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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANTHONY RATCLIFFE and ANDREAS KERN

Appeal 2015-001279^{1,2}
Application 11/893,802
Technology Center 3700

Before BIBHU R. MOHANTY, PHILIP J. HOFFMANN, and
CYNTHIA L. MURPHY, *Administrative Patent Judges*.

HOFFMANN, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134(a) from the Examiner’s final rejection of claims 1, 3, 4, 9, 10, 13, 15–17, 21–27, 34, and 36. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

According to Appellants, the invention is related to “fibrous structures that approximate the physical characteristics of soft tissue are useful as

¹ Our decision references Appellants’ Specification (Spec.,” filed Aug. 17, 2007) and Appeal Brief (“Br.,” filed May 20, 2014), as well as the Examiner’s Answer (“Answer,” mailed Sept. 5, 2014).

² According to Appellants, Synthasome Inc. is the real party in interest.
Br. 1.

implants to promote the repair of soft tissue.” Spec. 1, ll. 12–13. Claims 1, 34, and 36 are the only independent claims. *See* Appeal Br., Claims App. Below, we reproduce claims 1 and 34 as representative of the appealed claims.

1. A synthetic structure for repair of a rotator cuff comprising a polymeric fibrillar structure having a length and a width and having uniform fibrillar distribution, and a stiffness of about 10 to about 500 Newtons per millimeter (N/mm) along the length and along the width, wherein the fibrillar structure is a planar woven structure, the planar woven structure exhibiting mechanical properties of human rotator cuff tendon.

34. A synthetic structure for repair of a rotator cuff comprising a polymeric fibrillar structure, wherein the fibrillar structure comprises two planar woven layers having the same mechanical properties, the fibrillar structure exhibiting a stiffness of about 10 to about 500 Newtons per millimeter (N/mm), a tensile strength of about 20 to about 2000 Newtons and a failure strain at 105% to about 150% of original length.

Id.

REJECTIONS AND PRIOR ART

The Examiner rejects claims 1, 3, 4, 9, 10, 13, 26, and 27 under 35 U.S.C. § 103(a) as unpatentable over Hlavacek (US 4,942,875, iss. July 24, 1990) and Hwang (US 2004/0267362 A1, pub. Dec. 30, 2004).³

The Examiner rejects claims 15–17 under 35 U.S.C. § 103(a) as unpatentable over Hlavacek, Hwang, and Matsuda (US 2006/0252981 A1, pub. Nov. 9, 2006).

³ Although page 2 of the Answer references the rejection of claim 14, claim 14 was cancelled. *See* Br., Claims App.

The Examiner rejects claims 21–23, 25, 34, and 36 under 35 U.S.C. § 103(a) as unpatentable over Hlavacek, Hwang, and Bowlin (US 6,592,623 B1, iss. July 15, 2003).

The Examiner rejects claim 24 under 35 U.S.C. § 103(a) as unpatentable over Hlavacek, Hwang, and Chun (US 2004/0175408 A1, pub. Sept. 9, 2004).

See Answer 2–8.

ANALYSIS

Obviousness rejection of claims 1, 3, 4, 9, 10, 13, 26, and 27

For the reasons discussed in detail, below, we do not agree with Appellants that the Examiner errs in rejecting independent claim 1, or claims 3, 4, 9, 10, 13, 26, and 27 that depend from claim 1. Thus, we sustain the obviousness rejection of claims 1, 3, 4, 9, 10, 13, 26, and 27.

In the rejection of independent claim 1, the Examiner determines the following:

Hlavacek discloses a synthetic structure 1 (Fig. 1) fully capable for performing the intended use for repair of a rotator cuff comprising a polymeric fibrillar . . . having uniform fibrillar distribution . . ., wherein the fibrillar structure is a planar woven structure[, but Hlavacek does not disclose] a stiffness of about 10 to about 500 N/mm along the length and along the width and explicitly discloses the planar woven structure exhibiting mechanical properties of human rotator cuff tendon.

However, Hwang teaches a similar structure comprising a stiffness of about 10 to about 500 N/mm along the length and along the width (par. 0034 discloses the binding regions having a stiffness greater than 100 N/mm). Hlavacek discloses modifying the tensile strength and stiffness of the device by changing the number of fibers to achieve the needed tensile strength and stiffness (col. 7, lin. 42-49), therefore, it would have

been obvious . . . to modify the fibrillar structure in Hlavacek to change the number of yarns to exhibit stiffness of about 10 to about 500 N/mm along the length and width and exhibit mechanical properties of human rotator cuff tendon, as taught and suggested by Hwang, for the purpose of repairing a ligament such as the cruciate ligament (par. 0034 of Hwang) which is fully capable of being the human rotator cuff since the combination of Hlavacek and Hwang disclose the required structure and properties of the synthetic structure.

Answer 2–3. Thus, the Examiner determines, among other things, that it would have been obvious to change the number of fibers in Hlavacek’s device to achieve a desired, specific stiffness (as taught by Hlavacek), the stiffness being “a stiffness greater than 100 N/mm” (as taught by Hwang).

Appellants argue that “[c]ontrary to the Examiner’s assertion, Hlavacek has not been shown to disclose a structure ‘exhibiting mechanical properties of human rotator cuff tendon,’ as recited in claim 1.” Br. 4. We note, however, that the Examiner relies on a determination that Hlavacek, modified based on Hwang’s teaching of a specific, desired stiffness, exhibits mechanical properties of a rotator cuff tendon by having a stiffness of about 10 to about 500 Newtons per millimeter. *See* Answer 2–3, 9. Thus, this argument is not persuasive.

Appellants argue that Hlavacek does not disclose a planar woven structure that exhibits uniform fibrillary distribution. *See* Br. 4–5. We agree with the Examiner, however, that “the synthetic structure of Hlavacek at [F]igures 1 and 2 discloses both a uniform fibrillar distribution (the fibers are uniformly distributed in parallel configuration[]) . . . and a planar woven structure (claim 1 of Hlavacek discloses a woven structure and Fig. 1 discloses a flat or planar structure).” Answer 10. Thus, this argument is not persuasive.

Appellants argue that “Hlavacek’s structure does not have ‘a stiffness of about 10 to about 500 Newtons per millimeter (N/mm) along the length and along the width’ Hwang fails to cure these deficiencies of Hlavacek.” Br. 5; *see also id.* at 5–7. We conclude, however, that the Examiner’s determination that it would have been obvious to change the number of fibers in Hlavacek’s device to achieve a desired, specific stiffness (as taught by Hlavacek), the stiffness being “a stiffness greater than 100 N/mm” (as taught by Hwang), is reasonable and supported by substantial evidence. *See* Answer 2–3. Thus, this argument is not persuasive.

Appellants argue “even assuming that a person of ordinary skill . . . would have sought to impart the stiffness of Hwang’s binding regions 20a, 20b to Hlavacek’s structure 1, which Appellant[s] do[] not concede, increasing the number of yarns in Hlavacek would not have resulted in ‘a uniform fibrillar distribution.’” Br. 7. We note, however, that Appellants do not explain sufficiently why increasing the number of fibers in Hlavacek would result in a nonuniform fibrillar distribution. Thus, this argument is not persuasive.

Finally, after reviewing Appellants’ affidavits by Anthony Ratcliffe and Christopher Proctor, we are not convinced that the Examiner errs in determining the subject matter of claim 1 is obvious based on Hlavacek and Hwang. *See* Br. 7–8; *see also* DECLARATION OF ANTHONY RATCLIFFE, PH.D, dated Aug. 12, 2013; *see also* DECLARATION OF CHRISTOPHER S. PROCTOR, M.D., undated. Although evidence pertaining to secondary considerations must be taken into account, such evidence does not necessarily control the obviousness conclusion. *See, e.g.,*

Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1372 (Fed. Cir. 2007) (“the record establish[ed] such a strong case of obviousness” that allegedly unexpectedly superior results were ultimately insufficient to overcome obviousness conclusion). Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of a prima facie case was reached, not against the conclusion itself. *See In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990). “[E]vidence that has been presented . . . should not be ignored, but rather should be considered on the record. However, not all evidence need be accorded the same weight.” Manual of Patent Examining Procedure § 2145 (8th Ed. Rev. 9, 2012). In this case, the statements in the affidavits are not sufficient to persuade us that the Examiner’s obviousness determination is erroneous. We determine that the Examiner establishes a strong case of obviousness—as discussed above, Hlavacek teaches that it was known to change a number of fibers to achieve different stiffnesses, and Hwang discloses a specific, desired stiffness within the claimed range. Thus, this argument is not persuasive.

Therefore, based on the foregoing, we sustain the rejection of independent claim 1. We also sustain the rejection of claims 3, 4, 9, 10, 13, 26, and 27 that depend from claim 1 and which Appellants do not argue separately. *See* Br. 8.

Obviousness rejection of claims 15–17

Appellants separately argue the rejection of claims 15–17 that depend from claim 1. *See* Br. 8–9. However, inasmuch as Appellants rely on Matsuda’s inability to cure the deficiencies in the Examiner’s rejection of claim 1, and we conclude that there are no such deficiencies, we sustain the rejection of claims 15–17.

Obviousness rejection of claims 21–23, 25, 34, and 36

With respect to claims 21–23 that depend from claim 1, Appellants argue the following:

[T]he Examiner has not provided a rational underpinning for the proposed modification at least because the Examiner has not shown why a person of ordinary skill in the art would have looked to the fibers of Bowlin’s electrospun matrix for selecting a suitable fiber diameter of Hlavacek’s braided structure or why a person of ordinary skill in the art would have understood the diameter of Bowlin’s electrospun fibers to have strengthened and increased the surface area of Hlavacek’s braided structure in view of Hwang’s scaffold.

Br. 10. Based on our review of the record, we agree with Appellants. We are not convinced that because “Bowlin teaches a . . . polymeric fibrillar structure having a diameter ranging from about 50[–]80 microns” (Answer 6), when Bowlin discloses a different structure (i.e., a muscle implant) compared to Hlavacek and Hwang (i.e., devices to repair ligaments and tendons), and when Bowlin discloses a structure made from a different process (i.e., electrospinning) compared to Hlavacek and Hwang (i.e., woven fibers), that it would have been obvious to make Hlavacek’s fibers the same diameter as Bowlin’s. Thus, we do not sustain the obviousness rejection of claims 21–23.

With respect to claim 25 that depends from claim 1, Appellants argue that “the Examiner’s proposed modification of Hlavacek’s structure in view of Hwang’s scaffold to include a ‘polymeric fibrillar structure ha[ving] at least two layers’ based on the teaching of Bowlin has not been shown to have a rational underpinning.” Br. 11. Based on our review, we agree with Appellants. We are not convinced that because “Bowlin teaches a . . . polymeric fibrillar structure [that] has at least two layers” (Answer 6), when

Bowlin discloses a different structure (i.e., a muscle implant) compared to Hlavacek and Hwang (i.e., devices to repair ligaments and tendons), that it would have been obvious to make Hlavacek's structure have multiple layers. Thus, we do not sustain the rejection of claim 25.

With respect to independent claim 34, Appellants argue "a person of ordinary skill . . . would not have understood Hwang's scaffold 10 to have included 'two planar woven layers having the same mechanical properties.'" Br. 15. We agree with Appellants that Hwang appears to show one layer. *See, e.g.*, Fig. 1. Further, for reasons similar to those discussed above with respect to claim 25, we agree with Appellants that Bowlin does not remedy the deficiency of Hlavacek and Hwang. *See* Br. 15. Thus, we do not sustain the rejection of claim 34.

With respect to independent claim 36, we agree with Appellants, for reasons similar to those discussed above with respect to claims 25 and 34, that the Examiner does not establish that a combination of Hlavacek, Hwang, and Bowling discloses "two planar woven layers." *See* Br. 17. Therefore, we do not sustain the rejection of claim 36.

Obviousness rejection of claim 24

With respect to claim 24, Appellants argue that "the Examiner has not shown why a person of ordinary skill in the art would have sought to include fibers of different diameters in Hlavacek's structure." We agree with the Examiner, however, that this would have been an obvious modification. *See* Answer 12. Further, we note that it is well-known to use fibers of different diameters when different materials are used, as is apparently shown in Hlavacek (*see* Fig. 2). Thus, we sustain the rejection.

Appeal 2015-001279
Application 11/893,802

DECISION

We AFFIRM the Examiner's obviousness rejections of claims 1, 3, 4, 9, 10, 13, 15–17, 26, and 27.

We REVERSE the Examiner's obviousness rejections of claims 21–23, 25, 34, and 36.

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-IN-PART