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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BO RADMER

Appeal 2011-004328
Application 12/298,082
Technology Center 3700

Before DEMETRA J. MILLS, ERIC GRIMES, and LORA M. GREEN,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to drug mixing kits. 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 “mixing device for mixing the contents of two containers and for transferring the mixed solution to a standard syringe” (Spec. 2:27-28). Figure 1 of the Specification is shown below:

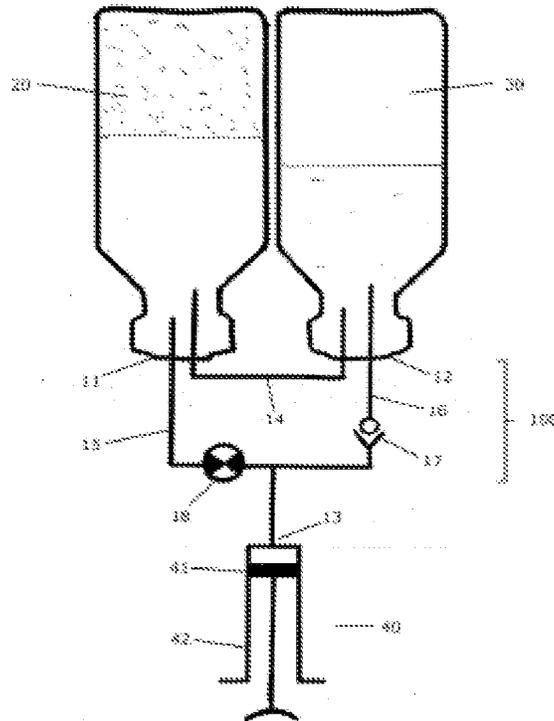


Figure 1 shows “a schematic representation of a transfer system 100 connected to a first container 20 ..., a second container 30 ... [and] a syringe 40” (*id.* at 14:14-17).

The transfer device has two ports (11 and 12) for coupling to the containers (*id.* at 13:26-27), and a third port 13 for coupling to a syringe (*id.* at 14:5-6). The Specification discloses that “channel 14 ... enables fluid communication between first container 20 and second container 30” (*id.* at 14:11-12), while channels 15 and 16 allow fluid communication between ports 11 and 13, and between ports 13 and 12, respectively (*id.* at 14:12-14). The Specification discloses that “flow control member 18, preferably in the form of a check-valve, is provided. In its closed position, fluid communication is disabled.” (*Id.* at 14:18-19). The Specification discloses that “flow control member 17, preferably in the form of a check valve or

non-return valve, is provided resulting in a one-way flow from port 13 to port 12” (*id.* at 14:12-17).

Claims 14 and 15 are on appeal. Claim 14, the only independent claim, reads as follows:

14. A drug mixing kit comprising:
a container unit comprising:

- a first container, said first container containing first contents, and
- a second container, said second container containing second contents to be mixed with the first contents to form a material, and

a transfer unit comprising:

- first and second ports adapted to receive first and second containers of a container unit, and
- a third port for coupling to a syringe, the transfer unit further comprising a number of flow channels, at least some of the flow channels pair-wise interconnecting two of the first port, the second port and the third port,
- a flow control member enabling one-way fluid flow through a flow channel from the second port to the third port, and
- a flow control member enabling one-way fluid flow through a flow channel from the third port to the first port,

wherein the container unit and the transfer unit are adapted to be coupled together to form a drug mixing kit.

The Examiner has rejected claims 14 and 15 under 35 U.S.C. § 102(b) as anticipated by Brenneman.¹ The Examiner finds that Brenneman teaches a drug mixing kit comprising all the limitations of claims 14 and 15 (Answer 3-4), including “**a flow control member** (30, *the connector forms a fluid passageway 21 that communicated with passage 25*) enabling one-way fluid flow through a flow channel from the second port to the third port, and a

¹ Brenneman, US 5,466,220 issued Nov. 14, 1995.

flow control member or valve (12) enabling one-way fluid flow through a flow channel from the third port to the first port” (*id.*).

Appellant argues that Brenneman “fails to disclose at least a ‘*flow control member enabling one-way fluid flow through a flow channel ...*’ in both instances” (Appeal Br. 6). Appellant argues that “while the piercing connector (30) and cannula (34) ... may provide one-way fluid flow ... (for instance if vacuum is created with the syringe, etc.), it is the syringe or pressure in the vial(s) which may provide one-way fluid flow, not the flow control member as claimed by Appellant” (*id.* at 7).

We agree with Appellant that the Examiner’s interpretation of the claim term “a flow control member enabling one-way fluid flow through a flow channel” is unreasonably broad.

[T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by ... the applicant’s specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Here, the Specification states that a “first flow control member enables one-way fluid flow between a syringe, coupled to the third port, and the second port. Thus, the first flow control member may either enable fluid flow in a direction from the syringe towards the second port, or in a direction from the second port towards the syringe” (Spec. 4:29-32). The Specification discloses that “the first flow control member may be adapted to enable one-way fluid flow in both directions, e.g. at different times during operation of the transfer system” (*id.* at 5:7-9). The Specification discloses

that the “first flow control member ... [is] preferably in the form of a check valve or non-return valve” (*id.* at 14:15-16). Thus, the Specification makes clear that a “flow-control member enabling one way fluid flow” is an element that regulates fluid flow such that fluid can flow in only one direction at a given time.

Brenneman discloses “a drug vial mixing and transfer device” (Brenneman, col. 1, ll. 6-7). Figure 1 of Brenneman is shown below:

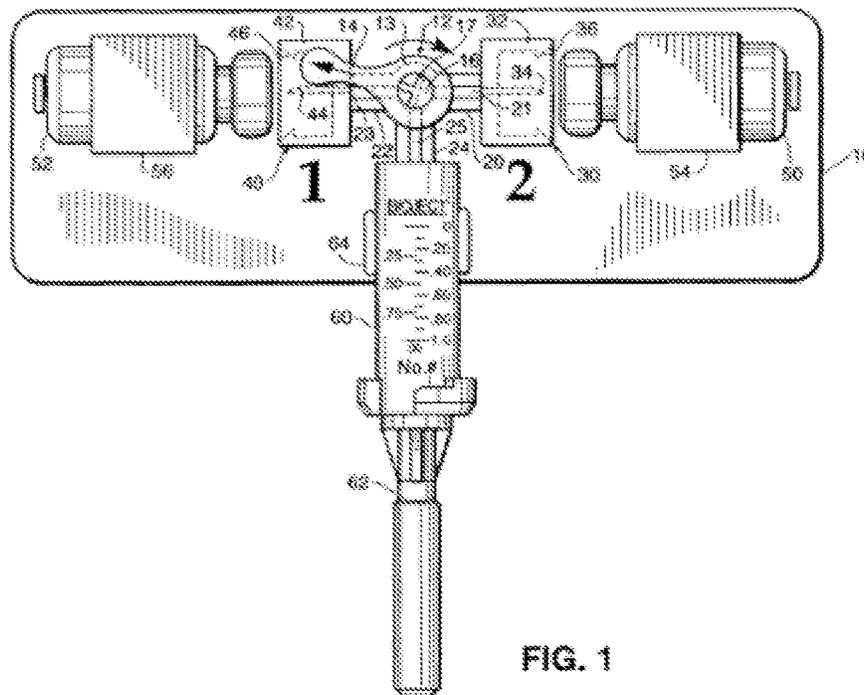


Figure 1 shows a top view of Brenneman’s device (*id.* at col. 2, ll. 41-45). Brenneman discloses that the device comprises “a stop cock type valve **12** mounted on the face of the base **10**” (*id.* at col. 3, ll. 3-4). “The valve **12** comprises ... a lever **14** ... [and] three ports **20, 22, 24**, with their corresponding fluid passageways **21, 23, 25**, [which] extend outwardly from the valve body **13**” (*id.* at col. 2, ll. 5-10). Brenneman discloses that the “piercing connector **30** comprises a cylindrically cup shaped housing **32**, a

piercing cannula **34**, and an internal annular claw **36**. The cannula **34** is axially fixed within the housing **32**, thus forming a fluid pathway, through the housing **32**, that communicates with the fluid passageway **21** of the port **20**.” (*Id.* at col. 3, ll. 25-30.)

The Examiner reasons that

the piercing connector (30) [is] the first control member because when a vial is connected to the port (20) the piercing cannula (24) in the piercing connector (30) can permit the passage of liquid from the syringe to the vial ... and the small diameter of the piercing cannula (24) can reduce the amount of liquid passing from the syringe to the vial ... thereby accomplishing the enablement requirement of one-way fluid flow.

(Answer 5). The Examiner argues that “the claim language as recited does not exclude fluid flow in two directions” (*id.*).

We disagree with the Examiner’s reasoning. As discussed above, when read in light of the Specification, the recited ““flow-control member enabling one way fluid flow” requires an element that allows fluid flow in only one direction at a given time. A cannula, small diameter or otherwise, allows fluid flow in both directions. The Examiner’s interpretation of “a flow control member enabling one-way fluid flow” as encompassing a fluid channel that allows two-way fluid flow is not consistent with the Specification’s description of the claimed element.

Thus, we reverse the anticipation rejection of independent claim 14 and dependent claim 15.

REVERSED

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