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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FRITZ HINDELANG and KARIN SCHWIND

Appeal 2012-002185
Application 12/105,304
Technology Center 3700

Before STEPHEN WALSH, ULRIKE W. JENKS, and SHERIDAN K.
SNEDDEN, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an analytical device and an analytical system. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Appellants' invention relates to an "analytical device . . . comprising a lancet and a test element in an integrated arrangement." (Spec., Abstract.)

A device of the invention may function as follows:

When the lancing process is triggered, the needle is moved forwards and in doing so exits at high speed from the opening through the protective cap. The entire lancing process occurs within a few milliseconds. After the skin has been punctured the needle is retracted again. In this process a catching device which is located on the lancet pulls along the protective cap and optionally additional seals. . . . The user (additionally) contacts the opening of the device with his collection device so that the suction opening (e.g. capillary) can take up a drop of blood. The suction action of the means for sample liquid transport transports the blood in the dispo to a site in the test chamber at which a test element comprising a detection element is located.

(*Id.*, 19-20.)

Claims 1-10 and 12 are on appeal. Claim 1 is representative and reads as follows (emphasis added):

1. An analytical device comprising a lancet and a test element in an integrated arrangement, the lancet comprising a lancet needle with a tip and a protective cap which generally completely surrounds the lancet needle at least in the area of the tip, wherein the lancet needle can be displaced in at least one direction relative to the protective cap, and wherein the lancet needle is configured to engage the protective cap after displacement of the lancet needle in the at least one direction and thereafter to pull the protective cap during displacement of the lancet needle in a retracting direction, the test element comprising a chamber containing a reagent system, *the chamber having a first opening configured to be generally sealed by the protective cap prior to and during displacement of the lancet needle in the at least one direction and configured thereafter to be generally opened upon displacement of the lancet needle in the retracting direction.*

The claims stand rejected as follows:

- I. Claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuhr¹ and Cohen.²
- II. Claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuhr and Fritz.³
- III. Claims 10 and 12 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuhr, Cohen and Uchigaki.⁴
- IV. Claims 10 and 12 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuhr, Fritz and Uchigaki.

I.

Issue

The Examiner has rejected claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuhr and Cohen. The Examiner finds that Kuhr does “not expressly disclose that the first opening of the chamber of the test element is configured to be generally sealed by the protective cap prior to and during displacement of the lancet needle.” (Final Office Action, 3.) The Examiner finds that “Cohen teaches a lancet needle (needle 14 Figures 1-3 and 5-7) configured to engage a protective cap (plug 30) after displacement of the lancet needle in the at least one direction (needle 14 engages plug 30 after the needle moves in the distal direction, Figures 1-3 and 5-7) and thereafter to pull the protective cap during

¹ Kuhr et al, US 2003/0050573 A1, published Mar. 13, 2003.

² Cohen et al, US 5,125,908, issued Jun. 30, 1992.

³ Fritz et al, US 2004/0034318 A1, published Feb. 19, 2004.

⁴ Uchigaki et al., US 6,830,551 B1, issued Dec. 14, 2004.

displacement of the lancet needle in a retracting direction (Figures 2-3 and 6-7).” (*Id.*, 4.)

The Examiner finds that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the pulling of the protective cap in a retracting direction as taught by Cohen with the invention of Kuhr et al. to provide an obvious sign to a user that the device has been used when they can no longer see the protective cap.” (Final Office Action, 4; see also Ans. 11.)

Appellants contend that “there is no disclosure, nor is there any suggestion in the combination of Kuhr and Cohen of claim 1’s specifically recited ‘test element comprising a chamber [...] having a first opening configured to be generally sealed by the protective cap prior to and during displacement of the lancet needle in the at least one direction and configured thereafter to be generally opened upon displacement of the lancet needle in the retracting direction.’” (App. Br. 23.)

The issue presented is: Does the evidence of record support the Examiner’s conclusion that the cited prior art renders claim 1 obvious?

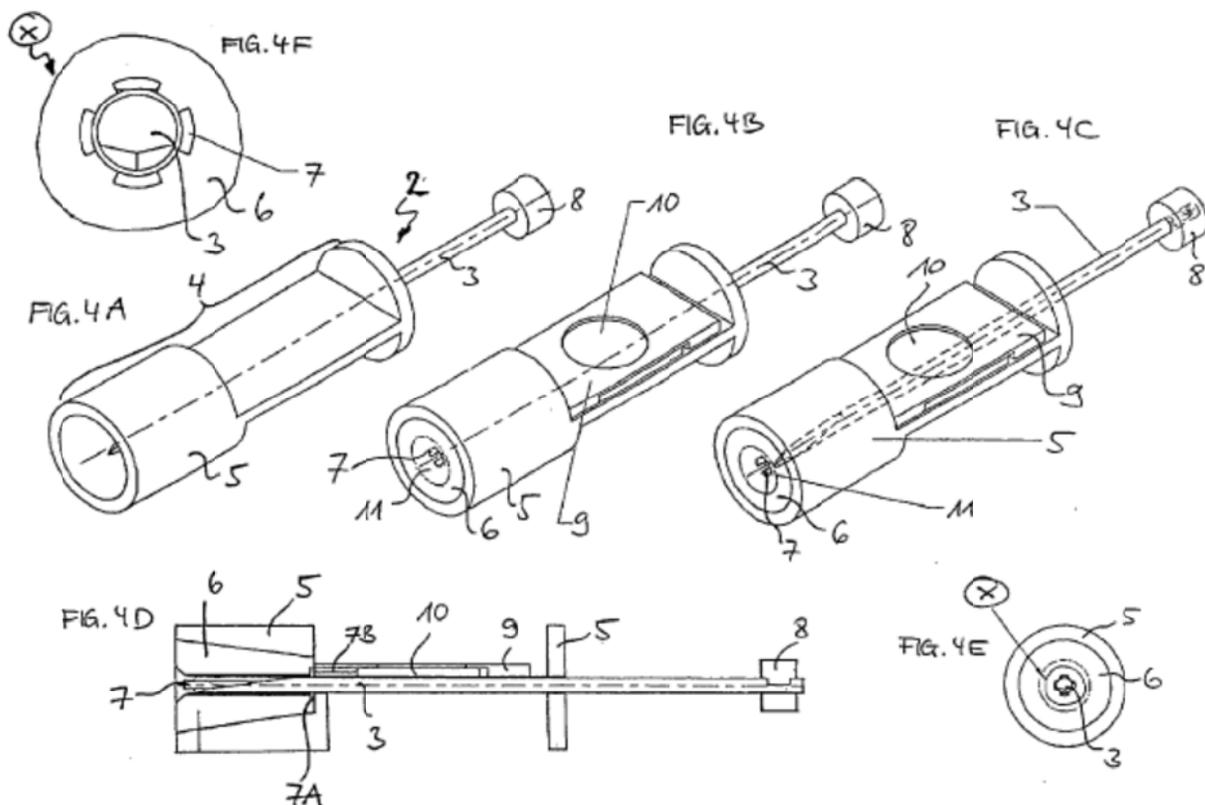
Findings of Fact

The following findings of fact (“FF”) are supported by a preponderance of the evidence of record.

FF1. Kuhr discloses “an analytical device containing a lancet comprising a lancet needle and a lancet body, the lancet needle being movable relative to the lancet body and the lancet body being composed, at least in the area of the tip of the lancet needle, of an elastic material in which

the tip of the lancet needle is embedded, and an analytical test element which is permanently connected to the lancet body.” (Kuhr, Abstract.)

FF2. Figure 4 of Kuhr is reproduced below.



“[T]he embodiment of **FIG. 4** is composed of a lancet (**2**) which contains a lancet needle (**3**) which is partially surrounded by a lancet body (**4**).” (*Id.*, 7, ¶[0111].) FIG. 4A shows “the lancet body (**4**) ... composed of a hard plastic part (**5**) and an elastic material (**6**) which in particular surrounds the lancet needle tip.” (*Id.*) In “**FIGS. 4B and 4C**, a test element (**9**) which contains a test field (**10**) is attached to the lancet body (**4**).” (*Id.*, 7, ¶[0112].) FIG. 4D shows that “the capillary gap (**7**) can be divided into three partial regions (**7, 7A and 7B**).” (*Id.*, 7, ¶[0110].) “**FIG. 4E** shows a front view of

the outlet opening of the lancet of the analytical device (1).” (*Id.*, 7, ¶[0114].) “**FIG. 4F** shows ... that four capillary channels (7)[,] which enable sample transport to the test element (9)[,] are present in the elastic material (6) of the lancet body (4).” (*Id.*, 7, ¶[0115].)

FF3. Kuhr discloses that

[t]he outlet opening of the lancet needle (3) is closed by a sealing foil (11) in this embodiment. When the lancet is used the sealing foil (11) can either be pierced by the lancet needle (3) or the sealing foil (11) is removed manually before use.

(*Id.*, 7, ¶[0113].)

FF4. Kuhr discloses that the “capillary gap (7) is worked into the hard plastic part (5) of the lancet body (4) and is used to transport the sample liquid.” (*Id.*, 6, ¶[0096]; *see also*, Kuhr at Figure 1-3, element (7).)

FF5. Cohen discloses a “syringe that includes a protective holder to prevent injury to the syringe user.” (Cohen, col. 1, ll. 9-10.)

FF6. Figures 1 and 3 of Cohen are reproduced below:

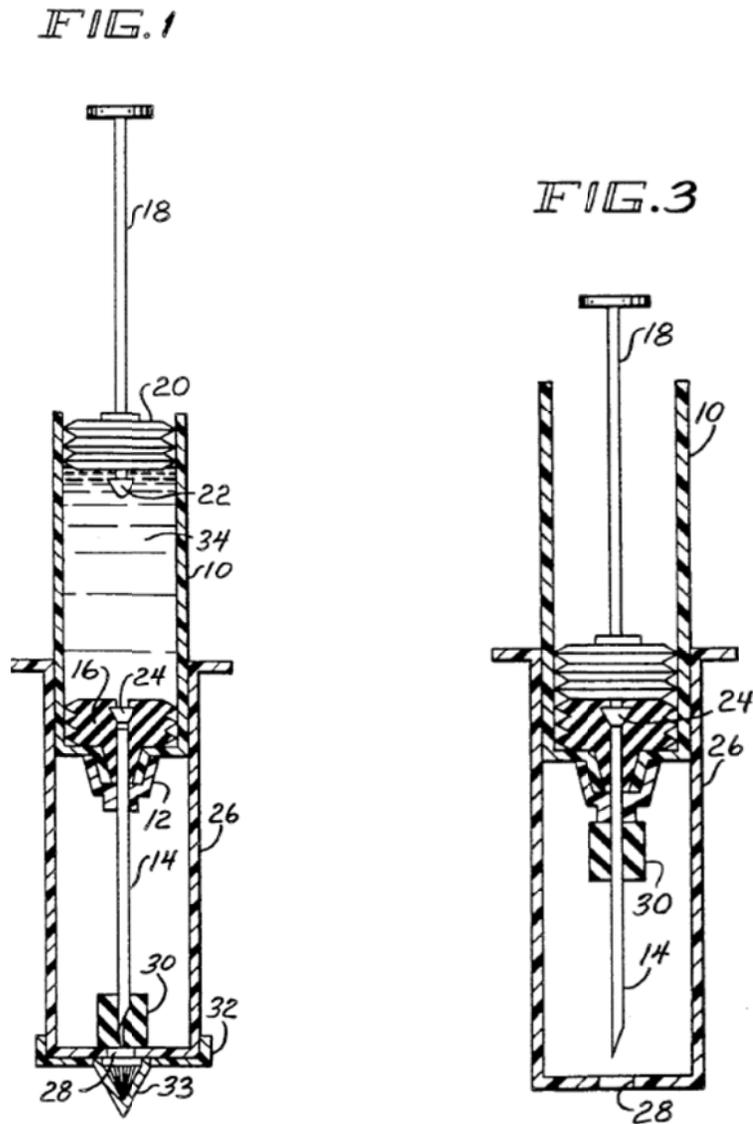


Figure 1 is “a side view in partial section of one embodiment of the present invention showing the syringe as stored prior to use.” (*Id.*, col. 1, ll. 64-66.) Figure 3 is “a view similar to **FIG. 1** ... showing the syringe retracted into the syringe holder after use.” (*Id.*, col. 2, ll. 1-2.)

FF7. Cohen discloses as follows:

The barrel **10** is mounted for slidable movement inside a cylindrical syringe holder **26**. The syringe holder **26** has an aperture **28** to allow passage of the needle **14** during use of the

syringe. A rubber plug **30** occludes the point of the needle, further reducing the chance of accidental injury prior to use of the syringe. Additionally, the plug **30** covers the aperture **28** and protects the needle **14** prior to use of the syringe.

...

The plug **30** continues to slide up the needle **14** until the plunger is fully compressed, ultimately coming to rest against the needle hub **12**. Thus, displacement of the plug **30** to expose the needle **14** requires no additional effort by the syringe user.

(*Id.*, col. 2, ll. 33-38 and 50-54.)

Principles of Law

When determining whether a claim is obvious, an examiner must make “a searching comparison of the claimed invention - - including all its limitations - - with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Int’l. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

Analysis

We agree with Appellants that the evidence of record does not support the Examiner’s finding that the combination of Kuhr and Cohen would achieve a device comprising a test chamber, where the chamber has an opening that becomes “generally opened upon displacement of the lancet needle in the retracting direction” as required by claim 1. (App. Br. 23.)

The “protective cap” of Kuhr is described as protecting the “outlet opening of the lancet needle”. (FF3.) The capillary channels (7) are not described by Kuhr to be part of this outlet opening of the lancet needle protected with a type of cap, but rather are described as being separately embedded into the lancet body. (*See e.g.*, FF2 and FF4.) Thus, modifying the “protective cap” of Kuhr with the “protective cap” of Cohen (FF5-FF7) does not necessarily achieve an arrangement where the capillary channels of Kuhr are protected. *See Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.”). *See also, In re Freed*, 425 F.2d 785, 787 (CCPA 1970) (Deficiencies in the factual basis cannot be supplied by resorting to speculation or unsupported generalizations.).

Conclusion of Law

The evidence of record does not support the Examiner’s conclusion that the combination of Kuhr and Cohen teaches or suggests all elements of claim 1 or dependent claims thereto.

II.

Issue

The Examiner finds that Kuhr does “not expressly disclose that the first opening of the chamber of the test element is configured to be generally sealed by the protective cap prior to and during displacement of the lancet needle in the at least one direction and configured thereafter to be generally opened upon displacement of the lancet needle in the retracting direction, and that lancet needle is configured to engage a protective cap after

displacement of the lancet needle in the at least one direction and thereafter to pull the protective cap during displacement of the lancet needle in a retracting direction.” (Ans. 7.) The Examiner relies on Fritz for this element. Specifically, the Examiner finds that Fritz discloses “a lancet needle (needle 31' Figures 9A-9C) configured to engage a protective cap (material 35) after displacement of the lancet needle in the at least one direction (needle 31' engages material 35 after the needle moves in the distal direction, Figures 9A-9C) and thereafter to pull the protective cap during displacement of the lancet needle in a retracting direction (Figures 9A-9C).” (*Id.* at 7.)

In reaching a conclusion of obviousness, the Examiner finds that Kuhr et al. as modified by Fritz et al. would have the first opening of the chamber of the test element configured to be generally sealed by the protective cap prior to and during displacement of the lancet needle in the at least one direction (Fritz et al. Figures 9A and 98) and configured thereafter to be generally opened upon displacement of the lancet needle in the retracting direction (Fritz et al. Figure 9C). *In other words, as combined, the protective cap/material of Fritz et al. would be at the distal end of Kuhr et al. (see, for example, Figure 4D of Kuhr et al.), and in this position would seal both the lancet and the capillary channels of Kuhr et al.*

(Ans. 8.) (Emphasis added.)

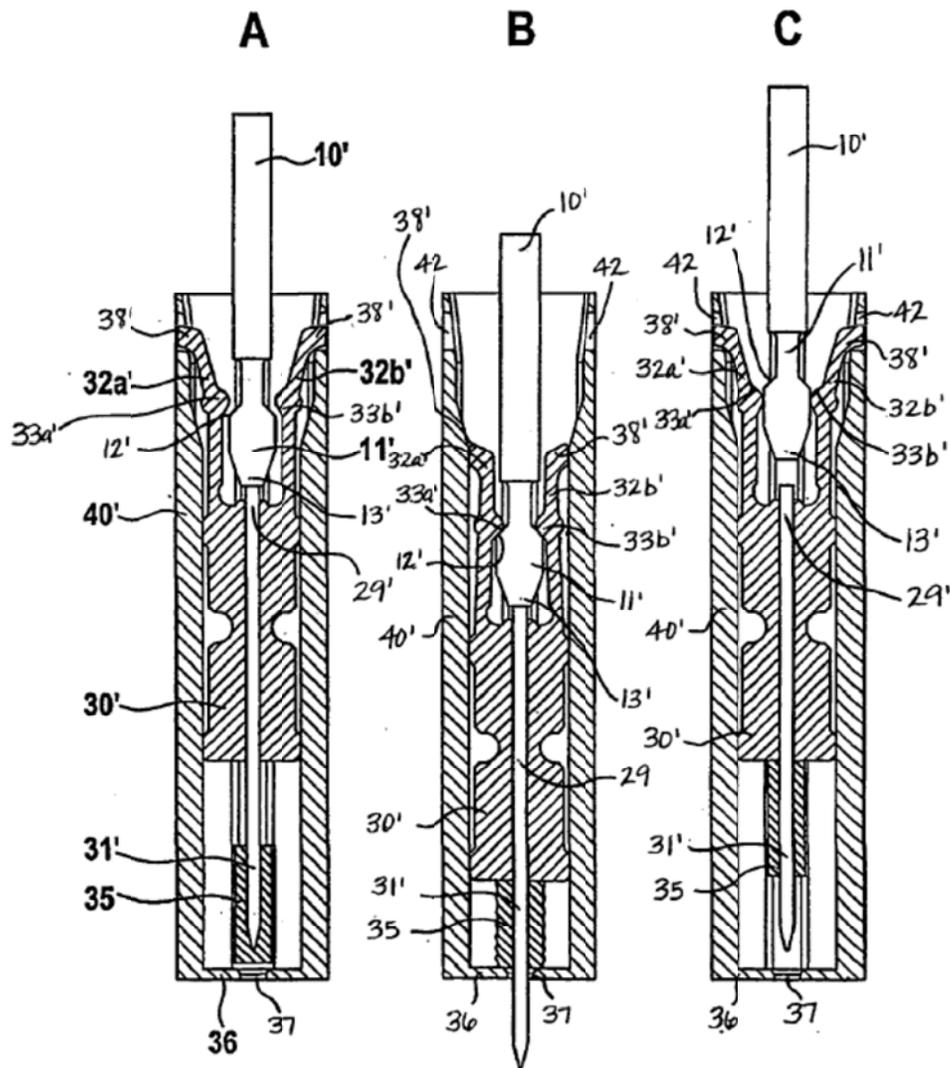
Appellants contend that the combination of Kuhr and Fritz fails to disclose a test element comprising a chamber “having a first opening configured to be generally sealed by the protective cap prior to and during displacement of the lancet needle in the at least one direction and configured thereafter to be generally opened upon displacement of the lancet needle in the retracting direction” as required by claim 1. (App. Br. 29.)

The issue presented is:

Does the evidence of record support the Examiner's conclusion that the cited prior art renders Claim 1 obvious?

Additional Findings of Fact

FF8. Figures 9A, 9B and 9C of Fritz are reproduced below.



“FIGS. 9A-9C are cross-sectional views of a lancing unit with a sterile protection, shown at three different positions (A, B, C).” (Fritz 3, ¶ [0035].)

FF9. With regard to Figures 9A, 9B and 9C, Fritz discloses as follows:

FIG. 9 also shows that the needle tip is arranged in a material **35**. This material **35** is preferably an elastomer which tightly encloses the needle tip to effectively prevent contamination of the needle tip. ... The material **35** used to prevent contamination of the needle tip In the initial position shown in **FIG. 9A**, before lancing the needle tip is located in the elastomer **35** which is pierced by the needle tip when a puncture is carried out as shown in **FIG. 9B**. For this purpose, the underside of the sleeve **40'** has a plate **36** with a central opening **37**. The plate **36** prevents the elastomer **35** from emerging through the opening **37** so that the elastomer **35** is pierced when the needle **31'** passes through the central opening **37**. When the lancet **30'** is retracted, the elastomer **35** remains on the needle **31'** and the needle tip is now exposed as shown in **FIG. 9C**.

(*Id.* 6-7, ¶ [0059].)

Analysis

We agree with Appellants that the evidence of record does not support the Examiner's finding that the combination of Kuhr and Fritz would achieve a device comprising a test chamber, where the chamber has an opening that becomes "generally opened upon displacement of the lancet needle in the retracting direction" as required by claim 1. (App. Br. 29.) The "protective cap" of Kuhr is described as protecting the "outlet opening of the lancet needle." (FF3.) The capillary channels (7) are not described by Kuhr to be part of this outlet opening of the lancet needle protected with a type of cap, but rather are described as being separately embedded into the lancet body. (*See e.g.*, FF2 and FF4.) Thus, modifying the "protective cap" of Kuhr with the "protective cap" of Fritz (FF8-FF9) does not necessarily

achieve an arrangement where the capillary channels of Kuhr are protected. *See Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”). *See also, In re Freed*, 425 F.2d 785, 787 (CCPA 1970) (Deficiencies in the factual basis cannot be supplied by resorting to speculation or unsupported generalizations.).

Conclusion of Law

The evidence of record does not support the Examiner’s conclusion that the combination of Kuhr and Fritz fail to teach or suggest all elements of claim 1 or dependent claims thereto.

III.

Claims 10 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuhr, Cohen and Uchigaki. Having reversed the rejection of claim 1 over the combination of Kuhr and Cohen, we necessarily reverse this obviousness rejection further relying upon Uchigaki because Uchigaki does not cure the deficiencies of Kuhr and Cohen discussed above.

IV.

Claims 10 and 12 are also rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuhr, Fritz and Uchigaki. Having reversed the rejection of claim 1 over the combination of Kuhr and Fritz, we necessarily reverse this obviousness rejection further relying upon Uchigaki because Uchigaki does not cure the deficiencies of Kuhr and Fritz discussed above.

SUMMARY

We reverse the rejection of claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuhr and Cohen.

We reverse the rejection of claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuhr and Fritz.

We reverse the rejection of claims 10 and 12 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuhr, Cohen and Uchigaki.

We reverse the rejection of claims 10 and 12 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuhr, Fritz and Uchigaki.

REVERSED

dm