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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/247,931	10/11/2005	David S. Utterberg	T6858-18432US01	1162
181	7590	02/27/2013	EXAMINER	
MILES & STOCKBRIDGE PC 1751 PINNACLE DRIVE SUITE 500 MCLEAN, VA 22102-3833			OSINSKI, BRADLEY JAMES	
			ART UNIT	PAPER NUMBER
			3767	
			NOTIFICATION DATE	DELIVERY MODE
			02/27/2013	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DAVID S. UTTERBERG and WILLIAM J. SCHNELL

Appeal 2011-002320
Application 11/247,931
Technology Center 3700

Before TONI R. SCHEINER, JEFFREY N. FREDMAN, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a closure for a lumen access port of a medical fluid flow line. The Examiner rejected the claims as indefinite, as anticipated, and as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part but designate the affirmance as a new grounds of rejection.

Statement of the Case

Background

The Specification teaches “a closure for a tubular access port in a medical fluid flow line or other container comprises: a removable, tubular cap for enclosing the tubular access port” (Spec. 2). According to the Specification, the “cap has a closed end wall, with or without a male member attached to its inner face, while typically the end wall’s outer face, in turn, carries an outwardly extending poker” (Spec. 2).

The Claims

Claims 1-13, 21, 22, and 24-29 are on appeal. Claims 1 and 21 are representative and read as follows:

1. A closure for a lumen-defining access port of a medical fluid flow line or other container, which comprises:
a removable cap for enclosing and sealing said tubular access port, said cap having a closed end wall, said end wall carrying an extending poker to facilitate the pushing of an antiseptic-containing material into a lumen of said access port, the poker having an outer diameter that is less than the inner diameter of said access port, to provide a space therebetween along substantially all of the length of the poker as the poker occupies said access port, said space being substantially filled with an antiseptic-containing material.

21. A removable cap for enclosing and sealing an access port of a medical fluid flow line or another container, which cap defines an attached, outwardly extending, C-shaped projection proportioned and of a stiffness to releasably grip medical tubing of said medical fluid flow line along substantially all of the length of said C-shaped projection, to permit releasable attachment of said cap to the flow line with the cap being spaced from the access port.

The issues

- A. The Examiner rejected claim 1 under 35 U.S.C. § 112, second paragraph as indefinite (Ans. 4).
- B. The Examiner rejected claim 21 under 35 U.S.C. § 102(b) as anticipated by Schnell¹ (Ans. 4).
- C. The Examiner rejected claims 1, 3, 4, 6-9, 13, 22-25, and 27-29 under 35 U.S.C. § 103(a) as obvious over Utterberg,² Hiroto,³ and Yamanaka⁴ (Ans. 4-7).
- D. The Examiner rejected claims 2, 11, and 12 under 35 U.S.C. § 103(a) as obvious over Utterberg, Hiroto, Yamanaka, and Atkinson⁵ (Ans. 7).
- E. The Examiner rejected claims 5, 10, and 26 under 35 U.S.C. § 103(a) as obvious over Utterberg, Hiroto, Yamanaka, and Schnell (Ans. 8).

A. *35 U.S.C. § 112, second paragraph - indefiniteness*

The Examiner finds that “[c]laim 1 claims a cap for a port. The port is not positively recited. However, Applicant claims a space that is defined by the poker and port, making the space indefinite” (Ans. 4).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that claim 1 is indefinite?

Principles of Law

“The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification.”

¹ Schnell, W., US 6,090,066, issued Jul. 18, 2000.

² Utterberg, D., US 5,951,519, issued Sep. 14, 1999.

³ Hiroto, A., JP 410035716 A, published Feb. 10, 1998.

⁴ Yamanaka et al., US 6,468,251 B1, issued Oct. 22, 2002.

⁵ Atkinson et al., US 4,535,819, issued Aug. 20, 1985.

Miles Laboratories, Inc. v. Shandon, Inc., 997 F.2d 870, 875 (Fed. Cir. 1993).

Analysis

We find that claim 1 is definite. The ordinary artisan would understand that the port must include sufficient space to permit an extending poker to occupy the port when there is some amount of antiseptic material coated on the poker.

Conclusion of Law

The evidence of record does not support the Examiner's finding that claim 1 is indefinite.

B. 35 U.S.C. § 102(b) over Schnell

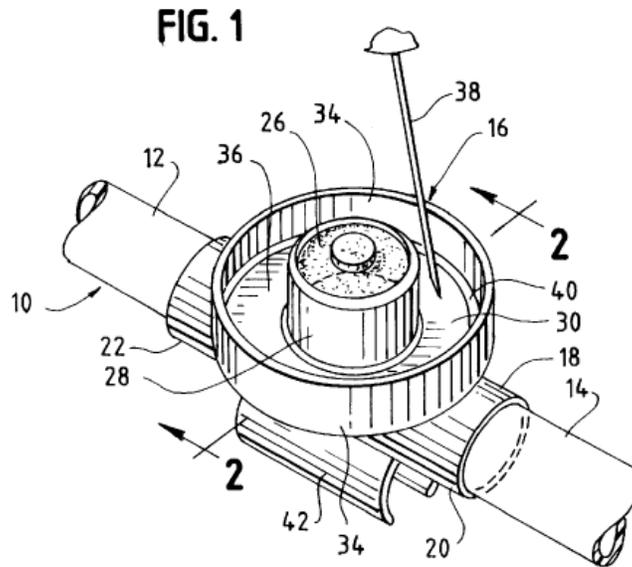
The Examiner finds that "Schnell discloses a cap 30 for sealing an access port 24 both removable from medical tubing with a C-shaped handle 42 for clipping onto tubing or other apparatuses along the handles length to keep the set in an orderly array during use" (Ans. 4). The Examiner finds that the "cap 34 is releasably attached to the flow line 14 and the cap 34 is spaced apart from the port 24" (*id.*).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Schnell anticipates claim 21?

Findings of Fact

1. Schnell teaches that the device comprises "a handle **42** which comprises a pair of convex walls **44** connected to body **18** at one end of the walls. . . it may clip to tubing" (Schnell, col. 3, ll. 55-62).

2. Figure 1 of Schnell is reproduced below:



“FIG. 1 is a fragmentary, perspective view of a medical fluid set comprising flexible tubing and a first embodiment of the injection site of this invention” (Schnell, col. 2, ll. 49-51).

3. Schnell teaches an “elastic, needle-pierceable and resealable plug **26** of generally conventional design is retained in a recess defined by annular wall **28**, in a position to occlude aperture **24** so that a needle cannot enter aperture **24** or lumen **23** without passing through needle pierceable plug **26**” (Schnell, col. 3, ll. 13-17).

4. Schnell teaches that the “needle penetrates plug **26** to enter into communication with aperture **24** and lumen **23**” (Schnell, col. 3, ll. 25-26).

Principles of Law

“A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation.”

Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368, 1375 (Fed. Cir. 2005).

Analysis

We agree with Appellants that “the Schnell device is not a cap, as required by the claim. Instead, the Schnell device is more akin to the access port with which the cap of the present invention would be used” (App. Br. 11). That is, while Schnell clearly teaches a C-shaped projection to grip medical tubing (FF 2), neither flange 30 nor plug 26 of Schnell can reasonably be interpreted as functioning as a removable cap (FF 3-4). Instead, the plug 26 functions as a port to permit entry into the tube and the flange 30 simply prevents needle access into the line in the wrong location (FF 3).

Conclusion of Law

The evidence of record does not support the Examiner’s conclusion that Schnell anticipates claim 21.

C. 35 U.S.C. § 103(a) over Utterberg, Hiroto, and Yamanaka

The Examiner finds that “Utterberg discloses a removable cap 32 which encloses and seals tubular access port 14. The cap also has a closed end wall 48” (Ans. 4). The Examiner finds that Utterberg “does not disclose a poker with an outer diameter less than the inner diameter of the access port nor does it teach an antiseptic containing material that fits between the poker and wall of the access port” (*id.* at 5).

The Examiner finds that “Hiroto discloses such a poker 54 on a threaded cap 52 to penetrate a closing film 55” (*id.*). The Examiner finds that Yamanaka teaches to “wipe out a residual liquid, or to disinfect the

mixing/charging port by using an alcohol-impregnated cotton, etc., easily and reliably” (Yamanaka, col. 3, ll. 14-16). The Examiner finds it obvious to “wipe out the port 16 with an alcohol impregnated cotton (either a pad or swab) as taught by Yamanaka et al so as to kill and remove any residual liquid or microbes from the port” (Ans. 5).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that Utterberg, Hiroto, and Yamanaka render claim 1 obvious?

Findings of Fact

5. The Specification teaches that the poker has an outer diameter that is less than the inner diameter of the access port, to provide space in the access port lumen for both the poker and the antiseptic-containing material. The antiseptic containing material may comprise fluid or gelled antiseptics, or antiseptic impregnated materials. Any appropriate antiseptic may be used, such as ethyl or isopropyl alcohol

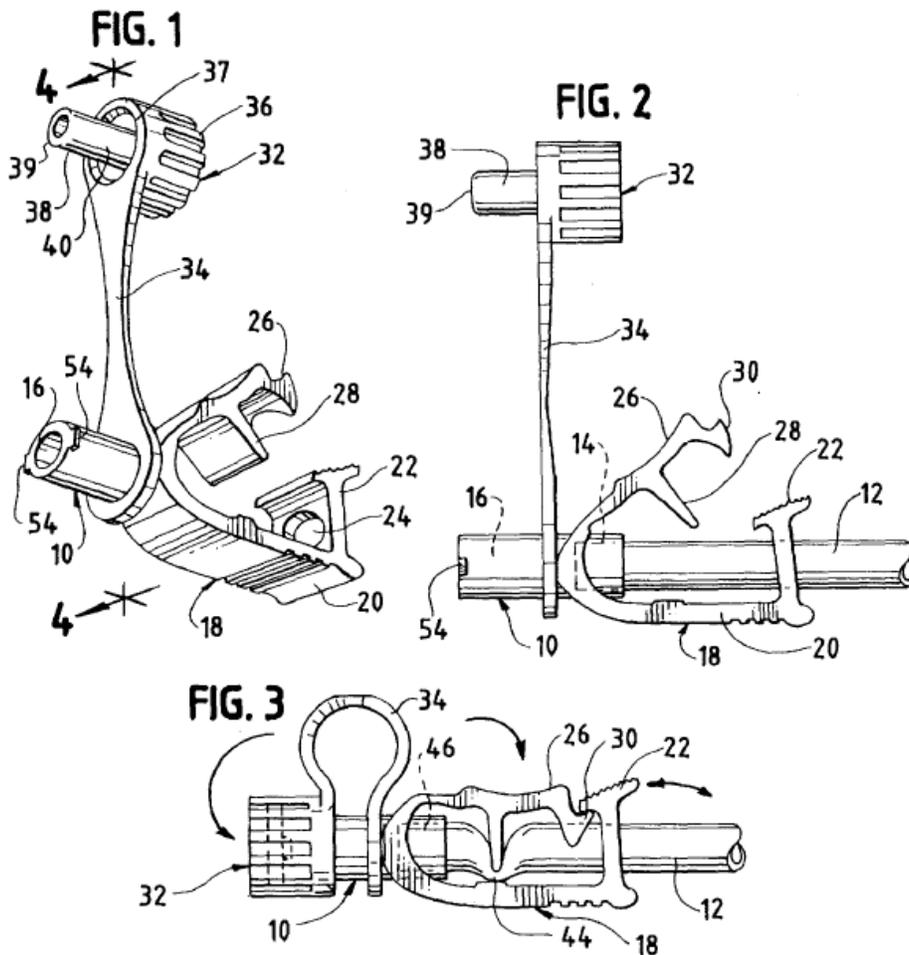
(Spec. 3).

6. The Specification teaches that “the narrow space between poker 24c and the inner diameter wall of lumen 30 may be filled with a fluid antiseptic agent 78, which may have been applied as a coating to poker 24c immediately prior to placement into connector 12b” (Spec. 16).

7. The Specification teaches that the “above has been offered for illustrative purposes only, and is not intended to limit the scope of the invention of this application, which is as defined in the claims below” (Spec. 17).

8. Utterberg teaches that the “complete, tapered socket of the connector is in engagement with the outer surface of the tapered projection and in contact with antiseptic, for improved internal surface sterilization” (Utterberg, col. 2, ll. 15-20).

9. Figures 1-3 of Utterberg are reproduced below:



“FIG. 1 is a perspective view of a female luer connector and an attached sealing cap . . . FIG. 2 is an elevational view of the tube connector and cap . . . FIG. 3 is an elevational view of the connector and cap” (Utterberg, col. 3, ll. 16-22).

10. Utterberg teaches a tubular access port where “[t]ubing **12** may be sealed into bore **14** of connector **10**, which is typically cylindrical and not tapered” (Utterberg, col. 3, ll. 38-40).

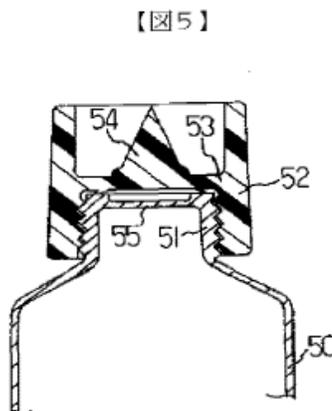
11. Utterberg teaches that “cap **32** and tether **34** may be added as a separate part. Cap **32** is tethered in adjacent relation with female luer connector **10**, being capable of entering into closing relation therewith” (Utterberg, col. 3, ll. 57-60).

12. Utterberg teaches that “[c]ap **32** comprises a cap body **36**, and a tapered projection **38**, which is proportioned to sealingly fit within tapered socket **16**” (Utterberg, col. 3, ll. 61-63).

13. Utterberg teaches that “the projection preferably has an outer surface that carries an antiseptic material, typically a volatile antiseptic material such as povidone iodine or alcohol” (Utterberg, col. 2, ll. 13-15).

14. Utterberg teaches that “[t]apered projection **38** may have an outer surface **40** which is coated with an antiseptic, for example by coating with a volatile antiseptic such as povidone iodine or alcohol immediately prior to closure” (Utterberg, col. 4, ll. 2-6).

15. Figure 5 of Hiroto is reproduced below:



The Examiner explains that Hiroto discloses a poker with an outer diameter less than the inner diameter of the access port teaching “such a poker 54 on a threaded cap 52 to penetrate a closing film 55” (Ans. 5).

16. Yamanaka teaches that

it is preferable in the mixing/charging port for medical treatment of the present invention that the cover further has a gentle taper on the front surface side. Providing a taper makes it possible to induce the insertion member, for example, a luer, etc. into a fitting hole easily, as well as to wipe out a residual liquid, or to disinfect the mixing/charging port by using an alcohol-impregnated cotton, etc., easily and reliably.

(Yamanaka, col. 3, ll. 9-16.)

Principles of Law

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417.

Analysis

Claim interpretation is at the heart of patent examination because before a claim is properly interpreted, its scope cannot be compared to the prior art. In this case, we find that both Appellants and the Examiner incorrectly interpreted the claim phrase “the poker having an outer diameter that is less than the inner diameter of said access port, to provide a space therebetween along substantially all of the length of the poker as the poker occupies said access port” in claim 1.

During prosecution, claim terms are given their broadest reasonable interpretation as they would be understood by persons of ordinary skill in the art in the light of the Specification. Therefore, we first turn to the Specification to interpret the phrase “the poker having an outer diameter that is less than the inner diameter of said access port, to provide a space therebetween along substantially all of the length of the poker as the poker occupies said access port.”

The Specification teaches that the “poker has an outer diameter that is less than the inner diameter of the access port, to provide space in the access port lumen for both the poker and the antiseptic-containing material” (Spec. 3; FF 5). Neither claim 1 nor the Specification impose any specific numerical values on how much space is required between the outer diameter of the poker relative to the inner diameter of the access port, other than the functional requirement to permit a coating of antiseptic material (FF 5-6).

We recognize that the Examiner, in response to Appellants’ amendment on June 11, 2008, accepted the Appellants’ interpretation of this phrase to exclude the relationship of the poker 38 to port 16 of Utterberg from satisfying the requirement for “a space therebetween along substantially all of the length of the poker” since Utterberg teaches “that the complete, tapered socket of the connector is in engagement with the outer surface of the tapered projection and in contact with antiseptic, for improved internal surface sterilization” (Utterberg, col. 2, ll. 15-20; FF 8).

We do not agree, however, that this limitation excludes Utterberg’s poker 38 and port 16. In order for Utterberg’s poker 38 to fully penetrate the port 16, the outer diameter of poker 38 is necessarily and inherently smaller

in diameter than the inner diameter of port 16. Even the phrase from column 2 of Utterberg “engagement with the outer surface . . . and in contact with antiseptic” teaches that the outer diameter of poker 38 is sufficiently smaller than the port 16 to permit contact with antiseptic as well as the poker 38 (FF 8). As Utterberg teaches, “tapered projection **38** . . . is proportioned to sealingly fit within tapered socket **16**” (Utterberg, col. 3, ll. 61-63; FF 12). In addition, Utterberg teaches the functional limitation required by the Specification that the projection is coated with antiseptic material (FF 5-6), specifically teaching that “[t]apered projection **38** may have an outer surface **40** which is coated with an antiseptic, for example by coating with a volatile antiseptic such as povidone iodine or alcohol immediately prior to closure” (Utterberg, col. 4, ll. 2-6; FF 14).

We therefore find that Utterberg suggests the elements of claim 1. Specifically, Utterberg teaches a removable cap 32 for enclosing a sealing a tubular access port 10 (FF 10). Utterberg teaches that the cap has a closed end wall body 36 (FF 9) with a poker 38 which may be coated with antiseptic material that is pushed into lumen 16 of port 10 (FF 9-14). The poker 38 inherently comprises an outer diameter less than the inner diameter of the socket 16 (FF 12) and inherently provides some amount of space, however small, along the poker length which is filled with the antiseptic material coated onto the outer surface 40 of poker 38 (FF 14).

We further find that Yamanaka teaches that the use of a taper, such as that of Utterberg (FF 12) “makes it possible to induce the insertion member, for example, a luer, etc. into a fitting hole easily, as well as to wipe out a

residual liquid, or to disinfect the mixing/charging port by using an alcohol-impregnated cotton” (Yamanaka, col. 3, ll. 12-15; FF 16).

Thus, consistent with the reasoning in *KSR* that combinations of ordinary elements in predictable ways is likely obvious, the artisan of ordinary skill would have been motivated to disinfect the port of a luer using a tapered insertion member where the insertion member is coated with alcohol or another antiseptic and is inherently smaller in diameter than the inner diameter of the port (FF 8-14, 16).

Currently, all of the evidence of record reasonably supports our finding that the outer diameter of poker 38 is necessarily and inherently smaller in diameter than the inner diameter of port 16, in light of the teaching by Utterberg that the poker fully enters port 16 while coated with antiseptic as discussed above (FF 5-14).

Because our reasoning substantially differs from that of the Examiner, we will designate this rejection as a New Grounds of Rejection, in order to provide Appellants an opportunity to respond.

Conclusion of Law

The evidence of record supports the conclusion that Utterberg, Hiroto, and Yamanaka render claim 1 obvious.

D. 35 U.S.C. § 103(a) over Utterberg, Hiroto, Yamanaka, and Atkinson

Appellants do not separately argue the rejection over Utterberg, Hiroto, Yamanaka, and Atkinson. We therefore summarily affirm the rejection of claims 2, 11, 12 over Utterberg, Hiroto, Yamanaka, and Atkinson. *See* Manual of Patent Examining Procedure § 1205.02 (“If a ground of rejection stated by the examiner is not addressed in the appellant's

brief, that ground of rejection will be summarily sustained by the Board.”); *See also In re Berger*, 279 F.3d 975, 984 (Fed. Cir. 2002) (in which the Board affirmed an uncontested rejection of claims under 35 U.S.C. 112, second paragraph, and on appeal the Federal Circuit affirmed the Board's decision and found that the appellant had waived his right to contest the indefiniteness rejection by not presenting arguments as to error in the rejection on appeal to the Board).

E. 35 U.S.C. § 103(a) over Utterberg, Hiroto, Yamanaka, and Schnell

Appellants contend that the rejection “fails to address why it would be obvious to utilize a C-shaped structure generally used to permanently secure with and form an access port on medical tubing as a combination with a cap for closing a medical access port, yet allowing removal and releasable attachment elsewhere” (App. Br. 12).

We are not persuaded. The Examiner finds it obvious “to modify Utterberg to include the c-shaped handle of Schnell for clipping onto tubing to keep the device organized when used with other apparatuses” (Ans. 8). We agree with the Examiner that the addition of Schnell’s clip (FF 1) to Utterberg’s cap (FF 7-13) would reasonably allow the ordinary artisan to keep multiple tubes together and organized when treating patients with multiple different solutions.

SUMMARY

In summary, we reverse the rejection of claim 1 under 35 U.S.C. § 112, second paragraph as indefinite.

We reverse the rejection of claim 21 under 35 U.S.C. § 102(b) as anticipated by Schnell.

We affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as obvious over Utterberg, Hiroto, and Yamanaka. Pursuant to 37 C.F.R. § 41.37(c)(1), we also affirm the rejection of claims 3, 4, 6-9, 13, 22-25, and 27-29 as these claims were not argued separately.

We affirm the rejection of claims 2, 11, and 12 under 35 U.S.C. § 103(a) as obvious over Utterberg, Hiroto, Yamanaka, and Atkinson.

We affirm the rejection of claims 5, 10, and 26 under 35 U.S.C. § 103(a) as obvious over Utterberg, Hiroto, Yamanaka, and Schnell.

Because our reasoning differs from that of the Examiner, we designate the rejections incorporating Utterberg, Hiroto, and Yamanaka as new grounds of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.”

37 C.F.R. § 41.50(b) also provides that the Appellants, **WITHIN TWO MONTHS FROM THE DATE OF THE DECISION**, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner....

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(2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record...

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-IN-PART, 37 C.F.R. § 41.50(b)

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