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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GORDON M. MACKAY[1]

Appeal 2017-011449
Application 13/455,581
Technology Center 3700

Before RICHARD M. LEBOVITZ, ULRIKE W. JENKS, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed to methods of surgical repair. The Examiner rejected the claims as anticipated under 35 U.S.C. § 102 and as obvious under 35 U.S.C. § 103. Pursuant to 35 U.S.C. § 134, Appellant appeals the Examiner's determination that the claims are unpatentable. We have jurisdiction under 35 U.S.C. § 6(b). We affirm the Examiner's decision.

STATEMENT OF THE CASE

The claims stand finally rejected by the Examiner as follows:

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[1] The Appeal Brief ("Br."; entered Jan. 27, 2017) identifies Arthrex, Inc., as the real party in interest.

1. Claims 45, 49, 51, 61 and 62 under pre-AIA 35 U.S.C. § 102(b) as anticipated by Kdolsky et al., *Journal of Orthopaedic Research*, 1997, 15(1): 1–10 ("Kdolsky"). Ans. 3.

2. Claims 46–48, 50, and 52–54 under pre-AIA 35 U.S.C. § 103(a) obvious in view of Kdolsky and Dreyfuss et al., US 2009/0222039 A1, published Sept. 3, 2009 ("Dreyfuss"). Ans. 5.

3. Claims 55, 63, and 64 under pre-AIA 35 U.S.C. § 103(a) obvious in view of Kdolsky and Hoof et al., US 2009/0198288 A1, published Aug. 6, 2009 ("Hoof"). Ans. 7.

4. Claims 56 and 57 under pre-AIA 35 U.S.C. § 103(a) obvious in view of Kdolsky and Tobis et al., WO 2009/113076 A1, published Sept. 17, 2009 ("Tobis"). Ans. 8.

5. Claim 60 under pre-AIA 35 U.S.C. § 103(a) obvious in view of Kdolsky and *ACL Reconstruction with LARS Ligament Surgical Tec*hnique (Brochure), 2009, distributed by Corin ("Corin"). Ans. 8.

Claim 45, the only independent claim on appeal, is reproduced below:

> 45. A method of surgical repair comprising
>
> securing a reconstruction system adjacent to a repaired or replacement ligament, wherein the reconstruction system is a reinforcement construct secured by fixation devices,
>
> wherein a first fixation device is secured adjacent to the repaired or replacement ligament's anatomical origin point, and a second fixation device is secured adjacent to the repaired or replacement ligament's anatomical insertion point.

ANTICIPATION BY KDOLSKY

The Examiner found that Kdolsky describes all the steps of the claimed surgical repair method. The Examiner found the Kdolsky describes a braided polypropylene augmentation device which serves as the claimed

"reconstruction construct." Ans. 3, 4. The Examiner found that the braided polypropylene augmentation device is attached "adjacent the autograft [the claimed "repaired or replacement ligament"] or reattached ligament in the bone tunnel." *Id.* at 3. The Examiner further found the braided polypropylene augmentation device is attached at both ends by fixation screws, meeting the limitation of claim 45 of being "secured by fixation devices." *Id.*

Appellant argues that Kdolsky does not teach fixating the reconstruction device with fixation devices as claimed. Appeal Br. 8. Appellant also contends there is no disclosure in Kdolsky of securing the augmentation device adjacent to the ligament's anatomical origin point or insertion point. *Id.* at 6. Appellant states:

> The anatomical origin point of the ACL is located at the posteromedial corner of the medial aspect of the lateral femoral condyle in the intercondylar notch, and the anatomical insertion point of the ACL is located at the fossa in front of and lateral to the anterior spine of the tibia.

Id.

In contrast, Appellant argues that the augmentation device (i.e., the "reinforcement construct" of the rejected claims) in Kdolsky is fixated by the over-the-top route which "passes the graft over the superomedial border of the lateral femoral condyle so it can be fixated on the lateral femoral shaft." Appeal Br. 7. Appellant also contends that the augmentation device of Kdolsky is not adjacent to the composite graft. *Id.*

"*reinforcement construct secured by fixation devices*"

As found by the Examiner, Kdolsky describes a "braided polypropylene ligament augmentation device" which serves as a

"reinforcement construct" as required by claim 45. The Examiner's finding is supported by the following disclosure from Kdolsky:

> FF1.[2]
>
> Between 1983 and 1992, 594 patients (255 female and 339 male; average age 28.3 years [range 16–49]) had reconstruction of a ruptured anterior cruciate ligament performed with use of the braided polypropylene ligament augmentation device (Kennedy; 3M, St. Paul, MN, U.S.A.) with temporary, rigid double-end fixation.

Kdolsky 2.

Kdolsky states that the reconstruction using the braided polypropylene ligament augmentation device is performed "with double-end fixation," indicating first and second fixation devices, as required by the claim, are used to "fix" the ligament augmentation device in position. In addition to this, Kdolsky discloses:

> FF2.
>
> In contrast to the original procedure and to the manufacturer's recommendations, *rigid double-end fixation was used* (8, 29). Prior to fixation of the reattachment or the composite graft, the ligament augmentation device was preloaded with 70-100 N, according to 10% of the patient's body weight, with the knee joint in extension. From 1983 to 1987, the fixation hardware was "Burri-plates" (Hug, Freiburg, Germany); since 1988, cancellous bone screws (6.5 mm diameter) with a washer (Mathys, Bettlach, Switzerland) have been used.

Kdolsky 2 (emphasis added).

Thus, Kdolsky again teaches double-end fixation for the augmentation device.[3] Appellant's argument that "fixation devices", as recited in claim

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[2] Finding of Fact ("FF").

[3] "Kdolsky discloses (page 2, column 2, lines 11-12) the use of rigid double end fixation for the composite graft. Because the composite graft consists of

45, are not disclosed by Kdolsky does not address the disclosure in Kdolsky (FF1, FF2) which refers to double end-fixation. Appeal Br. 8; Reply Br. 2. Furthermore, while Appellant argues that the disclosure in FF2 indicates that the screws are used to attach the composite *graft*, Appellants ignore the disclosure of "double-end fixation" in FF1 ("the braided polypropylene ligament augmentation device . . . with temporary, rigid double-end fixation."). Thus, even if the screws or plates are a reference to fixating the graft, it does not undermine the explicit disclosure of double-end fixation in Kdolsky for the augmentation device in FF1. Thus, we find Appellant's argument to be without adequate evidentiary basis.

"*ligament's anatomical origin point*"

Appellant contends that the over-the-top position utilized to attach the braided polypropylene ligament augmentation device is not "adjacent" to the graft's anatomical origin and insertion points as required by the claims and therefore the claims cannot be anticipated. Appeal Br 7.

Kdolsky has the following pertinent teachings:

FF3.

> The [anterior cruciate] ligament was reattached using a modified Marshall technique (multiple nonresorbable suture loops) (17,18) and augmented with the ligament augmentation device by the over-the-top route.

Kdolsky 2.

FF4.

From 1983 to 1987, the proximal route of the augmentation

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a replacement ligament and the ligament augmentation device, the ligament augmentation device must be anchored to the bone by the rigid double end fixation." Ans. 12.

> device was with the graft through the same bone tunnel in the femoral condyle (parallel augmentation route).

Kdolsky 2.

> FF5.
>
> Since 1987, the proximal routing for the augmentation device has been over the top through the posterior capsule (divergent augmentation route).

Kdolsky 2.

Based on Findings of Fact 3–5, there are two different proximal positions to which the ligament augmentation device was attached: 1) over-the-top (FF3, FF5); and 2) through a bone tunnel in the femoral condyle (FF4). Ans. 4, 11; Final Act. 4. Appellant explained that the 1) over-the-top position results in fixation is on the lateral femoral shaft. Appeal Br. 7. The Examiner did not challenge Appellant's explanation.

With regard to the bone tunnel disclosure (FF4), Appellant contends that the Examiner "appears to be confusing routing the augmentation device into the joint with securing the augmentation device into place." Appeal Br. 7. We do not agree.

Kdolsky refers to "routing" through a tunnel in the femoral condyle during the earlier time period in which the operations were performed and then "routing" over the top in a subsequent later time period. FF4, FF5. Appellant states that "the screws described at the cited section of Kdolsky appear to be used to fixate the composite graft within the bone tunnels. There is no *prima facie* evidence that the screws are also used to fixate the ligament augmentation device." Appeal Br. 8 (emphasis added). Yet, Appellant also states: "The cited reference discloses an augmentation within a bone tunnel. Thus, *Kdolsky* is teaching fixation from within bone." Reply

Br. 3. The "the augmentation device was with the graft." FF4. Because the augmentation device is "with" the graft, it was reasonable for the Examiner to believe that the device would be fixated at the same position as the graft, a fact which appears to have been admitted in the Reply Brief.

In sum, the finding that Kdolsky disclose fixation of a reinforcement construct at both the over-the-top and condyle tunnel locations is supported by a preponderance of the evidence.

"*secured adjacent to*"

The next issue to address is whether these locations are "adjacent" to the anatomical origin and insertion points as required by the claims. The meaning of the claim term "adjacent" is in dispute.

During patent examination proceedings, claim terms are given "the broadest reasonable meaning . . . in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

We first look to the specification for guidance on the meaning of "adjacent" to the anatomical origin and insertion points. While the Specification refers to these locations generally (Spec. ¶¶ 30, 34), there is no definition of the term "adjacent" and Appellant did not direct us to an example in the Specification of a location that is "adjacent" to anatomical origin and insertion points. Reply Br. 3. In the absence of such a definition, the Examiner reasonably consulted a general purpose dictionary and

interpreted "adjacent" to mean in the "vicinity of" or "near something."[4] Ans. 10. Appellant contends that the Examiner's interpretation is not the broadest reasonable interpretation of the disputed phrase, but did not identify a specific defect in the Examiner's interpretation nor provide their own interpretation. Reply Br. 2–3.

Consequently, we agree with the Examiner that the term "adjacent" means "nearby" and that the fixation devices must therefore be fixated nearby the ligament's anatomical origin and insertion points.

The Examiner found that the over-the-top and bone tunnel locations meet the claimed limitations of a fixation device "secured adjacent to the repaired or replacement ligament's anatomical" origin point or insertion point. Ans. 3–4, 11.

Appellant contends that the Examiner erred because "Anatomical origin and insertion points do not occur within the bone but rather at the interface between the ligament and the bone surface." Reply Br. 2 (emphasis added). This argument is not persuasive. The claim does not recite that the fixation occurs "at" these points, but rather "adjacent" to them.

Appellants also argue:

> The interpretation that "within a few inches" is still "adjacent" to the anatomical origin and insertion points is also not consistent with the meaning that those of ordinary skill in the art would reach. Persons of ordinary skill in the art in the field of surgery would understand that a "few inches" is a rather large distance as it relates to anatomy and performing surgical procedures. In this

[4] 1a : not distant : NEARBY (https://www.merriam-webster.com/dictionary/adjacent) (last accessed January 13, 2019)

> case, a more reasonable interpretation of "adjacent to" would be within a few millimeters rather than within a few inches.

Reply Br. 3.

However, Appellant has not established that the over-the-top[5] and bone tunnel locations are inches away from the insertion and origin points, rather than millimeters away. And more importantly, Appellant has not provided objective evidence as to why one of ordinary skill in the art would have interpreted the term "adjacent" to exclude certain distances and not others. Rather, Appellant has relied on unsupported attorney argument. An argument made by counsel in a brief does not substitute for evidence lacking in the record. *Estee Lauder, Inc. v. L'Oréal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997).

Appellant also states that "the ligament augmentation device of *Kdolsky* (i.e., the alleged reinforcement construct) is not secured 'adjacent' to the composite graft (i.e., the alleged repaired or replacement graft)." Appeal Br. 7.

"*securing a reconstruction system adjacent to a repaired or replacement ligament*"

Claim 45 recites "securing a reconstruction system adjacent to a repaired or replacement ligament." The system is "a reinforcement construct secured by fixation devices." We interpret the claim to require that the replacement construct, itself, to be "adjacent" to the ligament, or what Appellant refers to as the "composite graft."

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[5] Appellant does not provide any guidance whatsoever *where* the "over-the-top" location is on the knee in relation to the anatomical origin or insertion point of the ligament.

Kdolsky teaches that the ligament was (1) "augmented with the ligament augmentation device by the over-the-top route" (FF3) and that (2) "the proximal route of the augmentation device was with the graft through the same bone tunnel in the femoral condyle (parallel augmentation route)" (FF4).

In the (2) bone tunnel embodiment, Kdolsky explicitly teaches that device is "with" the graft (FF4), providing evidence that it is nearby and therefore adjacent to it as the claim requires. Ans. 11. Appellant contends "the augmentation device is not routed through any tunnel in the *Kdolsky* method" (Appeal Br. 8), yet ignores the explicit disclosure in Kdolsky that "the proximal route of the augmentation device was with the graft through the same bone tunnel in the femoral condyle (parallel augmentation route)" (emphasis added) (FF4).

In the (1) over-the-top route, Appellant contends:

> The "over-the-top route" would not position the ligament augmentation device "adjacent to" the composite graft. Instead, as is known in the art, the over-the-top route passes the graft over the superomedial border of the lateral femoral condyle so it can be fixated on the lateral femoral shaft. These fixation locations of the ligament augmentation device are not "adjacent" to the composite graft, let alone adjacent to the anatomical origin or insertion points.

Appeal Br. 7.

Appellant describes the graft position in Kdolsky as being passed over the condyle, but does not describe the position of the augmentation device. However, Kdolsky, in fact, discloses the position of the augmentation device. Kdolsky teaches that "[s]ince 1987, the proximal routing for the augmentation device has been over the top through the posterior capsule (divergent augmentation route)." FF5. Thus, the path of the augmentation

device is the same over-the-top path as Appellant admits is the path of the graft. Accordingly, it was reasonable for the Examine to conclude that Kdolsky describes "a reconstruction system adjacent to a repaired or replacement ligament" as required by the claim.

For the foregoing reasons, the anticipation rejection of claim 45 is affirmed. Claims 49, 51, 61 and 62 were not argued separately and fall with claim 45.

2. OBVIOUSNESS BASED ON KDOLSKY AND DREYFUSS

Claim 50

Claim 50 depends from claim 45, and further recites that the reinforcement construct is a biological construct.

The Examiner found that Dreyfuss describes "the use of a biological construct, which is fully capable of being used as a reinforcement construct for surgical repair, in the same field of endeavor, for the purpose of facilitating the healing of the original ligament after the operation." Final Act. 6.

Appellant states that Kdolsky teaches away from the modification. Appellant argues:

> The entire purpose of *Kdolsky* was to study the long term clinical performance of patients in whom a ruptured ACL was treated using the braided polypropylene augmentation device. *See* pages 1–2. Therefore, replacing the braided polypropylene augmentation device of *Kdolsky* with the biological construct of *Dreyfuss* would defeat the entire purpose for which the *Kdolsky* study was conducted in the first place. Thereby, a biological construct would render the *Kdolsky* augmentation device unsatisfactory for its intended purpose. The proposed modification is therefore improper.

Appeal Br. 11.

Appellant's arguments is not persuasive. As found by the Examiner, Dreyfuss teaches that surgical sutures and tapes can be made of biological materials. Dreyfuss ¶¶ 7–9, 16, 17. The Examiner's position is that it would have been obvious to have used the biological construct in Dreyfuss in place of the braided polypropylene augmentation device of Kdolsky. We agree. As held in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007):

> [I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. . . . [A] court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

Appellant did not provide evidence or adequate arguments as to why the biological material in Dreyfuss would not work nor did Appellant explain why it would not have been obvious to use it in place of Kdolsky's augmentation device. Appellant appears to be arguing that because Kdolsky was studying the performance of the braid, there would be no reason to replace it. But the Examiner gave reasons as indicated above (Final Act 6, Ans. 16). In addition, the Examiner stated:

> Based on the teachings of Dreyfuss, one of ordinary skill would have been motivated to replace the synthetic augmentation device of Kdolsky, which is known to cause chronic inflammation (see Kdolsky page 1, column 1), with a biological construct in order to reduce the risks of inflammation and to promote healing.

Ans. 16.

Thus, substituting the biological material of Dreyfuss in Kdolsky would not change its principle of operation as stated by Appellant, but would address a problem associated with it.

Claims 53 and 54

Claims 53 and 54 are argued by Appellant. The claims are reproduced below:

> 53. The method of surgical repair of claim 49, wherein the suture construct is a suture tape.
>
> 54. The method of surgical repair of claim 49, wherein the suture construct is a collagen tape.

The Examiner found that "Dreyfuss teaches (figures 1–2; [0023]–[0024]) the use of a surgical suture (100) formed from collagen, the collagen is provided as a suture tape for the purpose of enhancing the wound healing effect." Final Act. 7. The Examiner concluded it would have been obvious to one having ordinary skill in the art, at the time the invention was made, "to combine the braided polypropylene augmentation device of Kdolsky with a collagen tape, as taught by Dreyfuss, in order to enhance the wound healing effect. *Id.*

Appellant states that the Examiner's reasoning is conclusory. Appeal Br. 12. We do not agree. The Examiner explained the collagen would promote wound healing and further clarified that the augmentation device can cause inflammation and that the collagen would reduce the risk of inflammation and promote healing (Ans. 16). Thus, the Examiner provided a logical and scientific basis for determination that the claims are obvious. Appellant did not demonstrate an error in this reasoning and we find none.

The obviousness rejection of claims 50, 53, and 54 is affirmed. Claims 46–48, and 52 fall with these claims because separate reasons for their patentability were not provided. 37 C.F.R. § 41.37(c)(iv).

OBVIOUSNESS REJECTION 3, 4, AND 5

Appellant makes the same arguments for obviousness rejections 3, 4, and 5 (as numbered above) as they did for claim 45. Appeal Br. 12–17. Thus, the rejections are affirmed for the same reasons.

TIME PERIOD

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