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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ALESSIO PIGAZZI and GLENN KEILAR,
Appellants, Patent Owners

Appeal 2015-007832
Reexamination Control 90/013,088
Patent No. US 8,464,720 B1¹
Technology Center 3900

Before STEVEN D.A. McCARTHY, JEFFREY B. ROBERTSON and
DANIEL S. SONG, *Administrative Patent Judges*.

McCARTHY, *Administrative Patent Judge*.

DECISION ON APPEAL

1 STATEMENT OF THE CASE

2 The Appellant/Patent Owner appeals under 35 U.S.C. § 134(b) and 35
3 U.S.C. § 306 from a final rejection of unamended claims 1–13; and new
4 claims 14, 15, 17, 19, 20, 22–24, 26, 30–33, 36, 38, 43 and 44. Newly-

¹ Patent No. US 8,464,720 B1 (the “’720 patent”) issued June 18, 2013 to the Appellants. The ’720 patent is assigned to KHS GmbH and exclusively licensed to Xodus Medical, Inc., the latter of whom is the real party in interest. The ’720 patent issued from Appl. 13/737,552, filed January 9, 2013.

1 added claims 16, 18, 21, 25, 27–29, 34, 35, 37 and 39–42 are cancelled. We
2 have jurisdiction under 35 U.S.C. § 134(b) and 35 U.S.C. § 306.

3 We REVERSE.

4

5

THE '720 PATENT

6 Independent claims 1, 6 and 10 recite methods for minimizing injuries
7 caused when a patient is supported in on a surgical operating table in an
8 inclined position such as the “Trendelenburg” position.² The Trendelenburg
9 position is a position in which the operating table is inclined so that the
10 patient’s head and upper torso are lower than the patient’s upper legs. (’720
11 patent, col. 1, ll. 46–53 and Fig. 6). One problem associated with placing a
12 surgical patient in the Trendelenburg position is that the patient may slide or

² Claim 4 recites a “single-use Trendelenburg patient support system for performing the method according to claim 1” including “a single-use, viscoelastic Trendelenburg pad.” Claim 5 depends from claim 4. Claim 8 recites a “patient support system for performing the method according to claim 6,” including a viscoelastic pad. Claim 9 depends from claim 8. Claims 12, 33, 36, 38 and 43 recite “patient support system[s] for performing the method according to claim 10,” each such patient support system including a viscoelastic pad. Claim 13 depends from claim 12 and claim 44 depends from claim 12. The Requester and the Examiner treated system claims 4, 5, 8, 9, 12, 13, 33, 36, 38, 43 and 44 as ultimately dependent from one of the independent method claims, 1, 6 or 10. (*See, e.g.*, Request 4, 24–25, 28–29, 31–32, 35–40, 42–43, 45–48, 52 and 57–59; Ans. 4–5, 8–9, 14–15, 21, 22 (relying on the conclusion that “the claim is a method claim” to reject both claim 1 *and* claim 4) and 27–28). Because the Examiner’s reasoning underlying the rejections of claims 4, 5, 8, 9, 12, 13, 33, 36, 38, 43 and 44 is dependent on the Examiner’s conclusion that the subject matter of independent claims 1, 6 and 10 would have been obvious, we do not address the rejections of claims 4, 5, 8, 9, 12, 13, 33, 36, 38, 43 and 44 separately.

1 otherwise move during the surgery due to the effects of gravity. Another
2 problem associated with placing a surgical patient in the Trendelenburg
3 position is that the patient may suffer neuropathy in the shoulders or arms.
4 (*See* '720 patent, col. 1, l. 65 – col. 2, l. 13). The '720 patent addresses these
5 problems by laying the patient on a pad of viscoelastic foam material of
6 suitable thickness and mechanical properties. The patient may lie either
7 directly on the viscoelastic pad or on a lifting sheet covering the viscoelastic
8 pad. (*Id.*)

9 Claim 10 is illustrative:

10 10. A method of minimizing injuries caused by
11 pressure on portions of a body of a patient and minimizing
12 unwanted movement of said patient upon said patient being on
13 a medical procedure table, such as a surgical operating table or
14 a patient examination table, and upon placing said medical
15 procedure table in an inclined, Trendelenburg position, using a
16 patient support system comprising a viscoelastic pad, said
17 method comprising the steps of:

18 A) positioning said viscoelastic pad in a position on
19 said medical procedure table where the body of a patient will be
20 lying;

21 B) positioning said patient on said viscoelastic pad
22 and thereby deforming said viscoelastic pad, which said
23 viscoelastic pad comprises:

24 sufficient thickness and viscosity to sufficiently
25 cushion the body of said patient to at least one of:
26 minimize bottoming out and prevent bottoming out, on
27 said medical procedure table, of one or more of the
28 portions of the body of said patient during positioning of
29 said patient and during a medical procedure, and to
30 minimize injuries from pressure during a medical
31 procedure; and

1 sufficient compliance to conform to a substantial
2 portion of said body of said patient;

3 C) adjusting the angle of inclination of said medical
4 procedure table to orient said patient at an angle in said
5 inclined, Trendelenburg position, in which the head of said
6 patient is disposed below the body of said patient, or in which
7 the head of said patient is disposed above the body of said
8 patient, or in which the right side of said patient is disposed
9 above the left side or vice versa, or a combination of any of
10 these positions; and

11 D) assisting in substantially holding the body of said
12 patient on said medical procedure table using said viscoelastic
13 pad, of which said viscoelastic pad comprises:

14 sufficient thinness to stabilize said patient on said
15 medical procedure table upon said patient being in said
16 inclined, Trendelenburg position; and

17 sufficient thickness and sufficient compliance to
18 permit formation of a cavity in said viscoelastic pad of a
19 depth sufficient to at least one of: assist in holding said
20 patient on said medical procedure table, and assist in
21 minimizing undesired movement of the body of said
22 patient on said medical procedure table, during a medical
23 procedure performed while said patient is in said
24 inclined, Trendelenburg position.

25
26 THE RECORD

27 The Examiner's position is set forth in a Final Office Action, mailed
28 July 11, 2014; and an Answer, mailed June 11, 2015 ("Answer" or "Ans.").
29 The Patent Owner relies on an "Appeal Brief," dated January 9, 2015
30 ("Appeal Brief" or "App. Br."), to which are attached declarations of Dr.
31 Maheswari Senthil, Dr. Gustavo Plasencia, Mr. Craig Kaforey, Dr. Alessio

1 Pigazzi, Dr. Michael Madigan, Dr. Glenn Beltz, Mr. Paul Lloyd and Dr.
2 Thomas Ljungman. Oral argument was held December 14, 2015.

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4 THE GROUNDS OF REJECTION

5 The Examiner rejects claims 6, 8, 10–15, 17, 19, 20, 22–24, 26, 30–
6 33, 36, 38, 43 and 44 under pre-AIA 35 U.S.C. § 103(a) as being
7 unpatentable over Klauschie et al., *Use of Anti-Skid Material and Patient-*
8 *Positioning to Prevent Patient Shifting during Robotic-Assisted Gynecologic*
9 *Procedures*, 17 J. MINIMALLY INVASIVE GYNECOLOGY 504–07 (July–Aug.
10 2010) (“Klauschie”), VanSteenburg (US 6,701,558 B2, issued Mar. 9, 2004)
11 and Tursi (US 6,653,363 B1, issued Nov. 25, 2003). (Ans. 2).³ The
12 Examiner also rejects claims 7, 9, 16 and 18 under § 103(a) as being
13 unpatentable over Klauschie, VanSteenburg, Tursi, Biondo (US 6,817,363
14 B2, issued Nov. 16, 2004) and Bremer (US 4,840,362, issued June 20, 1989)
15 (Ans. 12); claims 1 and 4 under § 103(a) as being unpatentable over
16 Klauschie, VanSteenburg, Tursi, Biondo and Fash (US 2,835,902, issued
17 May 27, 1958) (Ans. 16); and claims 2, 3 and 5 under § 103(a) as being
18 unpatentable over Klauschie, VanSteenburg, Tursi, Biondo, Fash and
19 Bremer (Ans. 24).

³ Although the Answer says that claims 6, 8, 10–15, 17 and 19–42 are rejected as being unpatentable over Klauschie “in view of VanSteenburg, and in the alternative, in further view of Tursi,” the Examiner’s reasoning on pages 2–9 indicates that the rejection relies on the teachings of Klauschie, VanSteenburg and Tursi. Claims 21, 25, 27–29, 34, 35, 37 and 39–42 are cancelled.

1 FIRST GROUND

2 Independent claims 6 and 10 recite methods including the step of:

3 positioning said patient on said viscoelastic pad and
4 thereby deforming said viscoelastic pad, which said viscoelastic
5 pad comprises:

6 sufficient thickness and viscosity to sufficiently
7 cushion the body of said patient to at least one of:
8 minimize bottoming out and prevent bottoming out, on
9 said medical procedure table, of one or more of the
10 portions of the body of said patient during positioning of
11 said patient and during a medical procedure, and to
12 minimize injuries from pressure during a medical
13 procedure; and

14 sufficient compliance to conform to a substantial
15 portion of said body of said patient.

16 Each ground of rejection entered by the Examiner in this reexamination
17 relies on the combined teachings of Klauschie, VanSteenburg and Tursi in
18 finding the claimed methods obvious.

19 Klauschie describes a study to estimate the effect of what the article
20 describes as an “antiskid” material to prevent the shifting of a patient placed
21 in a steep Trendelenburg position during robotic gynecological surgery.
22 (Klauschie 504). During the study, patients were positioned as follows:

23 A 3- × 5-foot piece of blue blanket was placed
24 horizontally on the operating room table, on top of which was
25 placed a 2- × 3-foot antiskid material (egg-crate foam: Tyco
26 Healthcare/Kendall, Mansfield, MA), and a second piece was
27 placed over the initial piece with the flat sides of the foam
28 opposing each other. The pink foam was secured at 2 points
29 with broad strips of cloth tape All patients, positioned in a
30 modified dorsal lithotomy position with legs padded and
31 secured in stirrups (Welch Allyn, Inc., Acton, MA), laid
32 directly on the pink foam on their bare back. Both arms,

1 cradled in soft arm pads (David Scott Co., Framingham, MA)
2 were then tucked to the sides using the blue blanket. No
3 shoulder blocks, straps, or braces were used.

4 (Klauschie 505). According to Klauschie, the study “demonstrate[d] that
5 antiskid material [was] a safe alternative to prevent sliding and subsequent
6 consequences such as pain, neuropathetic injuries, and potential hernias.”

7 (*Id.*) Klauschie teaches that:

8 The Trendelenburg position and the techniques used to
9 prevent cephalad slippage of the patient in this position
10 contribute to nerve injury With increasing reports of
11 neuropathic injury as a result of shoulder braces and straps used
12 to prevent shifting, all members of our practice have
13 implemented the use of antiskid material and patient
14 positioning as described herein, avoiding the use of braces and
15 other devices for at least [five] years previous to this study.

16 (*Id.* at 506).

17 VanSteenburg teaches that, during surgery, “[p]ortions of the patient’s
18 skin may be subjected to very high pressures and shear forces exerted by the
19 material underlining skin[,] resulting in tissue loads that restrict blood flow
20 to a particular area of the skin[,] resulting in tissue damage or necrosis. This
21 is a major cause of ulcers.” (VanSteenburg, col. 1, ll. 23–27). Figure 5 of
22 VanSteenburg describes a combination of a cushion 132 and an anti-shear
23 layer 130 for supporting a patient. The combination is designed to reduce
24 skin shear and distribute the patient’s weight more evenly across the surface.
25 (*See* VanSteenburg, col. 6, l. 65 – col. 7, l. 2; *see also* VanSteenburg, col. 1,
26 ll. 28–36). The cushion 132 is divided into a head pad 72, a torso pad 74
27 and a foot pad 76. Each pad includes a layer of “slow recovery foam” 100,
28 108, 140 atop foam layers having different support characteristics. (*See*

1 VanSteenburg, col. 8, l. 25 – col. 9, l. 22). VanSteenburg describes “slow
2 recovery foam” as “foam material that easily conforms to the contour of the
3 patient when weight is applied and slowly returns to its uncompressed state
4 after the weight is removed.” (VanSteenburg, col. 7, ll. 27–31). The
5 Examiner correctly characterizes “slow recovery foam” as viscoelastic. (*See*
6 *Ans.* 10).

7 VanSteenburg describes each of the head pad 72, the torso pad 74 and
8 the foot pad 76 as being received in a cover 28 and a bottom coverlet 34.
9 VanSteenburg also teaches positioning an anti-shear layer 130 underneath
10 each cover 28, between the layer of “slow recovery foam” 100, 108, 140 and
11 the surface that supports the patient. (*See* VanSteenburg, col. 8, l. 25 – col.
12 9, l. 22). The anti-shear layer 130 comprises a material such as polyethylene
13 disposed between the cushion and the cover to permit the cover to slide
14 freely with respect to the cushion and to permit the cover to stretch without
15 being inhibited by the surface of the cushion. (*See* VanSteenburg, col. 5, ll.
16 3–14). VanSteenburg teaches that the presence of the anti-shear layer
17 reduces skin shear which, if not reduced, might increase the interface
18 pressure between the support surface and the patient’s skin. (*See*
19 VanSteenburg, col. 1, ll. 43–49).

20 Tursi describes a class of flexible, high firmness, temperature
21 sensitive viscoelastic polyurethane foams. (*See* Tursi, col. 3, ll. 21–27; *see*
22 *also id.*, col. 8, ll. 53–60 & Table 1). Tursi teaches the use of these foams in
23 bedding and furniture cushions. (*See, e.g.*, Tursi, col. 1, ll. 5 & 6).

24 With respect to independent claims 6 and 10, the Examiner finds that:
25 while [Klauschie’s] egg-crate foam is not specifically set forth
26 as being viscoelastic, VanSteenburg establishes, in the same

1 field of endeavor, i.e. patient support surfaces, that viscoelastic
2 foams were well known for managing pressure by distributing
3 the patient's weight more evenly across the surface to
4 significantly reduce pressure on the body's boney prominences.
5 VanSteenburg's foam pad is plainly adapted to more evenly
6 distribute the patient's weight.

7 (Ans. 9). The Examiner then concludes that it would have been obvious:

8 given the desire to prevent patient shifting and "*subsequent*
9 *consequences such as pain, neuropathic injuries, and potential*
10 *hernias*" ([Klauschie] 505), to have incorporated viscoelastic
11 foam in [Klauschie's patient] support table, either by replacing
12 the egg-crate foam with viscoelastic foam, or by making the
13 egg-crate foam out of viscoelastic material, in order to adopt the
14 intrinsic benefits of viscoelastic foam in a medical bed
15 environment such as decreased tissue load.

16 (Ans. 10; *see also* Ans. 30 ("Appellant argues that the teaching of increased
17 skin shear cannot be used as a motivation for modifying the patient support
18 of Klauschie[;] however[,] the rejection relies upon the decreased tissue load
19 and inherent properties of viscoelastic foam as a reason to modify the system
20 of Klauschie.")).

21 The Examiner's findings and reasoning are not persuasive. As noted
22 earlier, Klauschie recognizes a need to prevent surgical patients from
23 shifting while in a modified Trendelenburg position. Klauschie teaches that
24 this need may be addressed by placing an "antiskid" material on the surface
25 supporting the patient, regardless whether the undulating surface of "egg-
26 crate foam" actually provides such a surface. (*See* Ans. 29 ("Clearly the
27 intent here is to use anti-skid materials.")). On the other hand,
28 VanSteenburg describes supporting a patient by means of a cushion encased
29 by a cover and a bottom coverlet, where the cushion includes a viscoelastic
30 layer; and an anti-shear layer is positioned between the viscoelastic layer and

1 the cover. (*See generally* VanSteenburg, col. 8, l. 25 – col. 9, l. 22). The
2 Examiner has not shown that one of ordinary skill in that art would have
3 understood VanSteenburg to teach using this combination to support a
4 patient in an inclined position. (*See* “Declaration,” executed by Dr.
5 Maheswari Senthil on April 4, 2014, at ll. 142–44). Neither does
6 VanSteenburg describe the support surface created by this combination as
7 “antiskid” or the like, so as to suggest substitution for the egg-crate foam
8 described by Klauschie.

9 Instead, the Patent Owner and the Examiner appear to agree that
10 VanSteenburg taught, or at least suggested, that placing a patient directly on
11 a viscoelastic foam would have increased skin shear. (*See* App. Br. 24; *see*
12 *generally* Ans. 30 & 31). The Examiner cites this fact as supportive of, or at
13 least neutral with respect to, the Examiner’s conclusion that it would have
14 been obvious substitute a viscoelastic material for Klauschie’s egg-crate
15 foam. (*See* Ans. 30 & 31). The Patent Owner’s experts testify that this
16 teaching regarding an increased risk of skin shear, and the concomitant
17 increased risk of damage to vascular and connective tissues of a patient
18 supported by a viscoelastic foam in an inclined position, would have
19 discouraged one of ordinary skill in the art from substituting a viscoelastic
20 foam for the egg-crate foam described by Klauschie. (*See* App. Br. 24 & 25,
21 citing declarations of Pigazzi, Plasencia, and Ljungman; *see also*
22 “Declaration,” executed by Dr. Alessio Pigazzi on Sept. 10, 2014, at ll. 36–
23 93; “Declaration,” executed by Dr. Gustavo Plasencia on Sept. 8, 2014, at ll.
24 36–93; “Declaration,” executed by Dr. Thomas Ljungman on Sept. 8, 2014,
25 at ll. 98–163). The testimony is persuasive, despite VanSteenburg’s
26 teaching that a viscoelastic foam might distribute the patient’s weight better.

1 In this regard, when VanSteenburg is considered in its entirety, which
2 includes various other layers such as an anti-shear layer and the cover, a
3 person of ordinary skill in the art would have been “led in a direction
4 divergent from the path that was taken by the applicant.” *See In re Gurley*,
5 27 F.3d 551, 553 (Fed. Cir. 1994)). As such, the Examiner has not shown
6 that one of ordinary skill in the art, familiar with the teachings of Klauschie
7 and VanSteenburg, would have had reason to modify the teachings of
8 Klauschie in a fashion satisfying the limitations of independent claim 6 or
9 independent claim 10.

10 The Examiner has not persuasively explained how the teachings of
11 Tursi might remedy the deficiencies in the combined teachings of Klauschie
12 and VanSteenburg. We do not sustain the rejection of claims 6, 8, 10–15,
13 17, 19, 20, 22–24, 26, 30–33, 36, 38 43 and 44 under § 103(a) as being
14 unpatentable over Klauschie, VanSteenburg and Tursi.

16 SECOND, THIRD AND FOURTH GROUNDS

17 In the second ground of rejection, the Examiner cites Biondo as
18 disclosing “straps for engaging portions of the patient’s body” (Ans. 13,
19 citing Biondo, col. 10, ll. 20–24); and Bremer as teaching straps including
20 hook-and-loop material “to secure the board and assemblage to the operating
21 table” (Ans. 13, quoting Bremer, col. 7, ll. 59–64). The Examiner has not
22 persuasively explained how either teaching might remedy the deficiencies in
23 the combined teachings of Klauschie, VanSteenburg and Tursi as applied to
24 claim 6 or claim 10. We do not sustain the Examiner’s rejection of claims 7,
25 9, 16 and 18 under § 103(a) as being unpatentable over Klauschie,
26 VanSteenburg, Tursi, Biondo and Bremer.

1 With respect to the third ground of rejection, the Examiner cites Fash
2 as evidence that “the use of lift sheets for handling patients is notorious to
3 the art.” (Ans. 22). For reasons similar to those discussed in connection
4 with the first ground of rejection, the Examiner has not shown that a method
5 including the step of:

6 laying a patient in a supine position on said lift sheet and
7 said single-use, viscoelastic Trendelenburg pad by positioning
8 said patient so that the shoulders of said patient do not extend
9 past edges of said single-use, viscoelastic Trendelenburg pad,
10 and thereby deforming said single-use, viscoelastic
11 Trendelenburg pad, which said single-use, viscoelastic
12 Trendelenburg pad comprises:

13 sufficient thickness and viscosity to sufficiently
14 cushion the body of said patient to at least one of:
15 minimize bottoming out and prevent bottoming out, on
16 said medical procedure table, of one or more of the
17 portions of the body of said patient during positioning of
18 said patient and during a medical procedure, and to
19 minimize injuries from pressure during a medical
20 procedure; and

21 sufficient compliance to conform to a substantial
22 portion of said body of said patient,

23 would have been obvious from the combined teachings of Klauschie,
24 VanSteenburg, Tursi and Fash. We do not sustain the Examiner’s rejection
25 of claims 1 and 4 under § 103(a) as being unpatentable over Klauschie,
26 VanSteenburg, Tursi, Biondo and Fash.

27 Finally, we also do not sustain the fourth ground of rejection, whereby
28 the Examiner rejects claims 2, 3, and 5 under § 103(a) as being unpatentable
29 over Klauschie, VanSteenburg, Tursi, Biondo, Fash and Bremer, for reasons
30 already discussed.

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DECISION

We REVERSE Grounds 1–4 entered by the Examiner. As a consequence, we REVERSE the Examiner’s decision rejecting claims 1–15, 17, 19, 20, 22–24, 26, 30–33, 36, 38, 43, and 44.

REVERSED

Appeal 2015-007832
Reexamination Control 90/013,088
Patent No. US 8,464,720 B1

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