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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RANDOLPH W. HUBBELL, JAMES ECKHARDT, JEROME RIEBMAN, YUFU LI, and MICHAEL ELSER

Appeal 2018-004492
Application 13/937,292
Technology Center 1600

Before JEFFREY N. FREDMAN, TAWEN CHANG, and JAMIE T. WISZ, *Administrative Patent Judges.*

CHANG, *Administrative Patent Judge.*

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 9–13. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[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 Ethicon, Inc. Appeal Br. 3.

BACKGROUND

When bleeding occurs, the plasma protein fibrinogen reacts with water and the enzyme thrombin to form fibrin, which "is insoluble in blood and polymerizes to form clots." Spec. ¶ 2. Substantial bleeding, however, may also require the use of topical absorbable hemostats (TAHs). To improve the hemostatic performance of scaffolds based on TAHs, such scaffolds can be combined with biologically-derived clotting factors, such as thrombin and/or fibrinogen. *Id.* ¶ 4.

According to the Specification, the invention is directed towards "a hemostatic wound treatment device having a bioabsorbable scaffold," wherein "[t]he scaffold is wetted with a biocompatible liquid that is not blood or plasma and a hemostatic powder adheres as a result of the moisture from the biocompatible liquid to at least the wound facing surface of said . . . scaffold," and wherein "[h]emostatic powder means . . . a material that is in its dry, particle form and biologically or physically active in some fashion in the hemostatic blood clotting cascade." *Id.* ¶ 11. The invention is "also directed to a prep kit for a hemostatic wound treatment pad having at least one powdered hemostatic material; a bioabsorbable scaffold; a biocompatible liquid; and an application tray." *Id.* ¶ 15. The Specification states that "[t]he powdered hemostatic material can be packaged into [a] powder tray." *Id.*

CLAIMED SUBJECT MATTER

The claims are directed to a method of making and using a hemostatic wound treatment device. Claim 12, the only independent claim, is illustrative:

> 12. A method of making and using a hemostatic wound treatment device comprising: a bioabsorbable scaffold having a wound facing surface and an opposing surface; and a hemostatic powder that comprises a mixture of fibrinogen and thrombin, the method comprising:
>
> a) wetting the scaffold with the biocompatible liquid that is not blood or plasma selected from the group consisting of an aqueous solution, normal saline, ethanol, and ethanol-water mixture; then
> b) contacting the scaffold with the hemostatic powder in dry form in a powder tray onto the wet scaffold and adhering at least a portion of the hemostatic powder to at least the wound facing surface of the scaffold; and then
> c) applying the wound facing surface of the hemostatic wound treatment pad onto a wound.

Appeal Br. 9 (Claims App.)

REJECTION

Claims 9–13 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Larsen.[2]

OPINION

A. Issue

The Examiner finds that Larson teaches all of the steps of claim 12 but "does not specify the same order steps (i.e., wetting the scaffold, then contacting the scaffold with the hemostatic powder while still dry onto the wet scaffold, and then applying the pad surface onto the wound)." Ans. 3–5. However, the Examiner finds that "changes in the sequence of adding ingredients and selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results." *Id.* at 6.

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[2] Larsen, WO 2011/113436 A1, published Sep. 22, 2011.

Appellant contends that Larson teaches "deliver[ing] hemostatic agents by ultrasonic spraying" and does not suggest "contacting the scaffold with the hemostatic powder in dry form *in a powder tray* onto the wet scaffold," as required by claim 12. Appeal Br. 4–7 (emphasis added); *see also* Reply Br. 1–2.

The issue with respect to this rejection is whether Larson suggests a method of making and using a hemostatic wound treatment device comprising "contacting . . . the hemostatic powder in dry form in a powder tray onto the wet scaffold," as recited in claim 12.

B. Analysis

We agree with Appellant that the Examiner has not established a prima facie case that claim 12 is obvious over Larson. In particular, the Examiner has not persuasively shown that Larson suggests "contacting . . . [a] hemostatic powder in dry form in a powder tray onto [a] wet scaffold," as required by claim 12.

The Examiner asserts that claims are giving their broadest reasonable interpretation during prosecution and, since the term "in a powder tray" is not defined in the Specification, the term is "interpreted to mean that the 'contacting' method step is prepared in a tray containing the claimed hemostatic powder." Ans. 9. The Examiner asserts that, accordingly, Larson teaches the limitation regarding "contacting . . . the hemostatic powder in dry form in a powder tray," because Larson teaches "contacting [a] scaffold with a hemostatic powder composition by ultrasonic spray . . . to form . . . a particulate (i.e., a powder composition)" and also teaches a container comprising a tray that is used "both for 'storage and/or preparation' of a matrix material." *Id.*

We are not persuaded. Larson does teach a container for sterile storage and/or preparation of its device, which "can be used to add liquid to the matrix material prior to use," Larson 3:16–20; *see also id.* at 1:10–12, 3:35-4:2, 10:16–27, 15:27–31, 178:27–31, and further teaches that the container comprises a tray, *see, e.g., id.* at Fig. 2A, 19:23–27 (stating that "[t]he bottom of the inner tray is marked (1)"), 191:10–15 (describing inner tray notches), 249:12–18, 282:1–7. Nevertheless, even if we were to adopt the Examiner's claim construction that the "inner tray" is an equivalent of "in a powder tray" for the sake of argument, the Examiner fails to show how Larson suggests performing what is alleged to be the contacting step, i.e., the ultrasonic spraying, *in* the alleged "powder tray."

As discussed above, the Examiner also acknowledges that Larson does not teach "the same order steps [as the claimed method,] (i.e., wetting the scaffold, then contacting the scaffold with the hemostatic powder while still dry onto the wet scaffold, and then applying the pad surface onto the wound)." The Examiner asserts, however, that "changes in the sequence of adding ingredients and selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results." *Id.* at 6.

We are not persuaded. While we agree with the general proposition that changes in the order of performing process steps is prima facie obvious absent new or unexpected results, in this case the Examiner has not shown how Larson suggests the performance of one of the claimed steps at all, i.e., "contacting . . . the hemostatic powder *in dry form* . . . onto the *wet* scaffold."

The Examiner asserts that Larson teaches contacting the dry form of the hemostatic powder with the scaffold because it teaches that the fluid or

liquid composition deposited onto its matrix "may be any liquid or gaseous composition, and covers any solution, suspension and emulsion" and further teaches that, "[i]n one embodiment, the fluid or liquid composition is a particulate composition, which may be liquid, gaseous, solid or dry." Ans. 3, 9; Larson 22:23–26. The Examiner appears to allege that the limitation of contacting such hemostatic powder in dry form onto the *wet* scaffold is met because "the . . . scaffold is essentially wetted (i.e., the biocompatible liquid spray composition) and contacted with powder simultaneously via the ultrasonic spray." Ans. 4–5. To the extent the scaffold is *wetted* because the spray composition is in liquid form, however, the Examiner does not explain how such liquid spray composition can simultaneously meet the limitation of the hemostatic powder in *dry* form.

Alternatively, the Examiner appears to suggest that the limitation of "contacting . . . the hemostatic powder in dry form . . . onto the wet scaffold" is suggested by Larson because the reference suggests contacting the scaffold with the dry hemostatic powder using ultrasonic spray and then "wetting the scaffold (in addition to the initial spray) with biocompatible liquid." Ans. 3. The Examiner asserts that, accordingly, "the dry hemostatic powder . . . is in contact with/onto the biocompatible liquid wetted scaffold." *Id.* at 4. However, in this scenario, the wetting of the scaffold does not occur until *after* the contact between the scaffold and the hemostatic powder in dry form. Thus, the limitation of contacting the hemostatic powder in dry form onto the wet scaffold is still also not met. In either case, we decline to equate the terms "wet" and "dry" as being identical.

Accordingly, for the reasons discussed above, we reverse the Examiner's rejection of claim 12 as obvious over Larson. We reverse the

rejection of claims 9–11 and 13, which depend from claim 12, for the same reasons. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) ("Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.").

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
9–12	103(a)	Larson		9–12

REVERSED