



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/522,611	09/20/2012	Jörg Mayer	FRG-35911	1093
40854	7590	10/17/2019	EXAMINER	
RANKIN, HILL & CLARK LLP 38210 GLENN AVENUE WILLOUGHBY, OH 44094-7808			SIPP, AMY R.	
			ART UNIT	PAPER NUMBER
			3775	
			NOTIFICATION DATE	DELIVERY MODE
			10/17/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

40854@rankinhill.com
spaw@rankinhill.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JÖRG MAYER, MILICA BERRA, ANDREA MUELLER,
STEPHANIE GOEBEL-MEHL, ANDREAS WENGER, and
ELMAR MOCK

Appeal 2018-008027
Application 13/522,611
Technology Center 3700

Before LINDA E. HORNER, MICHELLE R. OSINSKI, and
BRANDON J. WARNER, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 11–15, 17, 20–22, and 26–28. Final Office Action (Sept. 14, 2017, “Final Act.”). We have jurisdiction under 35 U.S.C. § 6(b).

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 SportWelding GmbH. Appeal Br. 3.

The Examiner rejected the claims as unpatentable over various combinations of prior art. Appellant argues that the Examiner used impermissible hindsight to pick and choose features from the prior art and has failed to provide adequate reasoning to explain why one having ordinary skill in the art would have been led to modify the prior art in the manner claimed. Appeal Br. 19–20.

For the reasons explained below, we agree with Appellant that the Examiner has failed to provide adequate reasoning to support the determination of obviousness. Thus, we REVERSE.

CLAIMED SUBJECT MATTER

The claimed subject matter on appeal relates to fastening tissue or a prosthetic element, i.e., a graft, in an opening in a bone. Spec. 1:4–6, 7:2–6. The graft is fastened to the bone by press-fitting the graft in the opening using a fastener to clamp the graft against a first portion of the wall of the opening and anchoring the fastener in a second portion of the wall of the opening through a positive-fit connection between an anchoring element and the second wall portion. *Id.* at 7:18–24, Figs. 1(a)–1(f). The positive-fit connection is achieved using an anchoring element comprising a material that can be liquefied by the application of energy. *Id.* at 8:14–15. The anchoring element is liquefied *in situ* such that the liquefied material penetrates the bone tissue. *Id.* at 8:16–18. Once the anchoring element material re-solidifies, it creates an anchorage to the bone. *Id.* at 8:18–19.

Claim 11 is representative of the subject matter on appeal and is reproduced below, with the limitation relevant to the outcome of this appeal shown in italics.

11. A set for fastening tissue or a prosthetic element inside an opening provided in a human or animal bone, the set comprising a fastener, the fastener comprising:
- a proximal face,
 - a distal end,
 - a fastener axis extending between the proximal face and the distal end and a circumferential surface extending around the fastener axis, and
 - the fastener defining a guiding portion and further comprising at least one first portion of the circumferential surface and at least one second portion different from the first portion of the circumferential surface,
- the set further comprising at least one anchoring element and an anchoring tool,
- wherein the anchoring element comprises a material having thermoplastic properties, and
 - the anchoring tool comprises a distal end adapted to the anchoring element and is capable of transmitting energy to the anchoring element and advancing the anchoring element relative to the fastener,
- the set further comprising a guide tool,
- the guide tool comprising a distal end adapted in cross section to a proximal cross section of the fastener and further comprising a through channel adapted in cross section to a distal portion of the anchoring tool,
- wherein the distal end of the guide tool is adapted to hold the fastener,
- wherein the first portion comprises at least one first sector and is equipped for anchoring the fastener inside an opening,
 - wherein said guiding portion comprises a material having thermoplastic properties or is equipped to guide a material having thermoplastic properties to the at least one first portion,

wherein the second portion comprises at least one second sector designed as a pressing sector, said pressing sector being capable of clamping a tissue or prosthetic element against an inside wall of the opening, whereby the fastener is equipped for fastening the tissue or prosthetic element to the inside wall of the opening,

wherein the at least one second sector is at least one of:

flat, or substantially smooth, or comprises one of: a retainer or an axial shallow groove for accommodating the tissue or prosthetic element or a strand thereof,

wherein the proximal face of the fastener comprises a stepped profile, and

wherein the distal end of the guide tool comprises a stepped profile, the guide tool stepped profile meshing with the fastener stepped profile in such a manner as to prevent the fastener from rotating, and

wherein said fastener stepped profile defines a unique radial orientation position of the fastener.

Appeal Br. 27–28.

EVIDENCE

The Examiner relies on the following evidence in the grounds of rejection on appeal.

Simonian	US 6,099,530	Aug. 8, 2000
Aeschlimann	US 2004/0030341 A1	Feb. 12, 2004
Dorawa	US 2009/0018590 A1	Jan. 15, 2009
Schmieding	US 2009/0192546 A1	July 30, 2009
van der Burg ("Burg") ²	US 2010/0121348 A1	May 13, 2010

² The Examiner refers to this reference as "Burg." Final Act. 7. We do likewise for consistency.

REJECTIONS³

The following rejections under pre-AIA 35 U.S.C. § 103(a) are on appeal:

1. Claims 11–13, 15, 17, 20–22, and 26–28 are rejected as unpatentable over Simonian, Schmieding, Aeschlimann, and Burg.
2. Claim 14 is rejected as unpatentable over Simonian, Schmieding, Aeschlimann, Burg, and Dorawa.

ANALYSIS

Rejection of claims 11–13, 15, 17, 20–22, and 26–28

Claim 11 recites a set for fastening tissue or a prosthetic element inside an opening in a bone comprising a fastener, an anchoring element, an anchoring tool, and a guide tool. Appeal Br. 27–28. These claimed elements are shown in Figure 1(e), which is reproduced below, and has been annotated to identify the claimed elements.

³ The Final Office Action included a rejection of claim 11 under pre-AIA 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement, and of claims 11–15, 17, 20–22, and 26–28 under pre-AIA 35 U.S.C. § 112, second paragraph, as being indefinite. Final Act. 4–6. Later, the Examiner agreed to enter Appellant’s amendment to the claims that overcame these rejections. Adv. Act. 1–2.

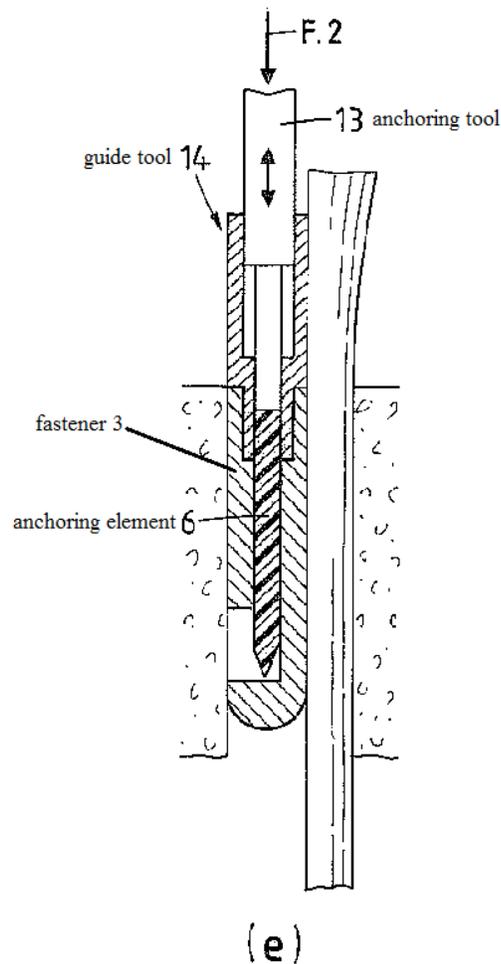


Figure 1(e) shows a phase of an exemplary extra-graft fixation in a bone tunnel using an exemplary embodiment of the invention.

Claim 11 recites that the guide tool has “a distal end adapted in cross section to a proximal cross section of the fastener” and “is adapted to hold the fastener” and the guide tool further has “a through channel adapted in cross section to a distal portion of the anchoring tool.” *Id.* at 27. The distal end of the guide tool also “comprises a stepped profile” that meshes with a stepped profile on the fastener “in such a manner as to prevent the fastener from rotating” relative to the guide tool. *Id.* at 28.

In the rejection of claim 11, the Examiner found that Simonian discloses a fastener 100 having a circumferential surface (defined by the

surfaces of channels 108, 110, 112, 114 and securing members 116, 118, 120, 122), and defining a guiding portion 138, at least one first portion (securing members) 116, 118, 120, 122 of the circumferential surface capable of anchoring fastener 100 inside the bone opening, and at least one second portion (channels 108, 110, 112, 114) different from the first portion of the circumferential surface in the form of an axial shallow groove for accommodating tissue and capable of use as a pressing sector to clamp tissue against the inside wall of the opening. Final Act. 7–8 (citing Simonian, Fig. 3).

The Examiner found that Burg teaches a set comprising a fastener 401 and a guide tool 400, where the distal end of the guide tool is adapted to hold the fastener, and wherein the proximal face of the fastener and the distal end of the guide tool comprise cooperating stepped profiles that prevent the fastener from rotating relative to the guide tool. Final Act. 15 (citing Burg, Figs. 26A, 26B, 27B, 28).

The Examiner determined that one having ordinary skill in the art would have been led to modify the fastening device of Simonian to add a stepped portion to the proximal end of the fastener and to add a cooperating stepped portion to the guide tool,⁴ as taught by Burg, “in order to stabilize

⁴ Simonian does not disclose a guide tool. The Examiner determined that one having ordinary skill in the art would have been led to modify Simonian’s device to include: (1) openings in the guiding portion (cannulation 138) of Simonian’s fastener, (2) an anchoring element (containing growth material); and (3) an anchoring tool, which includes a guide tool, as taught by Schmieding, and to further modify the anchoring element and anchoring tool to use a thermoplastic liquefiable material and ultrasound resonator, as taught by Aeschlimann. Final Act. 16.

and prevent any inadvertent rotation of the fastener (Burg ¶ 114) as rotation of the set is not required for insertion into a bone tunnel (Simonian col. 3 lines 47-49 and col. 4 lines 33-35) and inadvertent rotation could result in shifting between the soft tissue implant and the fastener and subsequently result in damage to the soft tissue implant.” Final Act. 17. We examine Simonian and Burg and the Examiner’s articulated reasoning for their combination.

Simonian discloses a fixation device for securing soft tissue to bone. Simonian, 1:5–8. The embodiment relied on by the Examiner is depicted in Figure 3 of Simonian, reproduced below.

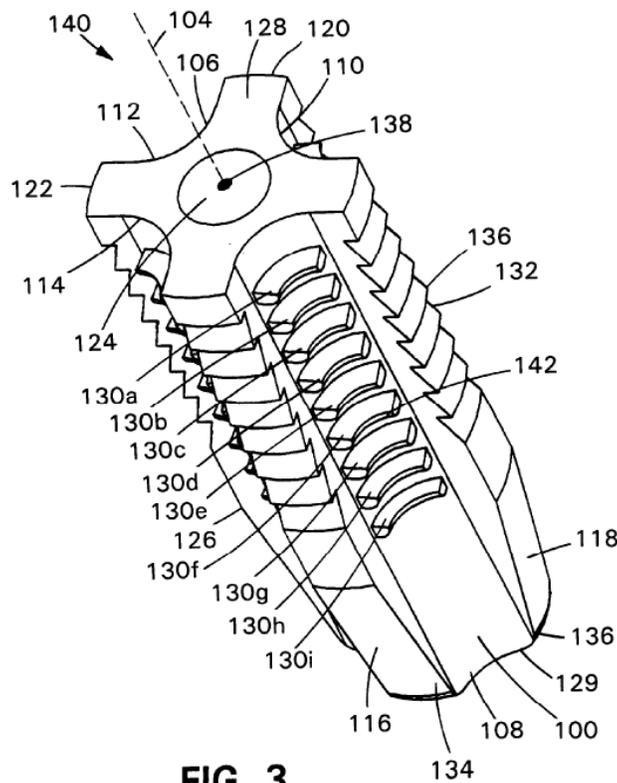


Figure 3 shows a soft-tissue fixation device.

Simonian describes that cannulation 138 runs through device body 106 for receiving a guidewire to aid in inserting fixation device 100 into bone tunnel 18. *Id.* at 4:27–29. In use, the guidewire is positioned through bone tunnel 18, fixation device 100 is passed over the guidewire into bone tunnel 18 with the aid of an insertion tool, not shown, located within recess 124. *Id.* at 4:29–33. Recess 124 is located on proximal end 128 of device body 106, and is shown as being circular in shape. *Id.* at 4:4–5, Fig. 3. Simonian describes that fastening device 100 is inserted into bone tunnel 18 and “neither rotation of the fixation device or [sic] insertion of [a] second member to expand the device or wedge the device in place is required to position the fixation device within the bone tunnel.” *Id.* at 4:34–37.

Burg discloses an insertion tool to secure a knotless suture anchor in bone and to adjustably apply tension to a suture. Burg ¶ 10. Figure 26B of Burg, reproduced below, shows insertion tool 400 in use with knotless suture anchor 401. *Id.* ¶ 53.

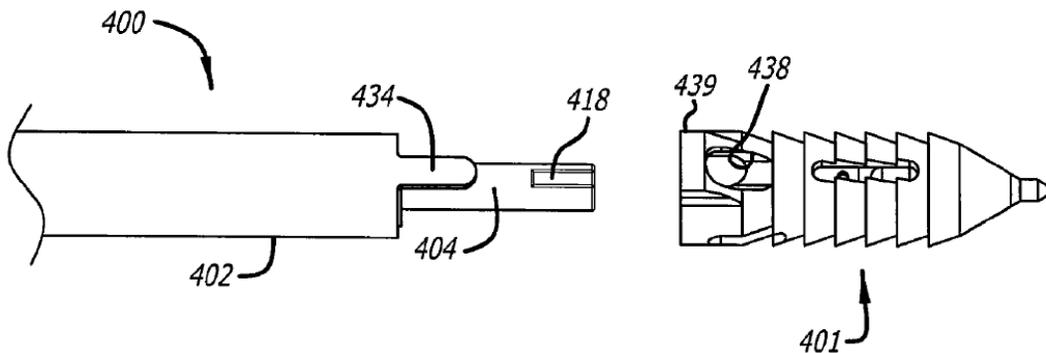


FIG. 26B

Figure 26B shows a partial side view of the distal end of insertion tool 400 as it is being inserted into knotless suture anchor 401.

Burg describes that insertion tool 400 includes outer shaft 402 and inner shaft 404, each having handle 406, 410, respectively (not visible in Figure 26B). Burg ¶¶ 112. These handles are used by the surgeon to hold outer shaft 402 stationary while rotating inner shaft 404 to wind the suture onto the knotless suture anchor. *Id.* ¶¶ 112, 116. In this embodiment of Burg, inner shaft 404 has notch-shaped engaging member 418 on its distal end that is configured to engage a pin (not visible in Figure 26B) in suture anchor 401. *Id.* ¶ 113. Burg teaches that engaging member 418 on tool 400 is shaped to matingly engage pin (or a similar element) in suture anchor 401 “for the purpose of rotating an inner tubular member 433 [(not visible in Figure 26B)] of the knotless suture anchor.” *Id.* ¶ 113. Burg describes that “[w]hen the inner shaft 404 of the insertion tool 400 is rotated to impart a rotational force to the inner tubular member of the knotless suture anchor, the outer shaft 402 of the insertion tool is used to stabilize and prevent any inadvertent rotation of the outer tubular member of the knotless suture anchor.” *Id.* ¶ 114. To prevent such rotation of outer tubular member 439 of suture anchor 401, Burg discloses protrusion 434 on the distal end of outer shaft 402 which engages aperture 438 in outer tubular member 439. *Id.*

The Examiner’s proposed modification to add a stepped profile to the distal end of a guide tool that is used in combination with Simonian’s fastener is not supported by adequate reasoning. For instance, Simonian’s fastener 100, shown in the Figure 3 embodiment relied on by the Examiner, is not a knotless suture anchor of the type disclosed in Burg having a rotatable inner tubular member. Thus, the problem addressed by Burg’s engaging protrusion 434 and aperture 438, i.e., to prevent outer tubular member 439 of the suture anchor from rotating during rotation of inner

tubular member, is not present in the embodiment of Figure 3 of Simonian. Further, the Examiner has provided no evidence that potential rotation of this fastener is a problem during insertion of Simonian's fastener into the bone opening. As discussed above, Simonian's fastener is press-fit in the hole using an insertion tool. Even if one were to modify Simonian to add the openings, anchoring element, and anchoring tool of Schmieding/Aeschlimann, the Examiner has not shown how such a modification would present a rotational component or potential problem with rotation of the fastener⁵ that would need to be solved with Burg's protrusion on the distal end of the insertion tool.

We recognize that Simonian discloses alternative fixation device 60 that calls for rotation of inner member 90 to deploy projections 86 into channels 66, 68, 70, 72. Simonian, 5:11–21, Figs. 5, 6. The Examiner expressly disavowed reliance on this embodiment of Simonian in the rejection. Ans. 5 (noting, in response to Appellant's discussion of the embodiment of Figures 5 and 6, that "the cited embodiment is that of Fig[ure] 3"). We decline to opine for the first time on appeal whether this alternative embodiment may suffer from a problem of inadvertent rotation of the outer portion of the fixation device similar to that discussed in Burg.

The Examiner's reasoning for modifying Simonian with the teachings of Burg "to align" the fastener and the tool (Ans. 14) and to prevent

⁵ Although Schmieding discloses a fixation device in the form of a bone screw that is rotated during insertion into the bone channel, the Examiner explained in the Answer that "[t]he combination does not propose rotating the device of Simonian Fig. 3" and that Schmieding is relied on to teach "adding openings, growth material/anchoring element, [and anchoring] tool." Ans. 4.

“inadvertent rotation” of the fastener (Final Act. 17; Ans. 14) is inadequate, because the Examiner has not provided sufficient evidence showing that one having ordinary skill in the art implanting Simonian’s fastener would have been concerned with rotational alignment of the fastener and the tool, or would have had any problem with inadvertent rotation of the fastener. For these reasons, the Examiner has failed to articulate adequate reasoning for the proposed modification of Simonian with the teachings of Burg. Thus, we do not sustain the rejection of independent claim 11 and its dependent claims 12, 13, 15, 17, 20–22, and 26–28 under 35 U.S.C. § 103(a).

Rejection of claim 14

The Examiner adds Dorawa to the underlying combination of Simonian, Schmieding, Aeschlimann, and Burg in the rejection of dependent claim 14. Final Act. 17–19. The Examiner does not rely on Dorawa to cure any of the above-noted deficiencies in the modification of Simonian with the teachings of Burg relied on in the rejection of independent claim 11. *Id.* at 19 (proposing to enlarge the diameter of the inner fastener cavity with the teachings of Dorawa). Thus, for the same reasons discussed above, we likewise do not sustain the rejection of claim 14 under 35 U.S.C. § 103(a).

DECISION

The decision of the Examiner rejecting claims 11–15, 17, 20–22, and 26–28 is reversed.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
11–13, 15, 17, 20–22, 26–28	§ 103(a) Simonian, Schmieding, Aeschlimann, Burg		11–13, 15, 17, 20–22, 26–28
14	§ 103(a) Simonian, Schmieding, Aeschlimann, Burg, Dorawa		14
Overall Outcome			11–15, 17, 20–22, 26–28

REVERSED