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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/206,892	08/18/2005	Paul Re	H-US-01409	7657
50855	7590	02/04/2013	EXAMINER	
Covidien I.P 555 Long Wharf Drive Mail Stop 8N-1, Legal Department New Haven, CT 06511			BOLES, SAMEH RAAFAT	
			ART UNIT	PAPER NUMBER
			3775	
			NOTIFICATION DATE	DELIVERY MODE
			02/04/2013	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PAUL RE, PETER F. MARSHALL, and JESSE SCOTT DRAKE

Appeal 2011-000397
Application 11/206,892
Technology Center 3700

Before ERIC GRIMES, ERICA A. FRANKLIN, and
JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

BONILLA, *Administrative Patent Judge*.

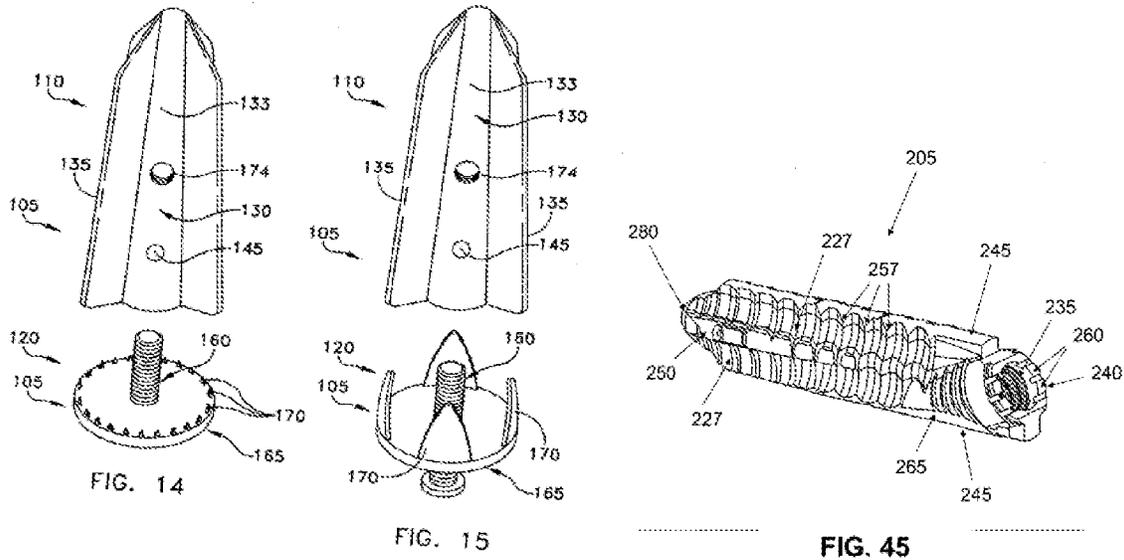
DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims directed to a system for reconstructing a ligament comprising a retainer configured to be disposed in a bone tunnel and a cap with a locking member configured to grip or compress graft ligament strands between the cap and retainer. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The Specification describes apparatuses for reconstructing a ligament, such as the anterior cruciate ligament (ACL) of the knee (Spec. 1-2).

Figures 14, 15, and 45 show embodiments.



Figures 14 and 15 depict different ligament fixation systems, each comprising a retainer (110) with grooves (130), and a locking cap (120) (Spec. 17-18). The retainer is disposed in a tibial tunnel, with graft ligament strands running alongside the retainer in the grooves (not shown) (*id.* at 20). A locking pin (not shown) pins the retainer to the host bone. The locking cap is secured to the retainer, and in the process secures graft ligament strands to the retainer (*id.* at 17-18, 29) (*see also* Fig. 81). The locking cap may include a plurality of distally-projecting fingers (170) (*id.* at 23).

Figure 45 depicts retainer (205) comprising four grooves (227) for receiving graft ligament strands, and a crosshole (235) for receiving a locking pin, and mounting shoulder (240) for seating graft ligament strands and a locking cap (*id.* at 35-36).

Claims 1-7, 10-26, 34-41, 43, 45-62, and 88 are on appeal.

Independent claims 1 and 34 are representative and read as follows:

1. A system for reconstructing a ligament by fixing at least one graft ligament strand in a bone tunnel, comprising:

a retainer for disposition in the bone tunnel, wherein the retainer comprises at least one longitudinally-extending groove formed in the outside surface of the retainer, wherein the groove is configured to seat a graft ligament strand therein, and further wherein the at least one longitudinally-extending groove has a floor which is ramped radially outwardly as the floor extends distally-to-proximally, such that non-rotational advancement of the retainer into the bone tunnel will apply a compressive force to hold the graft ligament strand against the sidewall of the bone tunnel, and wherein the retainer comprises a transverse bore extending therethrough;

a locking pin sized to pass through the transverse bore and into the sidewall of the bone tunnel so as to fix the retainer in place within the bone tunnel; and

a cap including at least one locking member configured to engage the retainer to facilitate gripping of the at least one graft ligament strand between the cap and the retainer.

34. A system for reconstructing a ligament by fixing at least one graft ligament strand in a bone tunnel, comprising:

a retainer configured for disposition in the bone tunnel, the retainer including a transverse bore for receiving a locking pin and a mounting shoulder formed about the transverse bore; and

a cap removably attached to the retainer for capturing the at least one graft ligament strand by compressing the at least one graft ligament strand between the cap and the retainer, wherein the cap includes at least one locking member configured to engage the mounting shoulder of the retainer to facilitate gripping of the at least one graft ligament strand between the cap and the retainer.

The claims stand rejected under 35 U.S.C. § 103(a) as obvious over Bickley (U.S. Pub. No. 2006/0189991 A1, published Aug. 24, 2006) in view

of Hays et al. (U.S. Pat. No. 6,554,862 B2, issued Apr. 29, 2003) and further in view of Ray et al. (U.S. Pat. No. 5,026,373, issued Jun. 25, 1991).¹

Claims 1-7, 10-26 and 88

The Examiner finds that Bickley discloses the apparatus recited in independent claim 1, except that the reference does not describe “that the retainer comprises at least one longitudinally-extending groove formed in the outside surface of the retainer” (Ans. 4-5). The Examiner finds that Hays discloses a graft ligament anchor comprising a retainer having such grooves (*id.* at 5; *see also* Hays, Figures 24, 26, and 27). Thus, according to the Examiner, it would have been obvious to an ordinary artisan to modify Bickley’s apparatus to include at least one longitudinally-extending groove formed in the outside surface of the retainer, as recited in claim 1. The Examiner notes that the cap in such a modified apparatus would not include “at least one locking member [that] comprises at least one longitudinally-extending projection extending distally away from the cap and configured to engage recess on the mounting shoulder of the retainer,” as recited in dependent claims, but relies on Ray for such teachings, referring to Figure 5 of Ray (*id.* at 5-6).

Appellants argue that the washer (28) in Bickley’s apparatus “does not include a locking member configured to engage any portion of interference screw 12” (App. Br. 5). Appellants further argue that in Hays, the “[s]heath expanding element 700 is not configured to facilitate gripping of a graft ligament strand between itself and the sheath 400” (*id.* at 6). Appellants also

¹ Claims 8, 9, 27-30, 42, 44 and 63-66 have been withdrawn, and claims 31-33 and 67-87 have been cancelled (App. Br. 2).

contend that “Ray does not teach longitudinally extending projections which facilitate gripping of tissue” (*id.* at 9). Appellants assert that “[w]ith regard to the modification of Bickley in view of Ray proposed by the Examiner, to facilitate gripping of a graft ligament in any manner, the projections formed on the end cap of Ray which are received in recesses 58 would have to pierce the graft ligament” (*id.*) Such piercing, according to Appellants, would “result in trauma to the tissue which could lead to complications,” thereby rendering “Bickley’s device unsuitable for its intended purpose” (*id.*).

An issue with respect to the rejection is: Does the Examiner establish by a preponderance of the evidence that claim 1 is obvious over Bickley in view of Hays and further in view of Ray?

Findings of Fact (FF)

1. Bickley discloses a graft anchor comprising an interference screw, cross member, and washer, as shown in Figure 1:

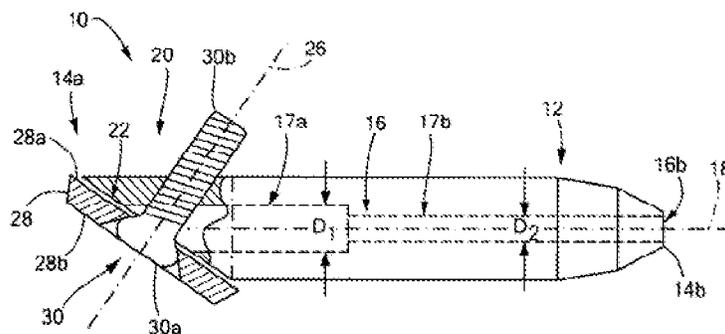


FIG. 1

Figure 1 is a side view of a graft anchor (10) comprising an interference screw (12), where a “portion **20** of the first end **14a** of body **14** corresponds to a so-called ‘head’ of the interference screw **12** and is provided having a

surface 22 onto which a washer 28 is disposed and secured with a cross member 30” (Bickley 2 ¶[0029]).

2. Bickley presents Figures 7 and 7A:

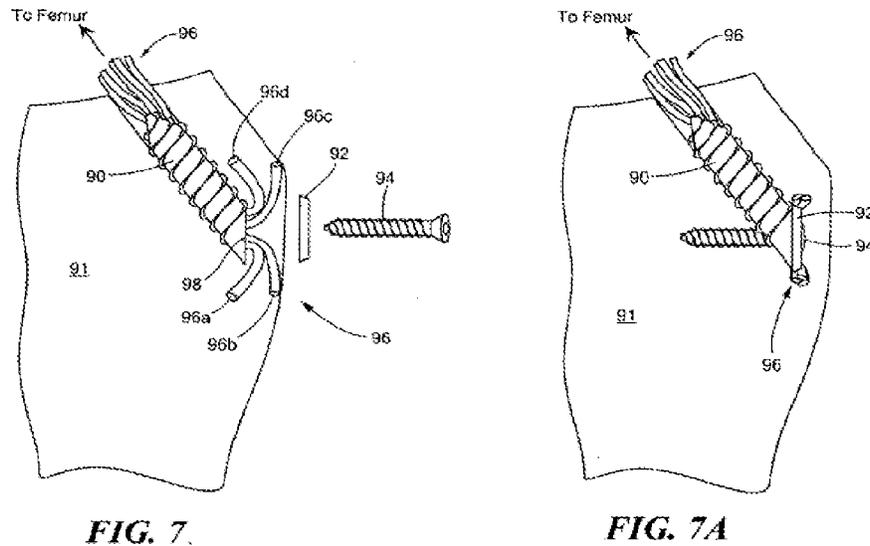


Figure 7 depicts a graft anchor being inserted into a tibia, and Figure 7A depicts the graft anchor after insertion in the tibia. The graft anchor comprises an interference screw (90), a washer (92), and a cross screw (94). The cross screw (94) advances washer (92) such that a surface of the washer compresses the ends of graft ligaments strands (96a-96d) against the angled face (98) of the interference screw (*id.* at 4 ¶[0047]).

3. Bickley teaches that “[b]oth the angled face of the interference screw and the under surface of the washer may be textured or grooved,” which “facilitates keeping the graft ends gathered in place once the graft ends are arranged between the angled face of the interference screw and a surface of the ... washer (... where a washer is used to help secure the grafts in place)” (*id.* at 2 ¶[0014]; *see also* ¶[0029] (describing “grooves, notches, or other

voids provided therein (collectively referred to as a textured surface)” in relation to the washer surface)).

4. Hays describes a graft ligament anchor comprising graft ligament engagement member for disposition in an opening in a bone (Hays, col. 2, ll. 33-42). Hays presents Figure 24:

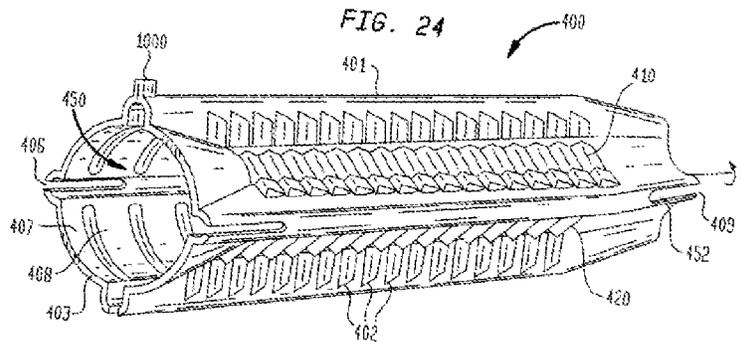


Figure 24 depicts a perspective view of a radially expandable sheath used in an embodiment of a graft ligament anchor.

5. As described in Hays, “sheath 400 is divided into four lon[g]itudinal side wall segments **405**, each having concave outer surfaces which provide regions **410**, **420**, **430**, and **440** where graft material may be disposed between the side wall segments and bone tunnel wall” (*id.* at col. 10, ll. 8-12).

Analysis

Like the Examiner (Ans. 4-5), we find that Bickley discloses the apparatus recited in claim 1, except for the requirement “that the retainer comprises at least one longitudinally-extending groove formed in the outside surface of the retainer” (Ans. 5; FF 1-3). Appellants do not persuade us that Bickley fails to teach or suggest “a cap including at least one locking

member configured to engage the retainer to facilitate gripping of the at least one graft ligament strand between the cap and the retainer,” as recited in claim 1. Figures 1 and 7A in Bickley, as noted by the Examiner (Ans. 4-5, 7 “Figure A”), depict a relevant system comprising a cap, i.e., washer (28) in Figure 1 or washer (92) in Figure 7A (FF 1-2).

As shown in Figures 7 and 7A in Bickley, the cap includes a member that engages the retainer (interference screw (90)) to facilitate gripping of graft ligament strands between the cap/washer and the retainer/interference screw (FF 2). We also note that Bickley teaches that the cap/washer may include textures, grooves, notches, etc., on its surface engaging with the retainer/interference screw, which “facilitates keeping the graft ends gathered in place once the graft ends are arranged between the angled face of the interference screw and a surface of the ... washer (... where a washer is used to help secure the grafts in place)” (Bickley 2 ¶[0014]; ¶[0029]; FF 3). Such textures, grooves, notches, etc., correspond to “at least one locking member” as recited in claim 1.

Regarding the “at least one longitudinally-extending groove” portion of the retainer recited in claim 1, we also agree with the Examiner that Hays teaches or suggests such grooves, and an ordinary artisan would have had reason to modify Bickley’s apparatus to include such grooves on the outside surface of the retainer (interference screw). Specifically, one reading Hays would have had reason to “provide regions ... where graft material may be disposed between the side wall segments and bone tunnel wall” (FF 5; *see also* FF 4; Hays, Fig. 24; *see also id.* at col. 2-3, Summary of the Invention; Ans. 5, 8).

Appellants' assertion that "[s]heath expanding element 700 is not configured to facilitate gripping of a graft ligament strand between itself and the sheath 400," as depicted in Figure 26 of Hays, does not persuade us otherwise (App. Br. 6-7). The Examiner reasonably relied on Hays as a secondary reference that would have suggested a modification of the Bickley apparatus to include "at least one longitudinally-extending groove formed in the outside surface of the retainer" as recited in claim 1 (Ans. 9).

In relation to Ray, Appellants do not persuade us that the Examiner has failed to establish by a preponderance of the evidence that claim 1 is obvious over the cited references. Even assuming Appellants correctly assess that "Ray provides no teaching that would suggest that projections 59 would facilitate gripping of a graft ligament" (App. Br. 9), the primary reference at issue here, Bickley, suggests the use of projections as part of a textured surface for this purpose, as discussed above (*see also* FF 3).

Moreover, contrary to Appellants' assertions, we do not find that Ray teaches or suggests that one must "pierce," and therefore cause "trauma," to a graft ligament when using projections and recesses as described in Ray as a locking member in the cap (washer) in Bickley's apparatus (*see also* Ans. 9-10). Even assuming the projections and recesses of Ray would necessarily pierce a graft ligament, however, Appellants provide no evidence that doing so would render Bickley's apparatus and graft ligaments inoperable. By contrast, *see* Spec. 22 (describing that "to the extent that locking pins 115 pass through the graft ligament 25, the locking pins 115 also serve to secure the graft ligament directly to the bone"—suggesting that piercing a ligament does not render it inoperable). We also disagree with Appellants' assertion

that Ray is non-analogous art with respect to the apparatus of Bickley and Hays for the reasons stated by the Examiner (Ans. 9).

Thus, we conclude that the Examiner establishes by a preponderance of the evidence that claim 1 is obvious over Bickley in view of Hays and further in view of Ray. Because Appellants do not argue dependent claims 2-7, 10-26, and 88 separately (App. Br. 5-10), these claims fall with independent claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

Claims 34-41, 43, and 45-62

Another issue with respect to the rejection is: Does the Examiner establish by a preponderance of the evidence that claim 34 is obvious over Bickley in view of Hays and further in view of Ray?

Although independent claim 34 differs in certain respects from independent claim 1, and Appellants argue claims 34-41, 43, and 45-62 separately, Appellants provide essentially the same arguments addressed above (App. Br. 10-12). For example, Appellants again assert that the washer in Bickley's apparatus "does not include a locking member configured to engage any portion of the interference screw" (*id.* at 11). Regarding Hays, Appellants assert that the "sheath expanding element is not configured to facilitate gripping of a graft ligament strand between itself and the sheath" (*id.*). Appellants also contend that "Ray does not teach longitudinally extending projections which facilitate gripping of tissue" (*id.*), and that "the projections formed on the end cap of Ray which are received in recesses 58 would have to pierce the graft ligament," thereby rendering "Bickley's device unsuitable for its intended purpose" (*id.* at 12).

For the same reasons discussed above, Appellants do not persuade us that the Examiner fails to establish by a preponderance of the evidence that claim 34 is obvious over Bickley in view of Hays and further in view of Ray. Because Appellants do not argue dependent 35-41, 43, and 45-62 separately (App. Br. 10-13), these claims fall with independent claim 34. 37 C.F.R. § 41.37(c)(1)(vii).

SUMMARY

We affirm the rejection of claims 1-7, 10-26, 34-41, 43, 45-62, and 88 as obvious over Bickley in view of Hays and further in view of Ray.

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).

AFFIRMED

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