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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* NANNETTE M. VAN ANTWERP, RAJIV SHAH,  
BRADLEY J. ENEGREN, RICHARD LEMOS JR.,  
LY PHOU, GARRY M. STEIL, and GAYANE R. VOSKANYAN

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Appeal 2011-002719  
Application 11/897,106  
Technology Center 3700

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Before FRANCISCO C. PRATS, 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 device for fluid dispensing and patient monitoring. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

*Statement of the Case*

*Background*

The Specification teaches that the “apparatus design described herein allows the sensor and infusion catheter to be built into a single set, which greatly improves comfort and convenience for the patient” (Spec. 15, ll. 29-31). The Specification teaches “a combination glucose sensor/insulin infusion reduces both the amount of hardware the patient has to wear on their body and the number of needle sticks required” (Spec. 15, ll. 31-33).

*The Claims*

Claims 1-3, 5-7, 9-13, and 15-19 are on appeal. Independent claim 1 is representative and reads as follows:

1. An apparatus for supplying a fluid to a body of a patient and for monitoring a body characteristic of the patient, the apparatus comprising:
  - a base adapted to secure the apparatus to the skin of a patient;
  - a first piercing member coupled to and extending from the base, wherein the first piercing member is operatively coupled to at least one cannula for infusing a fluid to an infusion site;
  - a second piercing member coupled to and extending from the base and operatively coupled to an electrochemical sensor having a sensor electrode for determining at least one body characteristic of the patient at a sensor placement site;
  - infusion set tubing adapted to connect to the cannula;
  - wherein:
    - the first and second piercing members are disposed on a hub that can operatively engage and disengage from the base; and
    - the first and second piercing members are coupled to the base in an orientation such that when the first and second piercing members are operatively coupled to the base and inserted into a patient, a first perforation channel made by the first piercing member is not in operable contact with a second perforation channel made by the second piercing member.

*The issues*

- A. The Examiner rejected claims 1-3, 5, 6, and 9-13 under 35 U.S.C. § 103(a) as obvious over Moberg<sup>1</sup> (Ans. 4-7).
- B. The Examiner rejected claim 7 under 35 U.S.C. § 103(a) as obvious over Moberg and Douglas<sup>2</sup> (Ans. 7).
- C. The Examiner rejected claim 15 under 35 U.S.C. § 103(a) as obvious over Moberg and Gross<sup>3</sup> (Ans. 7-8).
- D. The Examiner rejected claims 16-18 under 35 U.S.C. § 103(a) as obvious over Moberg and Clark<sup>4</sup> (Ans. 8-10).
- E. The Examiner rejected claim 19 under 35 U.S.C. § 103(a) as obvious over Moberg, Clark, and Gross (Ans. 10).
- F. The Examiner rejected claims 1-3, 5, 6, 9-13, and 15 under 35 U.S.C. § 103(a) as obvious over Gross, Fangrow,<sup>5</sup> and Mann<sup>6</sup> (Ans. 11-15).
- G. The Examiner rejected claim 7 under 35 U.S.C. § 103(a) as obvious over Gross, Fangrow, Mann, and Douglas (Ans. 15).
- H. The Examiner rejected claims 16-19 under 35 U.S.C. § 103(a) as obvious over Gross, Fangrow, and Clark (Ans. 15-19).

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<sup>1</sup> Moberg et al., US 2006/0253086 A1, published Nov. 9, 2006.

<sup>2</sup> Douglas, J., US 2005/0131346 A1, published Jun. 16, 2005.

<sup>3</sup> Gross et al., US 5,800,420, issued Sep. 1, 1998.

<sup>4</sup> Clark, Jr., L., US 4,680,268, issued Jul. 14, 1987.

<sup>5</sup> Fangrow, Jr., T., US 2005/0107743 A1, published May 19, 2005.

<sup>6</sup> Mann et al., US 6,809,653 B1, issued Oct. 26, 2004.

A. *35 U.S.C. § 103(a) over Moberg*

The Examiner finds that the device of the rejected claims differs from Moberg's device in that Moberg "teaches that the first and second piercing members [281][284] are disposed on separate hubs ('introducer needle hubs') that can operatively engage and disengage from the base [20]; however, Moberg et al does not teach that the first and second piercing members are disposed on the same one hub" (Ans. 5).

The Examiner finds it obvious to "modify the two separate hubs of the first and second piercing members to be one integral hub, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art" (Ans. 5).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Moberg renders claim 1 obvious?

*Findings of Fact*

1. Moberg teaches that "when used in conjunction with glucose sensors or monitors, insulin pumps may be automatically controlled to provide appropriate doses of infusion medium at appropriate times of need, based on sensed or monitored levels of blood glucose" (Moberg 1 ¶ 0006).

2. Moberg teaches that the delivery device **12** in **FIG. 28** also includes a disposable base portion **20** on which a reservoir canister **24** may be supported, as described above. An introducer needle **281** has a handle portion **282** and is positioned to allow the needle to be passed through the septum **27** of the reservoir **24**, when the reservoir **24** is supported on the base portion **20**.

(Moberg 11 ¶ 0098).

3. Figure 28 of Moberg is reproduced below

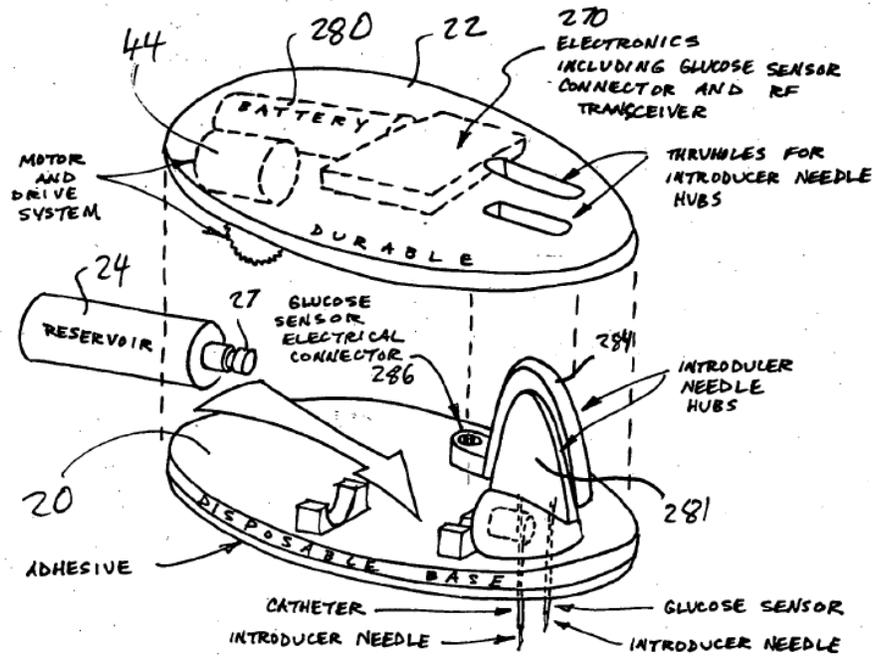


Fig. 28

Figure 28 shows “a generalized perspective view of needle insertion portions of delivery devices” (Moberg 1 ¶ 0015).

4. Moberg teaches that the “delivery device **12** in **FIG. 28** also includes a second needle **284** connected to sensor electronics. For example, the second needle **284** may be connected to electronics that produce an electronic signal representative of a sensed biological state, such as, but not limited to, blood glucose level” (Moberg 11 ¶ 0098).

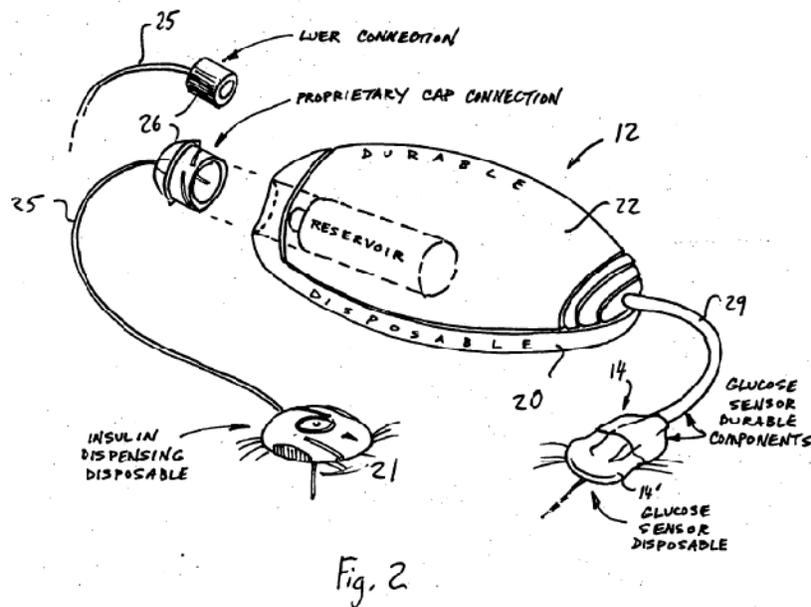
5. Moberg teaches that “reservoir **24** has a port and may be supported by the base portion **20** in a position at which a connector **26** may engage or otherwise come into fluid flow communication with the reservoir

port, when the connector **26** is connected to the port **23** on the base portion **20**” (Moberg 4 ¶ 0037).

6. Moberg teaches that “a needle hub comprises a needle **220** for piercing a septum of a reservoir canister **24**” (Moberg 9 ¶ 0087).

7. The Examiner finds that “Moberg et al teaches that the first and second piercing members [281][284] are disposed on separate hubs (‘introducer needle hubs’) that can operatively engage and disengage from the base [20]” (Ans. 5).

8. Figure 2 is reproduced below:



“FIG. 2 is a perspective view of a delivery device and related components” (Moberg 1 ¶ 0011).

9. Moberg teaches that the “base portion **20** may include a suitable opening or port **23** for connecting a hollow tube **25** to the reservoir, to convey infusion media from the reservoir” (Moberg 2-3 ¶ 0028).

10. Moberg teaches that the “other end of the tube **25** may connected to a hollow needle **21** for piercing the patient’s skin and conveying infusion media into the patient” (Moberg 3 ¶ 0029).

11. Moberg teaches that in “other embodiments, as described below, a hollow needle and insertion mechanism may be included within the delivery device **12**, so as to avoid the need for a port **23**, tube **25** and connector **26**” (Moberg 3 ¶ 0029).

*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*

Moberg teaches an apparatus that “when used in conjunction with glucose sensors or monitors, insulin pumps may be automatically controlled to provide appropriate doses of infusion medium at appropriate times of need, based on sensed or monitored levels of blood glucose” (Moberg 1 ¶ 0006; FF 1). Moberg teaches a base (FF 2) with a first piercing member for infusing a fluid (FF 2-3) and a second piercing member for sensing a body characteristic, specifically glucose levels (FF 4). Moberg suggests the use of infusion tubing connecting the reservoir to the needle (FF 8-9). Moberg teaches that the piercing members are on a hub which can engage and disengage from the base and which are operatively coupled to the base but which do not come into contact after piercing the patient (FF 3, 6, 7).

Applying the *KSR* standard of obviousness to the findings of fact, we conclude that the person of ordinary skill would have reasonably incorporated the infusion tubing of Moberg into the apparatus of figure 28 where the tubing was necessary to connect the needle to the reservoir or to refill the internal reservoir from an external reservoir. We also agree with the Examiner that forming the hub of the two needles into a single piece would have been reasonably obvious for the reasons given by the Examiner. Such a combination is merely a “predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. at 417.

Appellants contend that the “port in the delivery needle that allows a fluid medication to flow from the fluid medication reservoir to the site of infusion eliminates the need for infusion set tubing adapted to connect to a cannula” (App. Br. 5).

We are not persuaded. Moberg teaches an alternative embodiment in figure 2 (FF 8) where the “base portion **20** may include a suitable opening or port **23** for connecting a hollow tube **25** to the reservoir, to convey infusion media from the reservoir” (Moberg 2-3 ¶ 0028; FF 9). Moberg teaches that the “other end of the tube **25** may connected to a hollow needle **21** for piercing the patient’s skin and conveying infusion media into the patient” (Moberg 3 ¶ 0029; FF 10). We conclude that it would have been an obvious alternative to either refill the reservoir 24 in Figure 28 or directly infuse through the needle in figure 28 by using a tube such as that shown in figure 2 and discussed by Moberg (FF 8-10). Moberg specifically teaches that these are known alternatives or equivalents, stating that in “other embodiments, as described below, a hollow needle and insertion mechanism

may be included within the delivery device **12**, so as to avoid the need for a port **23**, tube **25** and connector **26**” (Moberg 3 ¶ 0029; FF 11).

Appellants contend that “the addition of infusion set tubing will contribute no benefit (or any function whatsoever) to this apparatus. In fact, the addition of infusion set tubing to Moberg’s apparatuses . . . will in fact compromise the operability of these devices” (App. Br. 6).

We are not persuaded. Moberg teaches embodiments in which infusion tubing is used (FF 8-10). There is no evidence that using tubing would, in any way, prevent the system of Moberg from operating. *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) (“Attorney’s argument in a brief cannot take the place of evidence.”). That Moberg teaches devices, some of which use infusion tubing and some of which do not use infusion tubing, does not teach away from the use of infusion tubing. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments. *See In re Susi*, 440 F.2d 442, 446 n.3 (CCPA 1971).

#### *Conclusion of Law*

The evidence of record supports the Examiner’s conclusion that Moberg renders claim 1 obvious.

#### *B.-E. 35 U.S.C. § 103(a)*

Appellants do not separately argue the claims in these obviousness rejections. Having affirmed the obviousness rejection of Claim 1 over Moberg, we also find the further combinations with Douglas, Gross, Clark, renders claims 7 and 15-19, obvious for the reasons given by the Examiner (*see* Ans. 7-10).

*F. 35 U.S.C. § 103(a) over Gross, Fangrow, and Mann*

The Examiner finds that Gross's device differs from the claimed device in that

Gross et al does not teach a first piercing member operatively coupled to the at least one cannula [15], since the cannula itself is a needle, thus not requiring a further piercing member for insertion of the cannula into the body. Fangrow teaches an apparatus (Figures 1-14) wherein a first piercing member (introducer needle [66]) is coupled to and extends from a base (base member [60]), wherein the first piercing member is operatively coupled to at least one cannula (soft cannula [52]) for infusing a fluid to an infusion site.

(Ans. 11). The Examiner finds that "Fangrow teaches that the first piercing member [66] is disposed on a hub (introducer cap [64]) that can operatively engage and disengage from the base [60]" (Ans. 12). The Examiner finds that Mann teaches "an apparatus (Figures 1-14), wherein a second piercing member (needle [14]), which is disposed on a hub (full round cross-sectional shape of the needle [14] that is disposed above the mounting base [30]), is operatively coupled to a sensor (cannula [16] with sensing portion [18])" (Ans. 13).

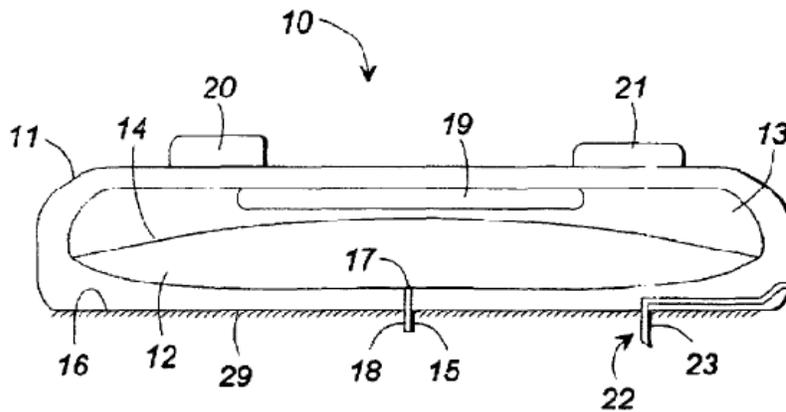
The Examiner finds it obvious to "substitute the cannula ('delivery needle'), of the apparatus of Gross et al, with a first piercing member and soft cannula, as taught by Fangrow, as a soft cannula with a removable piercing member is more comfortable to a patient" (Ans. 11-12). The Examiner further finds it obvious "to modify the second piercing member, of the modified apparatus of Gross et al and Fangrow, to be disposed on a hub and operatively engageable and disengageable from the base, as taught by

Mann et al, as the withdrawal of the second piercing member from the sensor after the sensor has been placed into the body of the patient will provide more comfort to the patient as an unnecessary piercing member will not be present in the body of the patient during the sensing procedure” (Ans. 13).

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

*Findings of Fact*

12. Figure 1 of Gross is reproduced below:



**FIG. 1**

“FIG. 1 is a cross-section through a liquid delivery device” (Gross, col. 14, l. 9).

13. Gross teaches that “device **10** comprises a housing **11** containing an insulin reservoir **12** for storing insulin” (Gross, col. 14, ll. 58-59).

14. Gross teaches that “delivery needle **15** penetrates through the epidermis and the dermis, thereby establishing communication between

insulin reservoir **12** and the subject's subcutaneous tissue via the hollow needle **15**" (Gross, col. 15, ll. 3-6).

15. Gross teaches that "[m]icroprocessor **21** controls . . . the rate of insulin delivery, by monitoring the patient's blood glucose level by means of a glucose sensor, indicated generally at **22**. Sensor **22** comprises a platinum-iridium sensor needle **23**" (Gross, col. 15, ll. 22-26).

16. Fangrow teaches that

Once the needle **66** and soft cannula **52** have been inserted to the desired depth, the introducer cap **64** can be removed from the base member **60** and from the patient . . . Once the introducer cap **64** is disengaged from the base member **60**, the cap is pulled outward and away from the patient, and the needle **66** is withdrawn from the soft cannula **52**. The soft cannula remains within the patient, extending to a desired depth within the patient's sub-dermal tissue and held in place by the base member **60** and the adhesive layer **50**.

(Fangrow 6 ¶¶ 0069-0070).

17. Fangrow teaches that "an infusion system may comprise additional tubes, connectors, or other components between the soft cannula and a fluid source" (Fangrow 7 ¶ 0079).

18. Fangrow teaches that in "alternative embodiments, the base member **60** shown and described herein can be employed to deliver medicants or other therapeutic fluids to a patient without the use of the other members of the infusion set described herein" (Fangrow 7 ¶0080).

19. Mann teaches that the

insertion needle **14** is adapted for slide-fit reception **30** through a needle port **42** formed in the upper base layer **36** and further through the lower bore **40** in the lower base layer **38**. As shown, the insertion needle **14** has a sharpened tip **44**

and an open slot **46** which extends longitudinally from the tip **44** at the underside of the needle **14** to a position at least within the bore **40** in the lower base layer **36**. Above the mounting base **30**, the insertion needle **14** may have a full round cross-sectional shape

(Mann, col. 7, ll. 30-38).

20. Mann teaches that “[a]fter insertion, the insertion needle **14** is withdrawn to leave the cannula **16** with the sensing portion **18** and the sensor electrodes **20** in place at the selected insertion site” (Mann, col. 6, ll. 29-32).

*Analysis*

Gross teaches a device which comprises a base (FF 13), a first needle to infuse a fluid (FF 14) and a second needle operatively connected to a sensor (FF 15) where the perforation channels of the two needles are not in operable contact (FF 12). Fangrow teaches the use of a needle for delivery of a cannula (FF 16) as well as infusion tubing to connect the cannula to a reservoir (FF 17). Mann teaches a sensor connected to a hub where the cannula may be withdrawn, leaving the sensor in place (FF 19-20).

Applying the *KSR* standard of obviousness to the findings of fact, we conclude that the person of ordinary skill would have reasonably incorporated the soft cannula and introduction system of Fangrow and the sensor hub of Mann into the apparatus of Gross since the Examiner finds that “a soft cannula with a removable piercing member is more comfortable to a patient, in an infusion procedure” (Ans. 12). In addition, we agree with the Examiner that infusion tubing provides “an efficient means for connecting and disconnecting the cannula with a pump or fluid source that is external to the base of the apparatus” (Ans. 12). Such a combination is

merely a “predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. at 417.

Appellants contend that the “compact arrangement of elements in the Gross apparatus therefore eliminates the need for an infusion tubing set (i.e. to form a fluid conduit between an external fluid source and the infusion site)” (App. Br. 8).

We are not persuaded. While Gross prefers the use of an internal reservoir, Fangrow teaches that in “alternative embodiments, the base member **60** shown and described herein can be employed to deliver medicants or other therapeutic fluids to a patient without the use of the other members of the infusion set described herein” (Fangrow ¶0080; FF 18). That is, the prior art as represented by Fangrow recognizes that the infusion system may comprise tubes (FF 17) but may also use a direct delivery method. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments. *See In re Susi*, 440 F.2d 442, 446 n.3 (CCPA 1971).

Appellants contend that “because infusion set tubing is made from materials that are not designed to be electrically conductive, a modification to Gross’s patch pump that added ‘infusion set tubing adapted to connect to the cannula’ would further render this apparatus unsatisfactory for its intended purpose by introducing an electrically non-conductive material barrier” (App. Br. 9).

We are not persuaded. We agree with the Examiner that whether or not the infusion set tubing is made from electrically conductive materials is a design choice for the material of the tubing. Electrically conductive tubing is well-

known in the art, thus an electrically non-conductive material barrier would not be introduced into the resultant apparatus of Gross and Fangrow that would disrupt the flow of electrical current within the sensor potentiostat circuit.

(Ans. 23).

Appellants also contend that “[o]ne of skill in the art would further disagree with Patent Office’s assertion that a motivation to combine the disclosure in Fangrow and Gross is present because infusion set tubing would provide the benefit of allowing the apparatus to be coupled to an external fluid source. Instead, the skilled artisan would note that the Gross device is already coupled to a fluid source, internal reservoir 12” (App. Br. 10).

We do not find this argument persuasive since the ordinary artisan would recognize that external and internal reservoirs are both known elements in the prior art, where the choice depends upon whether portability or volume is in greater demand for the device. Where there is a need to introduce large amounts of volume which would not fit within a compact device, the ordinary artisan would reasonably be motivated to select an external reservoir, as the Examiner notes that “[s]uch will be useful in the case that the reservoir [12] of Gross is depleted, thus requiring a means for providing additional fluid into the apparatus from a secondary external fluid source” (Ans. 24).

*G.-H. 35 U.S.C. § 103(a)*

Appellants do not separately argue the claims in these obviousness rejections. Having affirmed the obviousness rejection of Claim 1 over Gross, Fangrow, and Mann, we also find the further combinations with

Douglas, and Clark, render claims 7 and 16-19, obvious for the reasons given by the Examiner (*see* Ans. 15-19).

#### SUMMARY

In summary, we affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as obvious over Moberg. Pursuant to 37 C.F.R. § 41.37(c)(1), we also affirm the rejection of claims 2, 3, 5, 6, and 9-13 as these claims were not argued separately.

We affirm the rejection of claim 7 under 35 U.S.C. § 103(a) as obvious over Moberg and Douglas.

We affirm the rejection of claim 15 under 35 U.S.C. § 103(a) as obvious over Moberg and Gross.

We affirm the rejection of claims 16-18 under 35 U.S.C. § 103(a) as obvious over Moberg and Clark.

We affirm the rejection of claim 19 under 35 U.S.C. § 103(a) as obvious over Moberg, Clark, and Gross.

We affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as obvious over Gross, Fangrow, and Mann. Pursuant to 37 C.F.R. § 41.37(c)(1), we also affirm the rejection of claims 2, 3, 5, 6, 9-13, and 15 as these claims were not argued separately.

We affirm the rejection of claim 7 under 35 U.S.C. § 103(a) as obvious over Gross, Fangrow, Mann, and Douglas.

We affirm the rejection of claims 16-19 under 35 U.S.C. § 103(a) as obvious over Gross, Fangrow, and Clark.

Appeal 2011-002719  
Application 11/897,106

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

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