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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHRISTELLE LAURENSOU[1]

Appeal 2017-002753
Application 12/601,699
Technology Center 1600

Before FRANCISCO C. PRATS, ULRIKE W. JENKS, and JOHN G. NEW, *Administrative Patent Judges.*

NEW, *Administrative Patent Judge.*

DECISION ON APPEAL

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[1] Appellant identifies LABORATOIRES URGO as the real party-in-interest. App. Br. 2.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 6–8, 12, 13, 16, and 24–28. Specifically, claims 6, 7, 12, 16, and 24–28 stand rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Freeman (US 5,681,579, October 28, 1997) ("Freeman"), Lipman (US 2004/0241215 A1, December 2, 2004) ("Lipman"), Laskey (US 3,929,741, December 30, 1975), Seppic, *Sepinov EMT 10*, Doc. XP-002463431 ("Sepinov"), and, with respect to claim 24, Han et al. (US 2004/0043135 A1, March 4, 2004) ("Han").

Claims 8 and 13 stand rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Freeman, Lipman, Laskey, Sepinov, Han, and Michaeli (US 4,912,093, March 27, 1990) ("Michaeli").

We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

NATURE OF THE CLAIMED INVENTION

Appellant's invention is directed to the use of a known compound as an agent for promoting and/or accelerating fibroblast proliferation and/or differentiation and, consequently, cicatrization. Abstract.

REPRESENTATIVE CLAIM

Claim 6 is representative of the claims on appeal and recites:

> 6. A dressing for wound treatment, comprising a hydrocolloid; and

> an elastomeric mass comprising one or more elastomers and a copolymer of a salt of 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid and of 2-hydroxyethylpropenoate ester,
>
> wherein the copolymer is included in an amount sufficient for treating a wound of a subject, and
>
> wherein the amount of the copolymer is between 0.1% and 20% by weight relative to the weight of the mass into which the copolymer is incorporated.

App. Br. 10.

ISSUES AND ANALYSES

We agree with, and adopt, the Examiner's reasoning that the claims are prima facie obvious over the combined cited prior art. We address Appellant's arguments below.

A. Rejection of claims 6, 7, 12, 16, and 24–28

Issue

Appellant argues that the Examiner erred in concluding that the claims are obvious over the cited prior art. App. Br. 4.

Analysis

The Examiner finds that Lipman teaches a wound dressing comprising polymeric absorbing material. Final Act. 5 (citing Lipman Abstr., ¶¶ 2, 13, 31). The Examiner finds that Lipman teaches that the dressing comprises a layer comprising an adhesive and an absorbent material. *Id.* (citing Lipman ¶¶ 9, 5). The Examiner finds Lipman teaches that the adhesive comprises an

elastomer to add dry tack to the adhesive and that that the absorbing polymeric material, which adds wet tack, comprises hydrocolloid and hydrophilic copolymers, including polyacrylate polymer, in concentrations of 10–70%. *Id.* (citing Lipman ¶¶ 32, 38, 39, 51–58, 98).

The Examiner finds that Laskey teaches transparent copolymers capable of absorbing large amounts of liquid and water while maintaining their shape and physical stability, and having a high degree of biocompatibility. Final Act. 5 (citing Laskey Abstr., col. 1, ll. 30–59). The Examiner finds that Laskey teaches that the copolymer is useful as a wound and burn dressing, and for controlled release of drug including antibiotics and antimicrobial agents. *Id.* (citing Laskey col.2, ll. 46–47, 54–55). The Examiner finds that Laskey also teaches that the copolymer is a product of the polymerization of 2-acrylamido-2-methylpropanesulfonic acid and hydroxyethyl acrylate. *Id.* (citing Laskey, Ex. 3, 4, 7). The Examiner further finds that Laskey teaches a sodium salt of 2-acrylamido-2-methylpropanesulfonic acid
Id. (citing Laskey Ex. 9).

The Examiner next finds that Sepinov teaches that the Sepinov EMT 10 copolymer is non-hemolyzing, non-denaturing, non-irritant and non-sensitizing. Final Act. 7. The copolymer can be included in topical compositions in an amount from 0.3 to 1.5% of the composition. *Id.* (citing Sepinov 19, 22–30).

The Examiner concludes that it would have been obvious to a person of ordinary skill in the art to provide a wound dressing comprising hydrocolloid, elastomer, active agent and absorbent acrylate polymer as taught by Freeman and Lipman and, particularly to use the absorbent

acrylate polymer in concentrations of 10-70% as taught by Lipman. Final Act. 7. The Examiner concludes that it would have been further obvious to replace the acrylate absorbent polymer of Lipman with copolymer of 2-acrylamido-2-methylpropanesulfonic acid and hydroxyethyl acrylate, or its sodium salt, taught by Laskey. *Id.* The Examiner concludes that a skilled artisan would have been motivated to do so because Lipman teaches suitability of 10% of acrylate polymer as an absorbent in a wound dressing and because Laskey teaches that the copolymer of 2-acrylamido-2-methylpropanesulfonic acid and hydroxyethyl acrylate is useful for wound and burn dressing and for the controlled release of drugs including antibiotics and antimicrobial agents, and is further capable of absorbing large amount of liquid and water while maintaining shape and physical stability and having a high degree of biocompatibility. *Id.*

Finally, the Examiner concludes that Sepinov, which teaches the copolymer composition claimed by Appellant (*see* Spec. 4) teaches the use of the copolymer in the treatment of wounds in concentrations within the range claimed by Appellant.

Appellant argues initially that the claimed copolymer range of "between 0.1% and 20% by weight" recited in claim 6 excludes its endpoints, 0.1% and 20% by weight, respectively. App. Br. 4. Appellant then points to the Declaration of Christelle Laurensou, filed December 12, 2014 (the "Laurensou Declaration"), the inventor of the claimed invention. *Id.* Appellant points to Examples 6 and 7, which employ concentrations of the claimed copolymer at 0.05 and 0.1%, respectively, and Examples 8 and 9, which employ concentrations of 20% and 25%, respectively. *Id.* (citing Laurensou Decl. ¶¶ 4, 8 (including tables)). Appellant notes that the

Laurensou Declaration states, with respect to Examples 6 and 7, that both references demonstrate no significant fibroblast proliferation compared to control values presented in Example 1 of Appellant's Specification, whereas higher values within the claimed range demonstrated increased fibroblast proliferation.[2] *Id.* With respect to Examples 8 and 9, the Laurensou Declaration states that concentrations of 20% and 25% of their claimed copolymer are not suitable for preparing a wound dressing that includes a hydrocolloid and an elastomer due to degradation that results from the higher melting temperatures necessary to melt the claimed copolymer and the elastomer when preparing the wound dressing. *Id.* (citing Laurensou Decl. ¶¶ 8–9). Appellant therefore asserts that the results presented in Appellant's Specification and the Declaration establish that the claimed range is critical in achieving the superior effects in the context of a wound dressing that includes a hydrocolloid and an elastomer in accordance with claim 6. *Id.*

We do not find Appellant's arguments persuasive. We need not address Appellant's argument that the limitation reciting a range of: "between 0.1% and 20% by weight" necessarily excludes the endpoint values of 0.1% and 20%, because we do not find Appellant's contention that these endpoint values, and especially the data from Examples 6 and 7 of the Laurensou Declaration, for which data is provided, persuasive of Appellant's arguments that there is no substantial effect on fibroblast proliferation by Sepinov EMT 10 at these values.

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[2] Fibroblast proliferation is measured as the amount of incorporation of ^{3}H-thymidine in the DNA of fibroblasts incubated with the elastomer and Sepinov.

Specifically, Example 6 (with 0.05% of Sepinov EMT 10) demonstrated fibroblast proliferation of 308% and 352% of control proliferation at 24 and 48 hours incubation time respectively. Laurensou Decl. ¶ 5. Example 7 (with 0.1% EMT 10) demonstrated proliferation of 329% and 390% of control proliferation at 24 and 48 hours incubation time respectively. *Id.* These values both considerably exceed the values presented in Table 3 of Appellant's Specification for Example 2, which, in identical experiments, produced a lower value, 260% of control, for a concentration of Sepinov an order of magnitude greater or more (1%) than the concentrations of Examples 6 and 7. *See* Spec. 8, Table 1. Indeed, the Laurensou Declaration shows that proliferation of fibroblasts in the absence of Sepinov EMT 10 (377%) is similar to that of 0.5% and 0.1% after 48 hours.

We therefore find that the data presented by the Laurensou Declaration is inconclusive at best, significant methodological deficiencies of Appellant's analysis notwithstanding.[3] We are consequently not

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[3] For example, both the control and experimental values in Example 1 of Appellant's Specification are from triplicate runs (n=3) in the Specification and five runs (n=5) in the Declaration studies. Spec. 12. The control values are derived from a preparation without the dressing and without dilution, but with a plug that otherwise holds the dressing in place. *Id.* at 11. However, the proper control values to show the effect of Sepinov EMT 10 would have been obtained from compositions containing 0% of the copolymer (Sepinov EMT 10) incubated with the dressing in wells with fibroblasts because the data appear to indicate a positive effect resulting from incubation with the dressing without the Sepinov EMT 10 (*see* Example 1 of Spec., *but see infra*). *See* Table 3.

The three individual control values, quantified as ^{3}H-thymidine DNA incorporation measured *via* a scintillation counter, were presumably (it is not clear) averaged to provide a mean control value that was then

persuaded by Appellant's argument that the claimed concentration range necessarily defines a set of values within which the beneficial effects of Appellant's claimed composition are obtained.

Appellant next argues that Freeman and Lipman do not disclose a copolymer of a salt of 2-methyl-2-[(1-oxo-2-propenyl) amino]-1-propanesulfonic acid and of 2-hydroxyethylpropenoate ester within the ranges recited in claim 6. App. Br. 5. According to Appellant, Laskey is directed to providing new hydrophilic acrylamide polymers and is silent as to the amounts of the copolymer required by claim 6. *Id.* at 5–6 (citing Laskey col. 1, ll. 37–38).

Appellant argues further that the combination of Freeman, Lipman and Laskey does not provide any reason to expect that the use of the claimed copolymer in particular amounts within the context of a wound dressing containing a hydrocolloid and an elastomer as recited in claim 6 can lead to superior proliferation and/or differentiation as demonstrated, for example, by the data disclosed in Appellant's Specification and the Laurensou Declaration. App. Br. 6. Appellant notes that Laskey, which was published in 1974, is silent as to the particular effects of the claimed copolymer, much less whether its use would lead to fibroblast stimulation within the context of a wound dressing containing a hydrocolloid and an elastomer as recited in

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normalized to 100% and measured against the normalized mean of each of the experimentally-derived values (i.e., incubated with different concentrations of copolymer). *Id.* at 11–12. However, Appellant provides no statistical treatment of the data concerning the amount of variation between runs either within or between the control and sample groups. As such, it is impossible to evaluate the statistical significance of the data, or, indeed, whether there is any scientifically meaningful difference between the control and sample groups.

claim 6. *Id.* Appellant states that it is generally accepted in the art that there are numerous types of polymer materials that are applied to wounds in various ways to achieve different types of effects. *Id.* (citing, e.g., J.S. Boateng et al., *Wound Healing Dressings and Drug Delivery Sytems: A Review*, 97(8) J. PHARM. SCIENCES. 2892–23 (2008); J.L. Monaco et al., *Acute Wound Healing: An Overview*, 30 CLINICS IN PLASTIC SURG. 1–12 30 (2003); P. Martin et al., *Cellular and Molecular Mechanisms of repair in Acute and Chronic Wound Healing*, 173 BRIT. J. DERMATOL. 370–78 (2015)).

Appellant argues further that Sepinov and Han are similarly silent as to the distinct functions of hydrocolloids and the claimed copolymer within the context of the wound dressing. App. Br. 7. Therefore, Appellant asserts, it would not have been obvious to combine the references and achieve the advantageous effects allegedly demonstrated by the data disclosed in Appellant's Specification and the Laurensou Declaration.

We are not persuaded by Appellant's arguments. Sepinov teaches the claimed copolymers, as admitted by Appellant's Specification, being used in skin treatment compositions in concentrations that coincide with the range recited in the claims. *See* Sepinov 23–30 (teaching the use of Sepinov EMT 10 in concentrations of 0.9–2%).

Lipman teaches a wound dressing comprising a: "fluid-absorbing pressure-sensitive adhesive includes a mixture of an adhesive material and at least one water-soluble and/or water-swellable polymer." Lipman ¶ 31. Lipman teaches that: "In one embodiment, a particularly useful rubber-based adhesive is that which has *a thermoplastic elastomeric component* and a resin component." *Id.* at ¶ 38. Lipman further teaches that: "In one

embodiment, the water-soluble and/or water-swellable polymer comprises one or more hydrophilic absorbent polymers" and that: "In one embodiment, the water-soluble and/or water-swellable polymer may comprise one or more water-soluble hydrocolloids, alone or blended with one or more swellable polymers." *Id.* at ¶ 54–55. Lipman also teaches, with respect to the copolymers: "The amount of hydrophilic absorbent polymer, the water-soluble and/or water-swellable polymer, may be from about 10% to about 70% of the total weight of the fluid-absorbing pressure-sensitive adhesive material, in one embodiment from about 20% to about 55% of the total weight of the fluid-absorbing pressure-sensitive adhesive material." Lipman ¶ 58. Lipman thus teaches: "A dressing for wound treatment, comprising a hydrocolloid; and … an elastomeric mass [and]… a copolymer" in concentrations that overlap the range: "wherein the amount of the copolymer is between 0.1% and 20% by weight relative to the weight of the mass into which the copolymer is incorporated, as recited in claim 6.

Laskey is similarly directed to the use of hydrophilic polymers in the medical arts. Laskey col. 1, ll. 10–13. Laskey teaches compositions that comprise a hydrophilic polymer obtained by polymerization of an acrylamido sulfonic acid. *Id.* at col 1, ll. 62–64. Laskey further teaches that: "The most preferred polymer according to the present invention is obtained by polymerizing 2-acrylamido-2-methylpropane-sulfonic acid," closely related to Appellant's claimed 2-methyl-2-[(1-oxo-2-propenyl) amino]-1-propanesulfonic acid recited in claim 6. Laskey col. 2, ll. 34–36. Laskey further teaches the use of a salt of acrylamido-2-methylpropane sulfonic acid. *Id.* at col. 7, ll. 1–18. Laskey also teaches a copolymer of the latter compound with: "[u]nsaturated esters (e.g., hydroxyethyl methacrylate,

hydroxypropyl acrylate). *Id.* at col. 4, ll. 17–18. Hydroxyethyl acrylate, as recited in claim 6, is one such unsaturated ester.

Finally, and as we have noted *supra*, Sepinov expressly teaches Appellant's claimed copolymer for use in a variety of topical skin treatments, Sepinov 21, thus suggesting its equivalent use in other topically applied compositions that use similar copolymers, including the compositions of Lipman and Laskey.

We agree with the Examiner that a person of ordinary skill in the art would have found it obvious to combine the teachings of Lipman, Laskey, and Sepinov to arrive at Appellant's claimed invention. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

Furthermore, we are not persuaded by Appellant's argument that the "special properties," i.e., increased proliferation of fibroblasts, renders their claimed invention patentable distinct. As an initial matter, if Appellant means to argue, even impliedly, that the claimed composition has surprising or unexpected results, Appellant is required to show that the results would have been unexpected when compared to the closest prior art. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991) (holding that: "when unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art"). Appellant adduces no persuasive evidence to demonstrate that the allegedly unexpected and beneficial properties of their composition would have been unexpected and different in kind from those properties of compositions taught by the prior art. *See Iron Grip Barbell Co. v. USA*

Sports, Inc., 392 F.3d 1317, 1322 (Fed. Cir. 2004) (holding that unexpected results that are probative of nonobviousness are those that are "different in kind and not merely in degree from the results of the prior art").

Moreover:

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.... Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

In re Best, 562 F.2d 1252, 1255 (C.C.P.A. 1977). Appellant has adduced no persuasive evidence of record to demonstrate that the claimed composition has properties that would not have been present in the compositions taught by the combined prior art when combined in the concentrations taught by the prior art, as found by the Examiner. Absent any such evidence of record, Appellant has not met the burden of overcoming the Examiner's *prima facie* conclusion that the claims are obvious over the combined cited prior art. We consequently affirm the Examiner's rejection of claim 6.

Appellant argues separately that dependent claim 16 recites that the amount of the copolymer is between 1% and 5% by weight, relative to the weight of the mass into which the copolymer is incorporated. App. Br. 8. However, Appellant asserts, Lipman teaches a minimum amount of 10% and up to 70% by weight of the water-absorbing polymer. *Id.*

We do not find Appellant's argument persuasive, because Sepinov provides examples of Sepinov EMT 10 being used in skin treatments at

concentrations of 0.9% to 2.0%, which substantially overlaps Appellant's claimed range. Furthermore, because the concentration of the polymers is a result effective variable, as recited in the claims, we conclude that it would have been well within the skill of an ordinary artisan to determine an optimal value for the copolymer concentration corresponding to the claimed range. *See In re Boesch*, 617 F.2d 272, 276 (C.C.P.A. 1980) (holding that "discovery of an optimum value of a result effective variable ... is ordinarily within the skill of the art"). We therefore affirm the Examiner's rejection of this claim.

Appellant argues separately that dependent claim 24 recites that the amount of the copolymer is an amount sufficient for promoting and/or accelerating fibroblast proliferation *in vivo* or *ex vivo*, and that, as argued *supra*, this is not taught by the prior art. App. Br. 8. However, as we have explained, the Examiner has concluded that Appellant's composition is obvious over the cited prior art and, therefore, the burden of proof shifts to Appellant to demonstrate that the claimed properties would not have been present in a composition derived from the combined cited prior art. *Best*, 562 F.2d at 1255. Appellant has not met this burden, and we are therefore not persuaded by Appellant's argument. We consequently affirm the Examiner's rejection of claim 24.

Appellant further argues that dependent claim 25 recites that the amount of the copolymer is 5% or more and less than 20 % by weight relative to the weight of the mass into which the copolymer is incorporated. App. Br. 8. Appellant points out that Sepinov discloses amounts that are lower than 5% by weight. *Id.* However, as we have explained, Lipman teaches copolymer concentrations in its wound dressings of between from

about 10% to about 70%. Lipman ¶ 58. Appellant's contention throughout has been that the concentration range of the copolymer is essential to promote fibroblast proliferation and wound healing. *See, e.g.*, App. Br. 4–6. As such, Appellant is impliedly arguing that the concentration of copolymer is a result-effective variable. As such, we conclude that it would be within the skill of an ordinary artisan to determine the optimal range of concentrations of copolymer between the ranges taught by Sepinov and Lipman. *See In re Boesch*, 617 F.2d 272, 276 (C.C.P.A. 1980) (holding that "discovery of an optimum value of a result effective variable ... is ordinarily within the skill of the art"). We consequently affirm the Examiner's rejection of claim 25.

Finally, Appellant argues that dependent claims 26–28 recite the elastomer and/or the hydrocolloid used in the working examples of Appellant's Specification. App. Br. 8. Appellant contends that the alleged showing of superior effects in the experimental work of the specification and the Laurensou Declaration is commensurate in scope with at least these claims. *Id.* We are not persuaded. As we have explained *supra*, the data from the studies presented in the Specification are inconclusive, at best. Moreover, Appellant has not adduced any evidence to demonstrate that the results obtained are superior to those that would be obtained, by comparison, to the nearest prior art. *Baxter*, 952 F.2d at 392. We consequently affirm the Examiner's rejection if claims 26–28.

B. Rejection of claims 8–28

Appellant argues these claims together. App. Br. 8. Appellant relies on the arguments presented *supra*, and asserts that Michaeli does not remedy

the alleged deficiencies of the cited prior art relied upon in the rejection of claim 6. *Id.* We have explained our reasoning as to why we are not persuaded by Appellant's arguments with respect to claim 6, and we consequently affirm the Examiner's rejection of claims 8–28.

DECISION

The Examiner's rejection of claims 6–8, 12, 13, 16, and 24–28 as unpatentable under 35 U.S.C. § 103(a) is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED