

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SCOTT DOUGLAS AUGUSTINE

Appeal No. 2005-2706
Application No. 09/771,791

ON BRIEF

Before FRANKFORT, CRAWFORD, and BAHR, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 58 through 70, 75 through 88 and 93 through 95. Claims 71 through 74 and 89 through 92, the only other claims remaining in the application stand withdrawn from further consideration by the examiner. Claims 1 through 57 have been canceled.

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Appellant's invention relates to a surgical barrier device that incorporates an inflatable thermal blanket to control patient body temperature during a medical procedure such as surgery, and a surgical drape that provides a barrier between a surgical field and one or more other fields during surgery, while providing access to the surgical field. Figures 10 and 11 show a first embodiment of appellant's surgical barrier device including an inflatable thermal blanket (320) deployed over the pelvic area and lower extremities of a patient and an integrally formed surgical drape (321) constructed to provide a barrier between a surgical site (362) on the patient's body and the remainder of the patient's body and to allow access to the surgical site via a cutout (364). Figures 12 and 13 show a second embodiment of the invention including an inflatable thermal blanket (420) deployed for thermally bathing the chest and upper extremities of a patient with warm air and an integrally formed surgical drape (421) for covering additional portions of the patient's body and for providing access to a surgical site (462). Third and fourth embodiments of the invention are seen, respectively, in Figures 14 and 15, and Figures 16 and 17. Independent claim 58 is representative of the subject matter on appeal and a copy of that claim can be found in the Appendix I attached to appellant's brief.

The prior art references relied upon by the examiner in rejecting the appealed claims are:

Collins

3,750,664

Aug. 7, 1973

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Irani	5,405,370	Apr. 11, 1995
Augustine et al. (Augustine '482)	5,620,482	Apr. 15, 1997

Claims 58, 59, 61, 63, 69 and 70 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Augustine '482.

Claims 60, 62, 64 through 67, 75 through 85, 87, 88 and 93 through 95 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Augustine '482 in view of Irani.

Claim 68 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Augustine '482 in view of Collins.

Claim 86 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Augustine '482 in view of Irani as applied to claim 75 above, and further in view of Collins.

Rather than attempt to reiterate the examiner's full commentary with regard to the above-noted rejections and the conflicting viewpoints advanced by the examiner and appellant regarding the rejections, we make reference to the final rejection (mailed June 3, 2003) and examiner's answer (mailed January 29, 2004) for the reasoning in support

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of the rejections, and to appellant's brief (filed November 12, 2003) and reply brief (filed March 19, 2004) for the arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by appellant and the examiner. As a consequence of our review, we have made the determinations which follow.

With respect to the examiner's rejection of claims 58, 59, 61, 63, 69 and 70 under 35 U.S.C. § 102(e), we note that Augustine '482 discloses an inflatable thermal blanket or "self-erecting air flow cover" (col. 1, lines 49-50) which may be adapted to thermally control specific partial portions of the patient such as the legs and lower body (Figs. 8-9) or the arms and upper body (Figs. 10-11). As can be seen in Figures 3 and 4, the thermal blanket includes a flexible base sheet (50, 52) and a plastic material sheet bonded to an upper surface of the base sheet by a plurality of sealed seams (40, 54) to form an inflatable portion having a periphery. The base sheet includes a plurality of apertures (62) positioned within the periphery and along the footprints of the tubes forming the inflatable portion so as to allow the thermally-controlled inflating medium therein to escape and bathe the patient's body under the thermal blanket. An end

portion of the blanket may be adhesively attached to the patient (e.g., by adhesive strip 124 of Figures 8-9) to prevent the migration of the inflating medium toward a care area.

The foot ends of the thermal blankets seen in Figures 6-7 and 8-9 are provided with an uninflated drape forming section (70, 170, respectively). The patentee notes (e.g., col. 7, lines 29-33) that the uninflated drape forming section is “formed by a rearward extension of the base sheet 50/52 and a noninflatable portion of the heat-sealable plastic [sheet] bonded to the base sheet.” The uninflated drape forming section is intended to encompass the lower extremities of the patient and to retain heat around the patient’s feet and insulate the bare skin of the legs and/or feet. As shown in Figures 7 and 9, the uninflated drape portions optionally may be formed into a tented foot drape (90, 190) erectable under the force of the heated medium circulating around the patient under the blanket so as to trap and retain heat around the patient’s feet to warm the feet.

With regard to the anticipation rejection, we observe that on page 2 of the reply brief, appellant concedes that Augustine ‘482 includes every element of independent claim 58 except the last, i.e., “a surgical drape attached to, or formed integrally with, the inflatable portion.” According to appellant, no reference to a “surgical drape” can be found in Augustine ‘482. Moreover, appellant contends that the examiner’s position that the rectangular drape forming section (70) of Augustine ‘482 can be used as a sterile

covering to prevent the transportation of microorganisms, and thus be classified as a surgical drape, is mere speculation.

From the record, it is apparent to us that “surgical drapes” are typically made from sheets of flexible, drapable material which are impervious or resistant to the passage of body fluids or other liquids. Sterile surgical drapes are conventionally employed to cover portions of the body of a medical patient during an operative procedure to provide a barrier to prevent contamination of such body portions by blood or other body fluids. Thus, as appellant has indicated (brief, page 10), a surgical drape is generally used to form an aseptic field to prevent transportation of microorganisms during a surgical procedure.

Looking to the structure of the inflatable thermal blanket seen generally in Figure 6 of Augustine ‘482 and described at column 7, lines 28-36, we note that while the word “surgical drape” is not used to identify the uninflated drape forming section (70) therein, that portion of the barrier device of the patent is clearly recognized as being a “drape” formed as a rearward extension of the base sheet 50/52 and the noninflatable portion of the heat-sealable plastic sheet bonded to the base sheet. Thus, the plastic laminate material of the drape forming section (70) would have been recognized by those skilled in the art as being impervious or resistant to the passage of body fluids or other liquids. Moreover, it is readily apparent to us that the thermal blanket of Augustine ‘482 is

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usable to cover portions of the body of a medical patient during an operative procedure and in so doing would provide a barrier to prevent contamination of such body portions by blood or other body fluids. Accordingly, as the examiner has concluded, the drape forming section (70) in Augustine '482 would form an aseptic field to prevent transportation of microorganisms during a surgical procedure, and when used in that environment would be a "surgical drape."

Appellant's claim 58 is directed to the apparatus *per se*, not to the particular intended use set forth in the claims. Accordingly, while features of the apparatus may be recited either structurally or functionally, claims directed to the apparatus must distinguish from a prior art apparatus in terms of the structure rather than the function. See, e.g., In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In view of the foregoing, we conclude that there is no structural difference between the combination barrier device set forth in claim 58 on appeal and that described in Augustine '482. Claim 58 is directed to a combination "for use during surgery on a person." The combination thermal blanket and drape (70) of Augustine '482 discussed above includes all of the elements set forth in claim 58 and is clearly usable during surgery on a person.

Like the examiner (answer, pages 3-4), we find no requirement that a "surgical drape" must necessarily be used in a position directly adjacent a surgical site or be provided with an opening to provide access to a surgical site. A sheet formed of a

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flexible drapable material suitable for preventing strike-through of blood and other body fluids which is intended to cover a portion of a patient's body during a surgical procedure and thus form a barrier which defines an aseptic field to prevent transportation of microorganisms is a "surgical drape," whether it is used at a location directly adjacent a site of the surgery or laid across a patient's lower body or feet to protect that portion of the patient's body from exposure to blood and other body fluids encountered during surgery. Nor, in our view, does it matter that the "surgical drape" might also provide an additional benefit of holding heat in an area adjacent the patient's body, like the drape forming section (70) of Augustine '482.

Having found that the combination thermal blanket and drape of Augustine '482 is structurally the same as that broadly set forth in independent claim 58 on appeal, we will sustain the examiner's rejection of that claim under 35 U.S.C. § 102(e). Given appellant's indication on page 9 of the brief that dependent claims 59, 61, 63, 69 and 70 are intended to "stand or fall together" with claim 58, we also sustain the examiner's rejection of claims 59, 61, 63, 69 and 70 under 35 U.S.C. § 102(e).

Regarding the rejection of claims 60, 62, 64 through 67, 75 through 85, 87, 88 and 93 through 95 under 35 U.S.C. § 103(a) as being unpatentable over Augustine '482 in view of Irani, the examiner recognizes that Augustine '482 does not provide any

structure like that recited in these claims wherein the inflatable portion includes a recess at a first end or recesses at both ends and the drape portion includes an opening formed in the drape adjacent a recess to allow access to a surgical site on the patient's body. To account for the missing subject matter, the examiner points to Irani, urging that it teaches a thermal blanket with an inflatable portion configured to cover the upper and lower extremities of a person and teaches (Fig. 8) that it is known in the art to provide an opening (272) in the blanket to provide access through the blanket to perform a surgical procedure. From those teachings, the examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of appellant's invention "to include an opening and coverage of the upper and lower extremities as in Irani in the device of Augustine et al. to warm the entire body and provide for surgical access while using the device" (final rejection, page 3).

As both the examiner and appellant recognize, Augustine '482 does not teach or suggest an opening in the drape portion of the barrier device therein to provide access to a surgical site. Indeed, it would appear that providing any such opening in the drape portion (70), which is intended to trap and retain heated air around the patient's feet to warm the feet, would be antithetical to the teachings of Augustine '482. Irani likewise does not teach or suggest an opening in a drape portion of a thermal blanket to facilitate surgery, instead this patent teaches placing an opening (272) in the inflatable portion of the blanket to allow access for a surgical procedure. Nor do either of the applied

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patents address the requirement in these claims of a recess in the inflatable portion of the blanket with the above noted opening being positioned adjacent the recess. Thus, we conclude that the examiner has not made out a *prima facie* case of obviousness and for that reason we will not sustain the rejection of claims 60, 62, 64 through 67, 75 through 85, 87, 88 and 93 through 95 under 35 U.S.C. § 103(a).

Concerning the examiner's rejection of claim 68 under 35 U.S.C. § 103(a) based on Augustine '482 and Collins, appellant does not dispute the examiner's use of Collins to teach a frame (Figs. 4-5) for supporting a surgical drape, or its combination with Augustine '482. Instead, appellant contends (brief, pages 14-15) that Augustine '482 does not teach or suggest a "surgical drape" and that Collins does not rectify this omission. Having already found that line of argument unpersuasive in our treatment and discussion of Augustine '482 above, we will sustain the rejection of claim 68 under 35 U.S.C. § 103(a).

Claim 86 depends from independent claim 75 and stands rejected under 35 U.S.C. § 103(a) based on Augustine '482 in view of Irani and Collins. However, we note that the addition of the frame of Collins to the barrier device of Augustine '482 as urged by the examiner would not overcome the deficiencies of the base combination of Augustine '482 and Irani as highlighted above. Accordingly, the rejection of claim 86 under 35 U.S.C. § 103(a) will not be sustained.

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To summarize, we have determined that the examiner's rejections of claims 58, 59, 61, 63, 69 and 70 under 35 U.S.C.

§ 102(e) as being anticipated by Augustine '482 and of claim 68 under 35 U.S.C. § 103(a) based on Augustine '482 and Collins are sustained. Concerning the rejection of claims 60, 62, 64 through 67, 75 through 85, 87, 88 and 93 through 95 under 35 U.S.C. § 103(a) as being unpatentable over Augustine '482 in view of Irani and that of claim 86 under 35 U.S.C. § 103(a) as being unpatentable over Augustine '482 in view of Irani and Collins, those rejections have not been sustained. Thus, the decision of the examiner to reject the claims of the present application is affirmed-in-part.

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