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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WAYNE K. RASMUSSEN, DAVID OU-YANG,
GLADE H. HOWELL, and LANTAO GUO

Appeal 2011-002450
Application 11/829,010
Technology Center 3700

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and
STEPHEN WALSH, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to coated medical devices and a method of repressing pathogens in a device. The Examiner rejected the claims as anticipated and as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

Statement of the Case

Background

“When a vascular access device is contaminated, pathogens adhere to the vascular access device, colonize, and form a biofilm. The biofilm is resistant to most biocidal agents and provides a replenishing source for pathogens to enter a patient’s bloodstream and cause a [blood stream infection]” (Spec. 1-2 ¶ 0007).

The Claims

Claims 1-5, 7, 8, 10, 11, 13-15, 18, 20, 27, and 28 are on appeal.

Claim 1 is representative and reads as follows:

1. A medical device comprising:
 - a body having an interior lumen;
 - a septum housed within the interior lumen of the body, the septum having a slit to allow a separate extravascular device to access the interior lumen, wherein the septum includes an outer surface, an opening surface, a slit surface and an interior surface;
 - a first coating material including an antimicrobial agent, disposed on at least one of the opening surface, the slit surface and the interior surface, the first coating material being soluble to a first flush compound and insoluble to a second flush compound; and
 - a second coating material disposed on the first coating material, the second coating material being soluble to the second flush compound and insoluble to the first flush compound.

The issues

- A. The Examiner rejected claims 1, 3, 7, and 27 under 35 U.S.C. § 102(b) as anticipated over Leinsing¹ (Ans. 4-5).

¹ Leinsing et al., US 2002/0133124 A1, published Sep. 19, 2002.

- B. The Examiner rejected claim 2 under 35 U.S.C. § 103(a) as obvious over Leinsing and Khan² (Ans. 5-6).
- C. The Examiner rejected claims 4, 5, 11, 13-15, and 28 under 35 U.S.C. § 103(a) as obvious over Leinsing and Tomisaka³ (Ans. 6-7, 8-10).
- D. The Examiner rejected claim 8 under 35 U.S.C. § 103(a) as obvious over Leinsing and Matsuda⁴ (Ans. 7).
- E. The Examiner rejected claim 10 under 35 U.S.C. § 103(a) as obvious over Leinsing and Albrecht⁵ (Ans. 7-8).
- F. The Examiner rejected claim 18 under 35 U.S.C. § 103(a) as obvious over Leinsing, Tomisaka, and Matsuda (Ans. 10).
- G. The Examiner rejected claim 20 under 35 U.S.C. § 103(a) as obvious over Leinsing, Tomisaka and Albrecht (Ans. 10).

A. *35 U.S.C. §102(b) over Leinsing*

The Examiner finds that:

Leinsing et al. teach a body having an interior lumen; a septum . . . wherein the septum includes an outer surface, an opening surface, a slit surface and an interior surface slit (Fig. 15 see body surrounding septum 26); a first coating material a layer, including an antimicrobial agent . . . the first coating material being soluble to a first flush compound and insoluble to a second flush compound ([0081]); and a second coating material disposed on the first coating material, the second coating material being soluble to the second flush compound and insoluble to the first flush compound ([0081] the second material coats the first

² Khan et al., US 4,925,668, issued May 15, 1990.

³ Tomisaka et al., US 5,540,661, issued Jul. 30, 1996.

⁴ Matsuda et al., US 4,986,399, issued Jan. 15, 1991.

⁵ Albrecht et al., US 2005/0059731, published Mar. 17, 2005.

material on the peripheral surface, which would correspond to at least the Applicant's opening surface, the different materials would be soluble and insoluble to different compounds).

(Ans. 4).

Appellants contend that “Leinsing teaches that the flex-tube piston (26) includes an-antimicrobial agent included in the material itself, or added to the *outer surface* as a coating. Leinsing also teaches that the *peripheral surface* of the flex-tube piston (26) may be lubricated with a silicone oil” (App. Br. 5). Appellants contend that “Leinsing fails to specifically define what surface is the *outer surface* and what surface is the *peripheral surface*. . . . Leinsing allows one to infer which surface is which. Certainly they are distinct surfaces because the distinct terminology *outer surface* and *peripheral surface* is use by Leinsing in the same paragraph” (App. Br. 7).

Appellants contend that these surfaces are different and that “there is absolutely no teaching in Leinsing of a second coating material disposed **on** a first coating material” (App. Br. 7). Appellants also contend that “there is no teaching in Leinsing of first and second coating materials that are soluble in first and second flush compounds” (App. Br. 7).

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

Findings of Fact

1. Leinsing teaches that:

flex-tube piston **26** includes an-antimicrobial agent, such as silver, silver oxide or silver sulfadiazine. The agent may be included in the material forming the flex-tube piston or may be added to the outer surface of the piston as a coating.

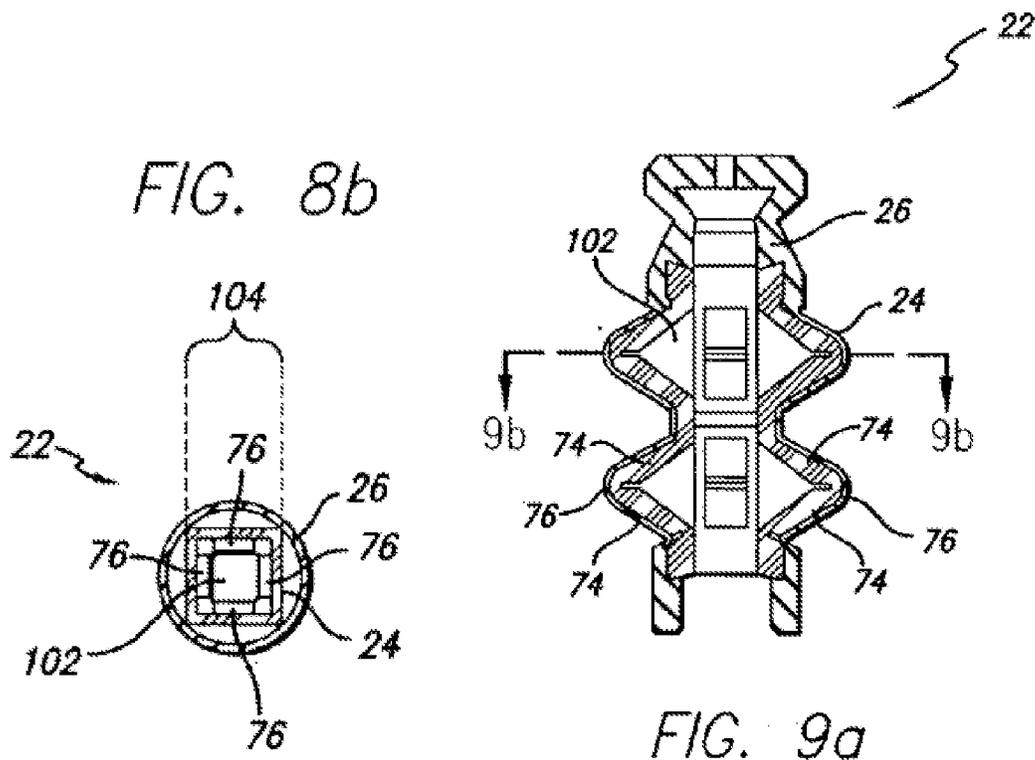
These agents reduce the incidence of infection if the valve is not properly disinfected with an alcohol wipe prior to use.

(Leinsing 5 ¶ 0081).

2. Leinsing teaches that the “flex-tube insert **24**, valve body **12** and/or male Luer-lock **16** insert may also include an antimicrobial agent” (Leinsing 5 ¶ 0081).

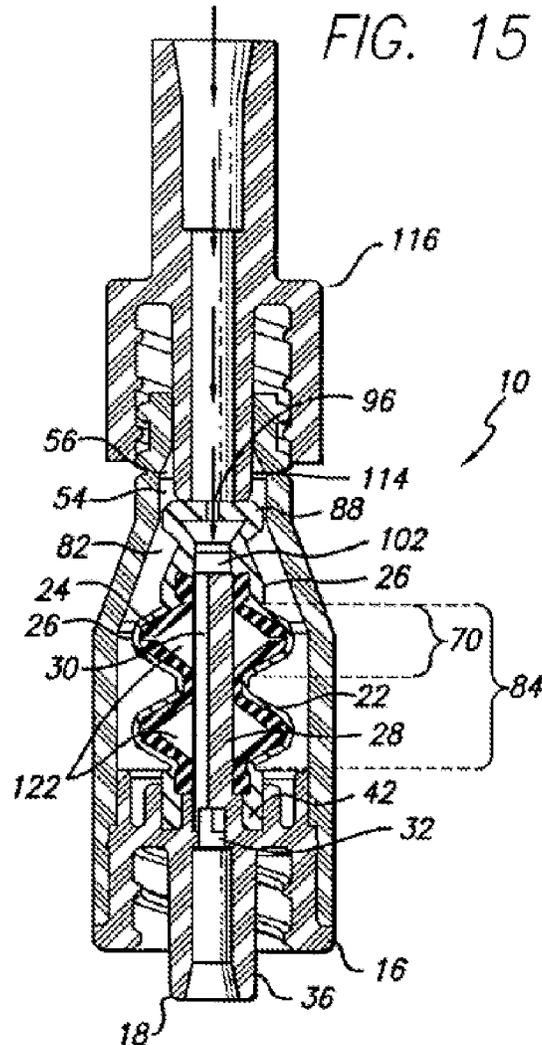
3. Leinsing teaches that the “peripheral surface of the flex-tube piston **26** is also lubricated with FDA approved silicone oil to facilitate movement of the flex-tube assembly within the connector” (Leinsing 5 ¶ 0081).

4. Figures 8b and 9a of Leinsing are reproduced below:



“**FIG. 8b** is a top view of the flex-tube assembly . . . **FIG. 9a** is a full sectional view of the flex-tube assembly” (Leinsing 4 ¶¶ 0034-0035).

5. Figure 15 of Leinsing is reproduced below:



“FIG. 15 is a full sectional view of a positive-bolus configuration of the medical connector” (Leinsing 4 ¶ 0043).

6. Table 2 of the Specification teaches first coatings comprising antimicrobial agents including silver oxide (*see* Spec 12 ¶ 0035).

7. The Specification teaches that the “lube oil coating may be applied to one or more layers of the present invention” (Spec. 18 ¶ 0051).

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

Leinsing teaches a medical device with a septum and a lumen (FF 4-5). Leinsing teaches that an antimicrobial agent such as silver or silver oxide or silver sulfadiazine “may be added to the outer surface of the piston as a coating” (Leinsing 5 ¶ 0081; FF 1). Leinsing also teaches that “the peripheral surface of the flex-tube piston 26 is also lubricated with FDA approved silicone oil to facilitate movement of the flex-tube assembly within the connector” (Leinsing 5 ¶ 0081; FF 3).

Appellants contend that “there is absolutely no teaching in Leinsing of a second coating material disposed on a first coating material” (App. Br. 7).

We are not persuaded. As we analyze the location of the two coatings in light of Figure 15, the locations disclosed for placement of the antimicrobial agent are reasonably understood as the outer surface of piston 26 which, as the Examiner notes, reasonably includes the opening surface (FF 1, 5). In addition, we agree with the Examiner that the peripheral outer surface of piston 26, which includes the opening surface, most reasonably represents a location where the silicone coating would be placed over the antimicrobial agent coating at the periphery or edge of piston 26 (FF 3, 5). Thus, the difference between the outer surface of piston 26 and the peripheral surface of piston 26 is that the outer surface encompasses the

entire outer surface of the piston including the opening, while the peripheral surface represents a subset of that outer surface which is the opening edge or periphery at the opening surface that permits movement of the flex tube assembly (FF 1, 3, 5).

At that peripheral location, the silicone oil coating will reasonably overlay the antimicrobial coating, satisfying the requirement of claim 1 for “a second coating material disposed on the first coating material”.

Appellants contend that “there is no teaching in Leinsing of first and second coating materials that are soluble in first and second flush compounds” (App. Br. 7).

The Examiner responds, finding that “Leinsing et al. teach using silver, silver oxide, or silver sulfadiazine and silicone oil which are compounds disclosed for use in Applicant’s specification. As the same compounds are used they would be expected to have the same results” (Ans. 11).

We find that the Examiner has the better position since the Specification teaches both silver oxide as a first antimicrobial coating material (FF 6) and silicone oil as a second coating material (FF 7). Along with the different chemical structures of silver oxide and silicone oil, the reliance on the Specification as evidence is sufficient for the Examiner to reasonably infer that Leinsing’s coating of silver oxide followed by coating with silicone oil would inherently satisfy the requirement of claim 1 for coatings which are differentially soluble to different flush compounds. *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (“Where, as here, the claimed and prior art products are identical or substantially identical, or are produced

by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.”) Appellants provide no evidence to rebut the Examiner’s inherency argument.

Conclusion of Law

The evidence of record supports the Examiner’s conclusion that Leinsing anticipates claim 1.

B. 35 U.S.C. § 103(a) over Leinsing and Khan

The Examiner finds that “Khan et al. teach coating medical devices with a solution of an antimicrobial agent and a silicone oil” (Ans. 5). The Examiner finds it obvious to “use a solution containing a mixture of an antimicrobial agent and a lube oil on the slit in the device of Leinsing et al. because Khan et al. teach an effective antimicrobial coating which provides both lubrication and an antimicrobial agent and is beneficial in prohibiting bacteria” (Ans. 5-6).

Appellants contend that the “first coating material is claimed as being a solution containing a mixture of antimicrobial agent and lube oil. These limitations are not taught in the combination of references cited by the Examiner” (App. Br. 10).

While Khan does teach a coating “applied by dipping the surface into a solvent solution of the anti-infective agent and lubricant” (Khan, col. 2, ll. 15-17), Khan does not teach the concept of using two coatings which are soluble to different flush compounds. Thus, if the ordinary artisan, contemplating Leinsing’s teaching of two coatings, first of an antimicrobial agent and then of silicone oil for lubrication was provided the Khan

reference, obvious changes would have been to either replace both coatings of Leinsing with the single coating of Khan, or to substitute the Khan coating for the antimicrobial coating. In the first case, the combination would not satisfy claim 2 because there would not be two coatings. In the second case, the combination would not satisfy claim 2 because there would have been no reason to select lubricants with different solubilities to different flush compounds. We therefore reverse this rejection.

C. 35 U.S.C. § 103(a) over Leinsing and Tomisaka

The Examiner finds that Leinsing teaches:

a method of repressing pathogens in a vascular access device, comprising: providing a vascular access device comprising a body and a septum, the body having an interior lumen and the septum being housed within the interior lumen, the septum having a slit for providing access through the vascular access device, wherein the septum includes an outer surface, an opening surface, a slit surface and an interior surface (Fig. 15 see septum 26 in body); disposing a first coating material on at least one of the opening surface, the slit surface and the interior surface of the septum, the first coating material being soluble to a first flush compound and insoluble to a second flush compound, the first coating compound having an antimicrobial agent ([0081]).

(Ans. 8). The Examiner finds that Tomisaka teaches “applying a lubricant to the opening surface and inside the slit” (Ans. 8). The Examiner finds it obvious to “use the second material on both the opening surface and slit surface in the device of Leinsing et al. because Tomisaka et al. teach it is beneficial for allowing easier use of the device and extending the lifespan of the device” (Ans. 9).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Leinsing and Tomisaka renders claim 11 obvious?

Findings of Fact

8. Tomisaka teaches "adding lubricity to the valve surface of a rubber valve piece having a slit access to be blunt cannula-accessible" (Tomisaka, col. 2, ll. 2-4).

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. As noted by the Court in *KSR*, "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." 550 U.S. at 421.

Analysis

Leinsing teaches incorporating antimicrobial agents with a medical connector with a body and septum to "reduce the incidence of infection if the valve is not properly disinfected with an alcohol wipe prior to use" (Leinsing 5 ¶ 0081; FF 1). Leinsing teaches disposing first coating where the "flex-tube insert **24**, valve body **12** and/or male Luer-lock **16** insert may also include an antimicrobial agent" (Leinsing 5 ¶ 0081; FF 2). Leinsing further teaches a second coating using a silicone lubricant on a peripheral surface (FF 3). Tomisaka teaches that the lubricant may be placed on a valve body surface to add lubricity to the valve (FF 8).

Applying the *KSR* standard of obviousness to the findings of fact, we agree with the Examiner that the ordinary artisan would have reasonably found it obvious to apply the silicone oil lubricant of Leinsing onto the valve of Leinsing since Tomisaka teaches that it would have been desirable to improve the lubricity of the valve. Such a combination is merely a “predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. at 417. The ordinary artisan, after applying the silicone lubricant of Leinsing as suggested by Tomisaka to the valve, already coated with the antimicrobial of Leinsing, would have disposed a first antimicrobial coating and a second silicone coating which are inherently soluble in different flush compounds. *Best*, 562 F.2d at 1255.

Appellants contend that “none of the cited references teach a soluble coating” (App. Br. 13).

We are not persuaded. Leinsing teaches coatings which are identical to those used in the Specification, and identified by the Specification as soluble (FF 6-7). As discussed above, these coatings would reasonably have the inherent properties of being soluble in different flush compounds, absent evidence to the contrary. Appellants have provided no such evidence.

Appellants also contend that “the lubricant of Leinsing is not located within the fluid flow path” (App. Br. 13).

We are not persuaded. Since Tomisaka teaches the location of the lubricant on the valve, this argument fails to incorporate the combination of references.

Appellants contend that “the covalently bonded lubricant is not soluble in any of the materials expected to be introduced into the device of Tomisaka” (App. Br. 12).

We are not persuaded. Since Leinsing teaches the use of lubricants which are not covalently bonded, it would have been obvious over Leinsing and Tomisaka to apply Leinsing’s lubricant to the valve as a known equivalent to the lubricants of Tomisaka, which would result in a lubricant identified by the Specification as soluble (FF 7).

Conclusion of Law

The evidence of record supports the Examiner’s conclusion that Leinsing and Tomisaka renders claim 4, 5, and 11 obvious.

D. and F. 35 U.S.C. § 103(a) over Leinsing and Matsuda and Leinsing, Tomisaka and Matsuda

The Examiner finds that “Matsuda et al. teach that fluorinated silicone oil is a lubricant known in the art (Col. 6 lines 29-32) and an equivalent to silicone” (Ans. 7). The Examiner finds it obvious to “use a fluorinated silicone oil in the device of Leinsing et al. because Matsuda et al. teach it to be an art recognized equivalent for use as a lubricant” (Ans. 7).

Appellants contend that “Matsuda is non-analogous to the medical arts. It would not have been obvious to modify or combine the teachings of Matsuda with the teachings of the medical device in Leinsing to produce the claimed invention” (App. Br. 11).

We find that the balance of the evidence supports the position of the Examiner. Matsuda teaches that both silicone oils and fluorinated silicone

oils are known lubricants (*see* Matsuda, col. 6, l. 32). In *Icon*, the Court found that

an inventor considering a hinge and latch mechanism for portable computers would naturally look to references employing other “ housings, hinges, latches, springs, etc.,” which in that case came from areas such as “ a desktop telephone directory, a piano lid, a kitchen cabinet, a washing machine cabinet, a wooden furniture cabinet, or a two-part housing for storing audio cassettes.”

In re ICON Health and Fitness, Inc., 496 F.3d 1374, 1380 (Fed. Cir. 2007) (*citing In re Paulsen*, 30 F.3d 1475, 1481 (Fed.Cir. 1994)). The instant situation is similar to that of *Icon* and *Paulsen*, since Matsuda demonstrates that fluorinated silicone oils and the silicone oils of Leinsing are known equivalent lubricants, so the ordinary artisan interested in lubricants would reasonably look to references teaching known equivalent lubricants.

E. and G. 35 U.S.C. § 103(a) over Leinsing and Albrecht and Leinsing, Tomisaka, and Albrecht

The Examiner finds “ Albrecht et al. teach using an antibacterial composition which is effected by radiation as a means to destroy harmful microbes” (Ans. 8). The Examiner finds it obvious to “ use the device of Leinsing et al. with a radioactive isotope because Albrecht et al. teach that such are effective in destroying harmful microbes and would yield the predictable result of providing the septum with antimicrobial properties” (Ans. 8).

Appellants contend that “ claim 10 states that a radioactive isotope is included within the second coating material” (App. Br. 12). Appellants

contend that “[t]here is no teaching in Albrecht of a radioactive isotope incorporated into a soluble coating material” (App. Br. 12).

We find that the balance of the evidence supports the position of Appellants. Albrecht teaches that “radiation of a suitable wavelength is applied to the area to activate Erythrosin B and by a photodynamic reaction to destroy the bacteria” (Albrecht 2 ¶ 0027). The Examiner does not identify, and we do not find, any teaching in Albrecht which teaches or suggests the use of a radioactive isotope whatsoever, much less the concept or idea of incorporating such a radioactive isotope into a coating on a medical device. We are therefore constrained to reverse these rejections.

SUMMARY

In summary, we affirm the rejection of claim 1 under 35 U.S.C. § 102(b) as anticipated over Leinsing. Pursuant to 37 C.F.R. § 41.37(c)(1)(2006), we also affirm the rejection of claims 3, 7, and 27, as these claims were not argued separately.

We reverse the rejection of claim 2 under 35 U.S.C. § 103(a) as obvious over Leinsing and Khan.

We affirm the rejection of claims 4 and 5 under 35 U.S.C. § 103(a) as obvious over Leinsing and Tomisaka.

We affirm the rejection of claim 11 under 35 U.S.C. § 103(a) as obvious over Leinsing and Tomisaka. Pursuant to 37 C.F.R. § 41.37(c)(1)(2006), we also affirm the rejection of claims 13-15, and 28, as these claims were not argued separately.

We affirm the rejection of claim 8 under 35 U.S.C. § 103(a) as obvious over Leinsing and Matsuda.

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We reverse the rejection of claim 10 under 35 U.S.C. § 103(a) as obvious over Leinsing and Albrecht.

We affirm the rejection of claim 18 under 35 U.S.C. § 103(a) as obvious over Leinsing, Tomisaka, and Matsuda.

We reverse the rejection of claim 20 under 35 U.S.C. § 103(a) as obvious over Leinsing, Tomisaka and Albrecht.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1).

AFFIRMED-IN-PART

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