

PATENTS EXAMINATION BOARD

Subject: The Drafting of Patent Specifications - Paper 2

Date: July 2015

Time: 09h00 - 13h00 (although candidates requiring extra time are entitled to an additional two hours)

Examiners: J Fiandero
V Williams

Moderator: J D Whittaker

Attached is an instruction from your client detailing an invention.

You are required to draft a full patent specification for your client's invention. The full patent specification must include: (1) a background to the invention, (2) a summary of the invention, i.e. consistory clauses, (3) a brief description of the drawings, (4) a detailed description of the invention, (5) a set of patent claims, and (6) an abstract.

Marks will be allocated as follows:

- 50% of the marks will be allocated to the claims.
- 50% of the marks will be allocated to the rest of the specification.

In order to obtain a pass for this paper, candidates must obtain not less than 40% for each of these two sections.

Your client writes:

"I have invented a locking assembly for a medication dispensing device which prevents delivery of a dose of medication from the dispensing device if the medication has been frozen before the first use of the device.

Certain medication needs to be refrigerated, but not frozen, prior to use. A dispensing device containing such medication may, for example during shipping or prolonged storage before use, be subjected to refrigeration conditions that result in the freezing of the medication, causing it to become unsuitable for use. While it is possible to mark the dispensing device with a label which indicates when freezing has occurred, such labels may be overlooked with the result that a patient may nevertheless unknowingly use the medication.

I have attached some drawings to explain my invention. In Figs. 1 to 3 of the drawings, I have shown some views of a disposable medication dispensing device 20 which includes my locking assembly.

At a distal portion 22 of the device 20, a clear retainer 24 holds a cartridge 28. The cartridge comprises a barrel 30 defining a chamber which is sealed at one end by a slidable plunger 32 and at the other end by a septum 33. A needle assembly 34 pierces the septum 33 to provide an outlet for medication 31 contained within the barrel 30.

At a proximal portion 29 of the device 20, a protective housing 35 contains a movable drive member 50. A dose delivery mechanism, which is illustrated in dotted lines at 55 in Fig. 3, operatively connects the drive member 50 to a control element 52 which projects from the housing 35. The mechanism 55 is shown in more detail in Fig. 2. As can be seen, the mechanism 55 includes a plunger piece 55a which receives one end of a spring 55b, a plunger element

55c which engages the other end of the spring 55b, a gear set 55d, and a gear-engaging piece 55e. When the control element 52 is pulled outwardly from the housing 35 and then pushed back to the position shown in Fig. 1, the mechanism 55 forces the drive member 50 forward in an axial direction, to the left in Fig. 3, to advance the plunger 32 forward and deliver a desired dose of medication.

The drive member 50 has a rod-shaped body 60 attached to a foot 64 for engaging the plunger 32. The body 60, which is shown in more detail in Figs. 7A and 7B, defines a row of one-way ramping ratchet teeth 66 extending along each lateral side of the body 60 towards a flat end 62. A side edge 67 of the body 60 defines a channel 69 which serves as a guide. An opening 72, which extends through the body 60, is provided near one end of the channel 69, as shown. The opening 72 serves as a lock actuating element which is designed to cooperate with a complementary actuating element on a lock member 90, which will be described in more detail below.

With reference again to Fig. 3, the ratchet teeth 66 on the body 60 are operatively engaged by a pair of tabs or pawls 68 integrally formed with the housing 35. The pawls 68 slide over the teeth 66 when the drive member 50 is advanced within the housing 35 during use, but are engaged by the teeth 66 to prevent the drive member 50 from backing up when subjected to normal loads.

The lock member 90 is shown in Figs. 6A to 6C as a single piece component with a base flange 92 defining an opening 93 for operatively receiving the drive member 50. The base flange 92 is fixed within the housing 35. A pair of spring arms 94 extends orthogonally from the flange 92 when in a non-stressed state. These spring arms 94 can be bent relative to the base flange 92 to allow a locking plate 96 to be angled relative to the base flange 92, as best shown in Fig. 4. A bent portion of the locking plate 96 forms a skid 100 that serves as an actuating element of the locking assembly. The end 102 of

the skid 100 is angled relative to the locking plate 96 to enable the skid end to slidingly accommodate the drive member 50 as the drive member advances during normal use. The locking plate 96 includes two elongate eyelets 106 with contact surfaces 108. Two upturned edges 110 on the locking plate 96 allow for camming over hooks 112 on the plunger element 55c.

The device 20 is shown in Figs. 3 and 4 in a form in which it is initially shipped after manufacture. Since the needle assembly 34 is not mounted to the device when it is shipped, the medication 31 does not have an outlet through the septum end of the cartridge 28. Thus, if the medication 31 freezes it will tend to drive the plunger 32 rearwards within the cartridge 28 toward the drive member 50.

If the medication 31 does not freeze before its first use, the locking assembly will not be activated, leaving the lock member 90 in the unlocked condition illustrated in Figure 4. In this condition, the spring arms 94 are biased upwardly so that the locking plate 96 is angled relative to the base flange 92 and the skid 100 bears against the drive member 50, within the channel 69 defined by the side edge 67 of the body 60. In this condition, the drive member 50 may be forced axially forward (to the left in Fig. 4) by activation of the dose dispensing mechanism 55 to advance the plunger 32 forward (to the left in Fig. 4) and deliver a desired dose of medication. As each dose is dispensed, the drive member 50 advances forward with the skid 100 of the lock member 90 riding along the drive member 50 within the channel 69.

If the medication 31 freezes, its expansion will drive plunger 32 rearwards, forcing the drive member 50 rearwards (to the right in Fig. 4). The pawls 68 are designed to deform under these loads so as to permit rearward movement of the drive member 50 within the housing 35. When the drive member 50 has moved sufficiently rearwards, such that the rearward end 73 of the slot 72 reaches the rearward end 101 of the skid 100, the skid 100 snaps into the slot

72 (as shown in Fig. 5) under the bias of the spring arms 94 to lock the drive member 50 against forward movement. The downward movement of the locking plate 96 simultaneously causes the eyelets 106 to snap over the hooks 112 on the dose dispensing mechanism 55. With the lock member 90 in the locked condition illustrated in Figure 5, the locking plate 96 engages the hooks 112 and holds the dispensing mechanism 55 captive so as to lock the device 20 from further dose dispensing.

Please prepare a patent specification for my invention."

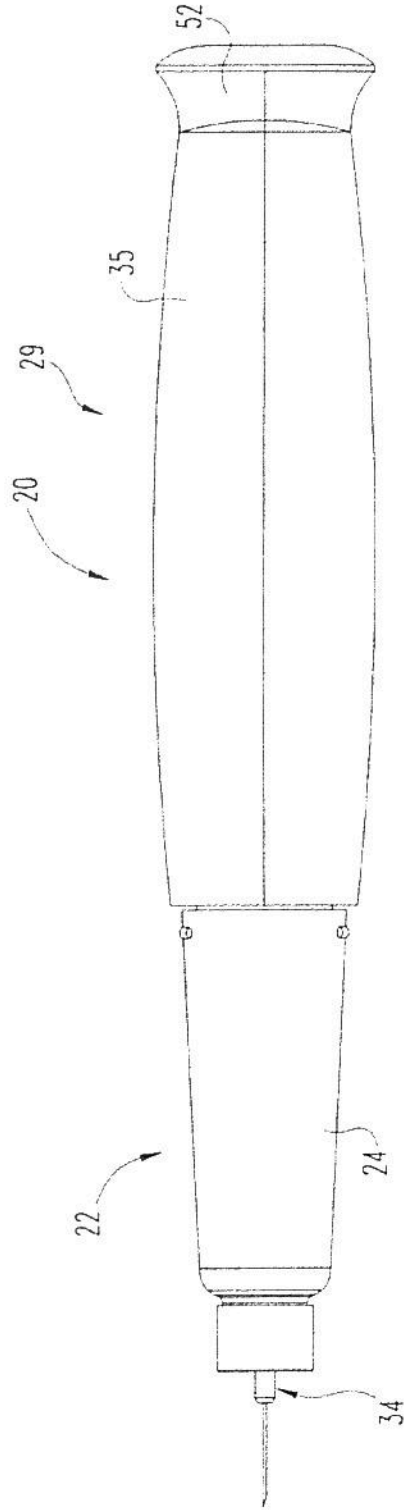


Fig. 1

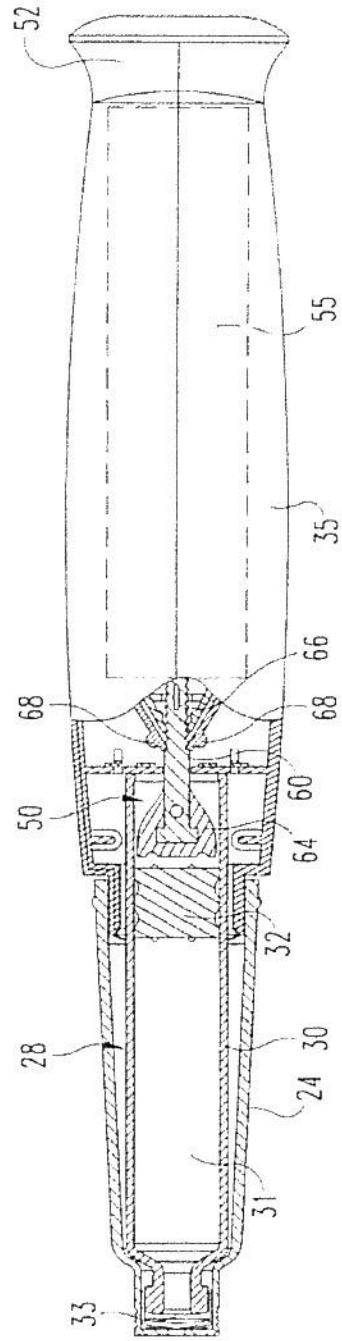


Fig. 3

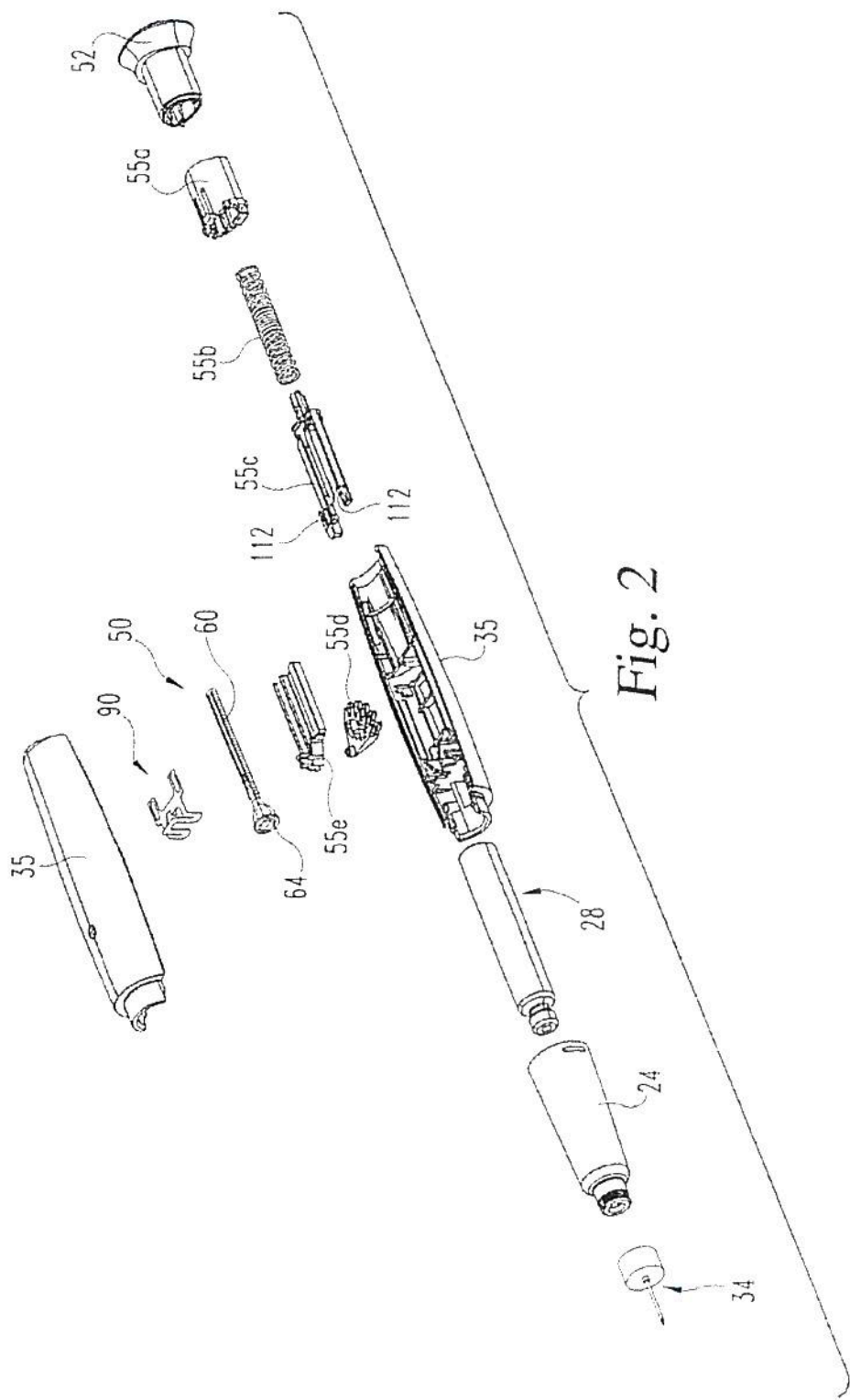


Fig. 2

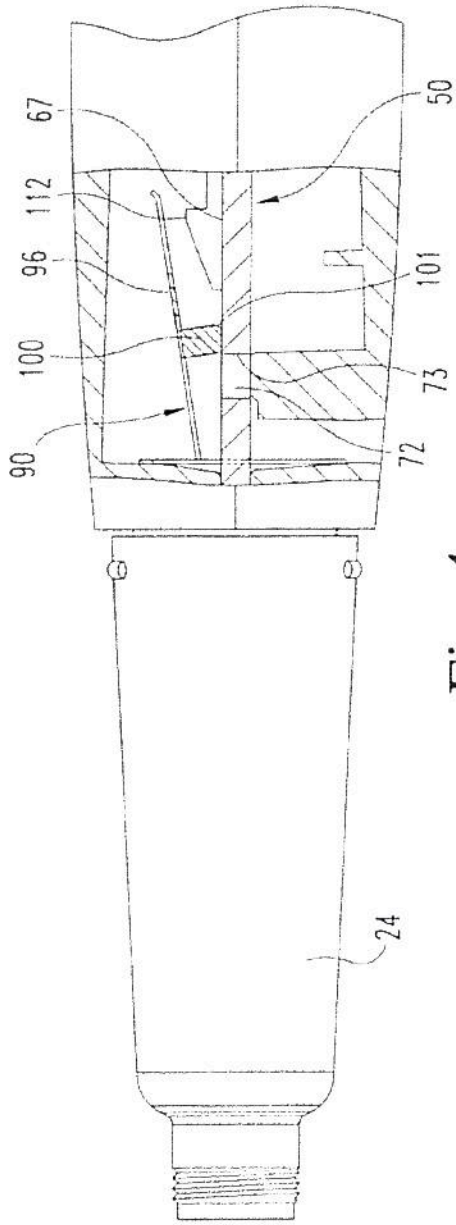


Fig. 4

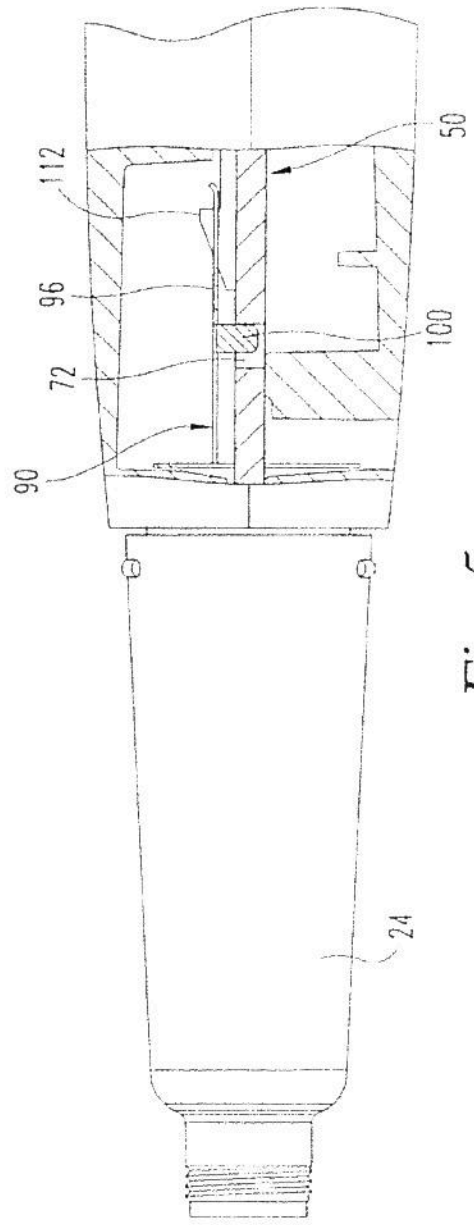


Fig. 5

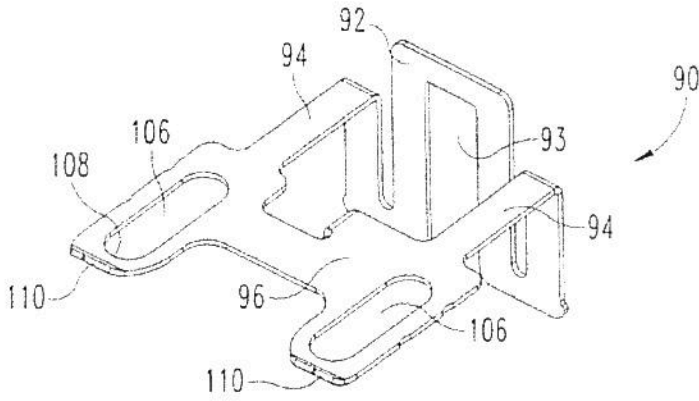


Fig. 6A

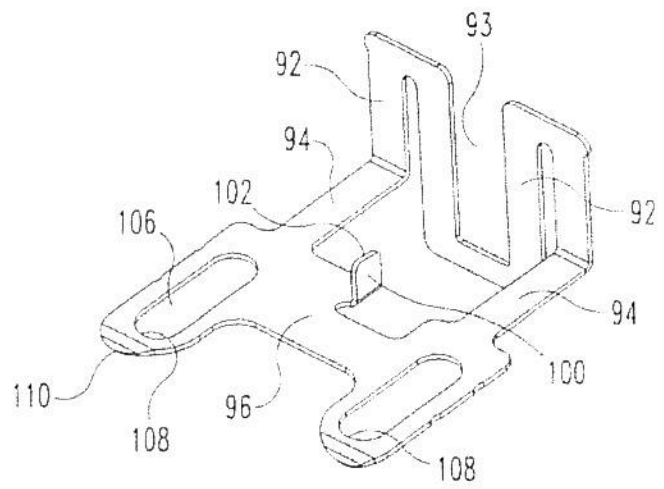


Fig. 6B

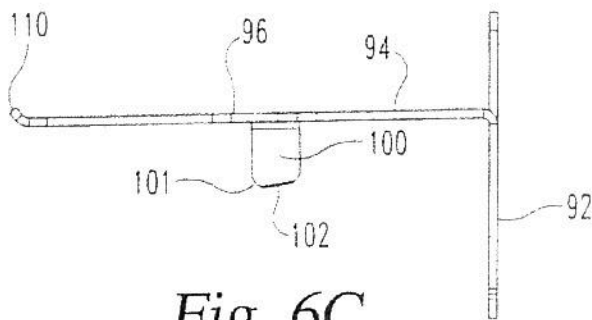


Fig. 6C

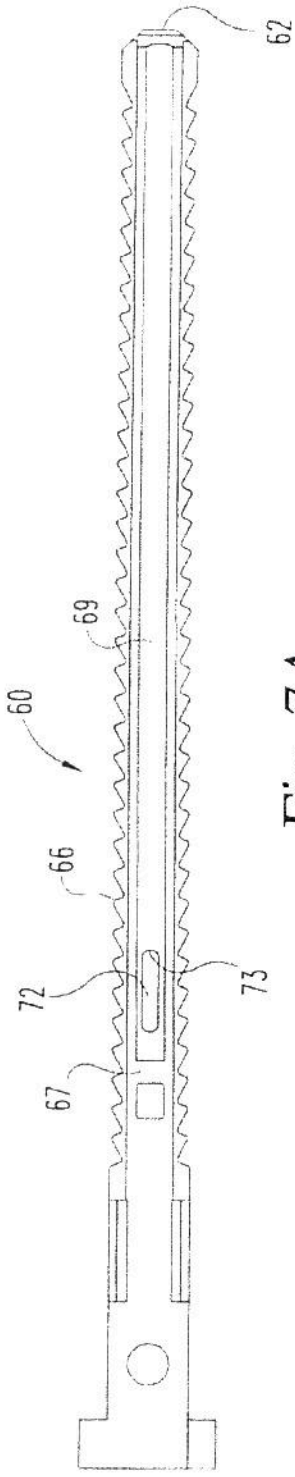


Fig. 7A

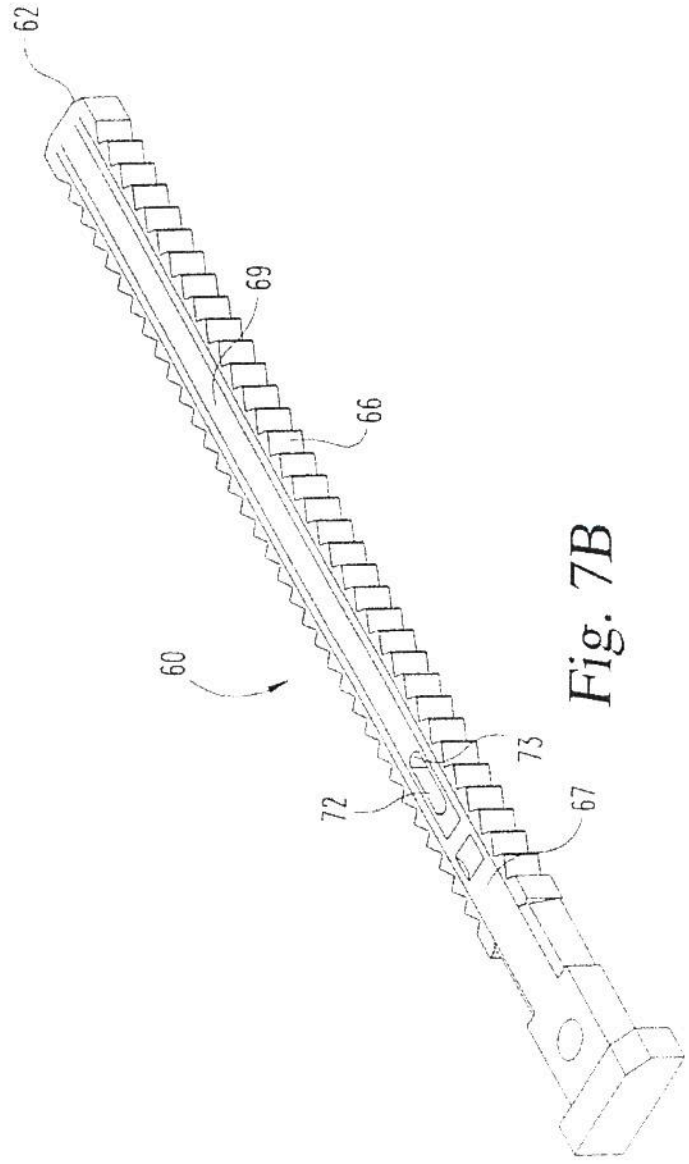


Fig. 7B