

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JEAN CURUTCHARRY

Appeal 2008-1357
Application 10/433,455
Technology Center 3700

Decided: July 24, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

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

STATEMENT OF THE CASE

The Specification discloses a device adapted to carry out “the mixing of one substance with another substance, particularly in the medical field, so as for example to reconstitute a medication by means of a diluant” (February 2006 Substitute Specification (Spec.) 1). In Figure 1, the Specification depicts a reconstitution device that “comprises a hollow needle 2 passing through a circular support 3 prolonged toward each pointed end of the needle, by a cylindrical socket” (*id.* at 5). The Specification states that the device “is of one-piece construction and made for example by molding a suitable plastic material” (*id.* at 7).

Claims 9-16 are pending and on appeal. We will focus on claim 9, which reads as follows:

9. A reconstitution device, comprising:
 - a one-piece support;

a hollow needle, pointed at both ends and fixed on said support, said support defining two coaxial sockets enclosing each end of said needle, a first one of said sockets being adapted to receive a plugged mouth of a vial and a second one of said sockets being adapted to receive a tip of an injection tube of a flexible bag, so that perforating a plug of a vial and a tip of an injection tube places a vial in communication with a flexible bag via said needle,

said first one of said sockets including a continuous or discontinuous flange projecting inwardly adjacent an inlet opening of said first one of said sockets and at least one resiliently retractable projection within said first one of said sockets and spaced apart from said flange that together with said flange engage a tip of an injection tube in a first stable position in which said device is secured to a flexible bag without said needle being in contact with a tip of an injection tube,

said first one of said sockets being slidably mounted on a tip of an injection tube so as to pass, by simple sinking of the device against a tip of

an injection tube, from said first stable position to a second stable position, said needle piercing a tip of an injection tube in said second stable position.

Claims 9-16 stand rejected under 35 U.S.C. § 102(e) as anticipated by Fowles (US 6,113,583, Sep. 5, 2000).¹

The Examiner contends that Fowles discloses a connecting device that anticipates claim 9 (Ans. 6). The Examiner finds that “the term ‘one-piece’ is not interchangeable with the term ‘unitary’” and “that ‘one-piece’ simply means that the device is joined such that parts are joined together” (*id.* at 7). The Examiner also finds that Appellant “fails to define exactly what is meant by ‘one-piece’ in the specification. The only mention of the word ‘one-piece’ in the specification states that the one-piece construction may be made *for example* by molding a suitable plastic material” (*id.*).

Appellant contends that Fowles does not disclose a one-piece support (App. Br. 7). In particular, Appellant argues that Fowles “does not even disclose an integral member formed of two or more pieces that are connected together as an integral unit. Rather, . . . FOWLES discloses two sleeves 33, 34 that are mounted for translational motion, with sleeve 33 sliding within sleeve 34.” (*Id.*)

ISSUE

The issue is whether Fowles describes a one-piece support defining two coaxial sockets enclosing each end of a needle.

¹ We recognize the Examiner’s objection to the Specification and claim 16 (Ans. 4-5). We note, however, that the Examiner expressly withdrew the objection to the Specification (*id.* at 7). Because claim 16 was objected to “for the reasons set forth . . . in the objection to the specification,” it is our understanding that the Examiner has also withdrawn the objection to claim 16 (*id.* at 5).

FINDINGS OF FACT

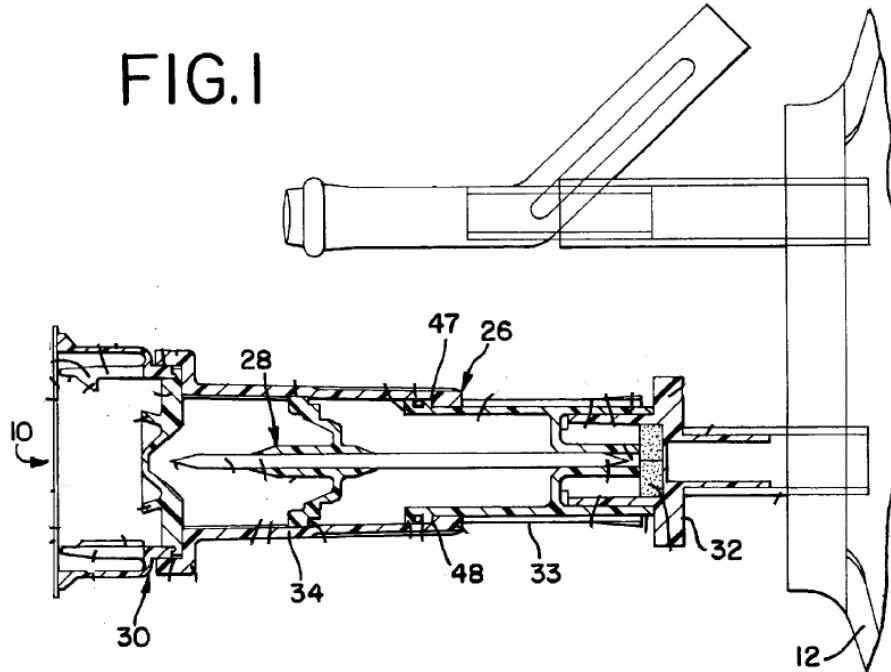
1. Claim 9 recites a reconstitution device comprising a one-piece support and a needle, the support defining two coaxial sockets enclosing each end of the needle.

2. Fowles discloses “a connector device for establishing fluid communication between [a] diluent container . . . and a drug vial” (Fowles, col. 4, ll. 44-47).

3. In particular, Fowles discloses a connector having a piercing member mounted to a liquid container and having a vial receiving chamber (*id.* at col. 4, ll. 47-53).

4. Fowles states that the “device is movable from an inactivated position, where . . . no fluid flows between the liquid container and the drug vial, to an activated position, where fluid flows through the fluid pathway between the liquid container and the drug vial” (*id.* at col. 4, ll. 58-62).

5. A redacted version of Fowles Figure 1 is reproduced below:



This figure depicts a cross sectional view of a connector device 10 attached to a flexible container 12 (*id.* at col. 6, ll. 42-43, & col. 8, ll. 4-9).

6. “As shown in FIG. 1, the connector **10** generally comprises a sleeve assembly **26**, a piercing assembly **28** . . . , a cup assembly **30** and a port connector **32**” (*id.* at col. 8, ll. 48-51).

7. “As further shown in FIG. 1, the sleeve assembly **26** generally comprises a first sleeve **33** and a second sleeve **34**. The first sleeve **33** and second sleeve **34** are mounted for translational motion with respect to one another from the inactivated position to the activated position.” (*Id.* at col. 8, l. 66, to col. 9, l. 3.)

8. Fowles also discloses that “the first sleeve **33** has a stop surface **47** that cooperates with a stop surface **48** on the second sleeve **34** that prevent the first sleeve **33** from sliding out of the second sleeve **34**” (*id.* at col. 9, ll. 35-38).

9. Sleeves 33 and 34 together form an assembly having two coaxial sockets enclosing each end of the piercing assembly (*id.* at Fig. 1).

ANALYSIS

We agree with Appellant that the Examiner has not set forth a *prima facie* case that Fowles anticipates claim 9. Claim 9 recites a reconstitution device comprising a one-piece support and a needle, the support defining two coaxial sockets enclosing each end of the needle (Finding of Fact (FF) 1). We interpret the term “one-piece” to require that a single unit has two coaxial sockets enclosing each end of the needle. Sleeves 33 and 34 together form an assembly having two coaxial sockets enclosing each end of a needle (FF 9). However, we agree with Appellant that sleeves 33 and 34

Appeal 2008-1357
Application 10/433,455

constitute two pieces (FF 5-8). Thus, we agree with Appellant that these two pieces do not anticipate the one-piece support of claim 9.

CONCLUSION

The Examiner has not shown that Fowles describes a one-piece support defining two coaxial sockets enclosing each end of a needle. We therefore reverse the anticipation rejection of claim 9 and of claims 10-16, which also recite or depend from a claim that recites a one-piece support defining two coaxial sockets enclosing each end of a needle.

REVERSED

Ssc:

YOUNG & THOMPSON
209 MADISON STREET
SUITE 500
ALEXANDRIA, VA 22314