enable “porous” nor does Nahas teach forming a sponge. Appeal Br. 19–20.

However, as quoted above, Nahas discloses that the porosity “facilitat[es] cell migration and nutrient diffusion” which undermines Appellant’s argument that Nahas does not disclose “a product capable of acting as a manifold for transmission of fluid.” Nahas, 48:11–12; Appeal Br. 13. Furthermore, Appellant’s Specification does not explicitly define porous but equates “porous” and “sponge-like” or “sponge” as synonymous terms. *See, e.g.*, Spec. ¶¶ 23 (“the extracellular matrix proteins can be further treated to produce a three-dimensional porous, or sponge-like material.”); 25 (“resuspending the tissue in a solution to form a porous matrix or sponge.”). Therefore, we do not agree with Appellant that Nahas teaches away from a porous sponge having a three-dimensional structure and, in fact, find that Nahas discloses such a structure as one embodiment. “The prior art’s mere disclosure of more than one alternative does not constitute a teaching away from . . . alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.” *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

Appellant also asserts that the Examiner bases a *prima facie* determination of obviousness on unsupported assumptions of the state of the art, motivation to combine elements, and reasonable expectation of success. Appeal Br. 14–20. Appellant contends that the Examiner’s *Graham* analysis is insufficient because the scope and content of the prior art are not determined and considered in their entirety. *Id.* at 14–17 (citing *Graham v. John Deere*, 383 U.S. 1 (1966)). Specifically, Appellant asserts that “Nahas does not enable removal of lipid and cellular material in the absence of acid” and “explicitly teaches steps to form an injectable porcine tissue product, not a stable three dimensional structure.” *Id.* at 16–17. Appellant further

contends that “Nahas does not disclose an enabling procedure for stabilizing a sponge after freezing and drying by heating to produce a stable three-dimensional structure.” *Id.* at 17. Furthermore, according to Appellant, one of ordinary skill would not find motivation or other rationale to combine elements of Nahas to exclude use of an acid when washing tissue to remove lipids and treating the tissue to remove cellular material. *Id.* at 18–20.

Appellant’s arguments are similar to those discussed above and fail for the same reasons as previously discussed. Furthermore, we are not persuaded that one of ordinary skill in the art would not be motivated to combine elements of Nahas to exclude the use of acid to remove cellular tissue. As discussed *supra*, Nahas explicitly discloses using acid *or* detergent for this step. Therefore, Nahas itself provides motivation to use detergent in the washing steps disclosed therein.

For the reasons described herein and those already of record, we sustain the Examiner’s rejection of independent claim 1 under 35 U.S.C. § 103(a) as being obvious over Nahas. Claims 6, 10–13, and 57–59 are not argued separately, and, therefore, fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Rejection of claims 1, 6, 9–13, and 56–59 under 35 U.S.C. § 103(a) as obvious over Nahas and further in view of Hassingboe

The Examiner acknowledges that Nahas teaches heated cross-linking but does not specifically teach heating in a vacuum or heating to 70° C to 120° C, as recited in claim 9, but finds that Hassingboe cures this deficiency. Final Act. 5. Specifically, the Examiner finds that Hassingboe, which teaches production of scaffolds for tissue repair and implants using extracellular matrix materials obtained from mammals, teaches that such

materials can be cross-linked by heat treating the material in a vacuum oven at 120° C. *Id.* (citing Hassingboe ¶ 66). According to the Examiner, Hassingboe discloses that heat treatment is preferred over chemical use and heat treatment under a vacuum is more effective towards cross-linking than heat treatment at ambient pressure. *Id.* (citing Hassingboe ¶¶ 43, 78).

The Examiner concludes:

The teachings of Nahas et al. and Hassingboe et al. are each directed to biopolymer implants that are cross-linked. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine their teachings by using the heat treatment method of Hassingboe et al. to cross-link the tissue material of Nahas et al. as discussed above, such that the tissue is heated to 120°C in a vacuum, which would produce a stable three-dimensional structure as instantly claimed, with a reasonable expectation of success.

Id. at 5–6. The Examiner also finds that, “[a] person of ordinary skill in the art at the time the invention was made would have been motivated to combine these teachings in order to cross-link the material while reducing potentially harmful chemicals using a method more effective than heat treatment at ambient pressure, as suggested by Hassingboe et al.” *Id.* at 6.

Appellant argues that combining Hassingboe with the teachings of Nahas frustrates the purpose of Nahas. Appeal Br. 21. Specifically, Appellant asserts that “Nahas teaches crosslinking by adding a polymerizing agent prior to injection, then exposing the injected material to a cross-linking activator, such as light, after injection” and “[c]rosslinking Nahas’ tissue product prior to injection would change the viscoelastic properties of Nahas’ product making it too rigid for injection.” *Id.* (citing Nahas, 26:2–8). Appellant concludes, “[c]onsequently, there would be no motivation or other

reason for a skilled artisan to combine Nahas with Hassingboe because Nahas teaches a viscoelastic product suitable for injection, which would be impossible if cross-linked by heating as taught by Hassingboe.” *Id.*

We are not persuaded by Appellant’s arguments and agree with the Examiner that, as discussed above, Nahas teaches that the composition can be injected into a mold, the biomaterial allowed to harden, then the material implanted, wherein such hardened implant would have a three-dimensional structure. Ans. 8 (citing Nahas, 36:14–15). We further agree with the Examiner that the heated cross-linking of Hassingboe, which would harden the composition, “would occur after injection into a mold, and would occur before implantation, and therefore the resulting combination would not be too rigid for injection and would not require heating in a living subject.” *Id.*

For the reasons described herein and those already of record, we sustain the Examiner’s rejection of claims 1, 9, and 56 under 35 U.S.C. § 103(a) as being obvious over Nahas and Hassingboe. Claims 6, 10–13, and 57–59 are not argued separately, and, therefore, fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Rejection of claims 1, 6, 10–14, and 57–59 under 35 U.S.C. § 103(a) as obvious over Nahas and further in view of Ksander

The Examiner’s findings with respect to Nahas are discussed *supra*. The Examiner acknowledges that, although Nahas “teaches that the implant can be formed into a desired shape for implantation, [Nahas] does not specifically teach contacting the tissue with a flat surface and applying force to compress the tissue to a thickness of about 2.0mm or less,” as recited in claim 14. Final Act. 7. The Examiner finds that this deficiency is cured by Ksander, which discloses collagen implants that are compressed to increase

the tensile strength of the implant, including an example in which an implant is compressed to a thickness of about 1 mm, which increases density and tear resistance. *Id.* (citing Ksander 8:30–40).

The Examiner concludes that “[i]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine their teachings by compressing the implants of Nahas et al. as discussed above to a thickness of about 1 mm using a press as suggested by Ksander et al., with a reasonable expectation of success.” Final Act. 7–8.

Appellant does not present any additional arguments regarding this rejection. We, therefore, affirm the Examiner’s obviousness rejection of claims 1, 6, 10–14, and 57–59 for the reasons discussed above.

Rejection of claims 1, 6, 10–13, 15, 16, and 57–59 under 35 U.S.C. § 103(a) as obvious over Nahas and further in view of Brown

The Examiner’s findings with respect to Nahas are discussed *supra*.

The Examiner acknowledges that, although Nahas:

teaches that the implant can be formed into a desired shape for implantation, [Nahas] does not specifically teach processing the tissue to form a drain or drain manifold in the form of a tube, column, or sheet, further processing the tissue to add grooves, channels, or holes; or processing the tissue to form thin strips hav[ing] a thickness of up to about 2.0mm and rolling the thin strips to form a drain in the shape of a hollow tube.

Final Act. 8–9. The Examiner finds that this deficiency is cured by Brown which discloses scaffolds comprising extracellular matrix having these limitations. *Id.* at 9 (citing Brown ¶¶ 23, 30, 262, 267, 271, 272, 274, 277–280).

The Examiner concludes that:

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine their teachings by forming the implant of Nahas et al. as discussed above into 0.5 to 3 mm thick flat sheets which are cut into rectangular strips and rolled into a tube, and wherein smaller tubes are inserted inside larger tubes, all as suggested by Brown et al., with a reasonable expectation of success.

Final Act. 9.

Appellant does not present any additional arguments regarding this rejection. We, therefore, affirm the Examiner's obviousness rejection of claims 1, 6, 10–13, 15, 16, and 57–59 for the reasons discussed above.

CONCLUSION

For the reasons described herein and those already of record, we affirm the Examiner's rejections of claims 1, 6, 9–16, and 56–59.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 6, 10–13, 57–59	103(a)	Nahas	1, 6, 10–13, 57–59	
1, 6, 9–13, 56–59	103(a)	Nahas, Hassingboe	1, 6, 9–13, 56–59	
1, 6, 10–14, 57–59	103(a)	Nahas, Ksander	1, 6, 10–14, 57–59	
1, 6, 10–13, 15, 16, 57–59	103(a)	Nahas, Brown	1, 6, 10–13, 15, 16, 57–59	
Overall Outcome			1, 6, 9–16, 56–59	

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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