

Patent	EP(UK) 1351732
Proprietor(s)	NOVO-NORDISK A/S
Exclusive Licensee	
Requester	Marks & Clerk, on 19 October 2005
Observer(s)	Novo Nordisk A/S
Date Opinion issued	13 January 2006

The request

1. This request is directed to the question of whether EP(UK) 1351732 (“the patent”) is novel and inventive over the following documents:

- A1 WO 01/72361 (Sams)
- A2 US 5320609 (Habley Medical)
- A3 Owen Mumford Product Range catalogue
- A4 US 5104380 (Holman)
- A5 US5383865 (Eli Lilly)
- A6 EP 0554996 (Becton)
- A7 US 5226896 (Eli Lilly)
- A8 US 5308340 (Eli Lilly)
- A9 US 5295976 (Eli Lilly)
- A10 US 5626566 (Novo Nordisk)

2. In particular the requester seeks an opinion as to whether claims 1 to 4 of the patent are novel in the light of document A1 and document A2; and as to whether claims 1 to 20 are inventive in the light of documents A2 to A10.

Observations; observations in reply

3. Observations were filed on behalf of the patentee on 25 November 2005 maintaining that the patent is valid and stating that “the references cited by the Requester either are not relevant to the invention claimed in European Patent No 1351732; or have already been fully considered in pre-grant proceedings”. The patentee does not go into further detail.

4. No observations in reply were filed by the requester.

The documents

5. Document A1 was published on 4 October 2001 and *prima facie* has a

priority date of 24 March 2000 as evidenced by the priority document also filed. The priority date of the patent is 5 January 2001 and A1 therefore represents a document relevant only to novelty as defined by section 2(3).

6. Regarding document A3, the requester has exhibited a product called the "Autopen", and states:

"With regard to A3, we submit herewith a product currently sold by Owen Mumford (Woodstock, England) under the mark AUTOPEN. This product is functionally identical to the product advertised in A3. The AUTOPEN has been on the market since 1990. The AUTOPEN is also the subject of patent A4 which contains a detailed technical description of the structure and operation of the AUTOPEN."

7. Document A3 bears no date other than a label from the requester stating that it is a "pre-2001 product catalogue", and the exhibit carries an earliest date of May 2004. There is no evidence to confirm when either the catalogue or the exhibit was first made available to the public. However document A4 is clearly in the section 2(2) field, and I shall therefore take that into account but not document A3 nor the exhibit. I do not think this affects the conclusions I come to below.

8. The remaining documents lie in the 2(2) field and are therefore potentially relevant both to novelty and inventiveness.

9. I note that documents A4 and A10 are referred to in the patent. I also note that document A9 was erroneously quoted as US 5292976 in the request as filed, and subsequently corrected.

The patent

10. International patent application number PCT/DK02/000004 was filed on 4 January 2002, claiming priority from Danish application DK 2001 00018 filed on 5 January 2001. The international application was published on 11 July 2002, entered the regional phase before the European Patent Office as EP 02726984.4 and was granted as EP(UK) 1351732 on 1 June 2005 under the title "Automatic injection device with reset feature".

11. I note that no X or Y category documents were cited at the search stage by the international search authority, or at the examination stage before the European Patent Office, where the application was forwarded for grant after the filing of voluntary amendments on 16 December 2002. Of the documents referred to by the requester only A10 appears in the international search report (as a category A, or background document) and that document is in fact referred to in the patent itself. I find no substance therefore in the observer's submission that the requester's case has been fully considered in pre-grant proceedings, and therefore no reason to refuse the request under rule 77D(1)(b).

12. The patent relates to syringes, and in particular to dispensing pens for

the injection of insulin or growth hormone from a cartridge. The background to the invention is set out in the patent as follows.

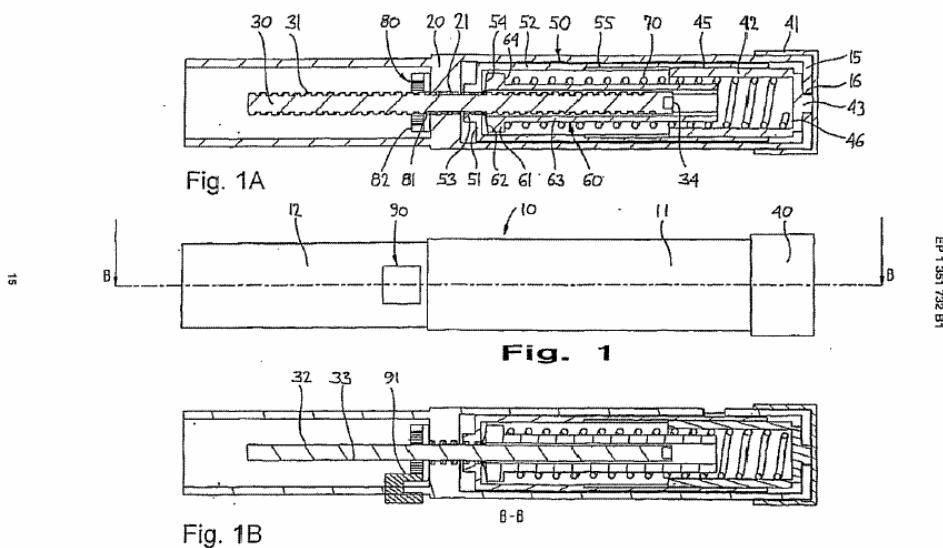
13. Syringes are known where the user dials a desired dose and then actuates the syringe to express the dose (hereafter "manual" syringes). This has the advantage that the injection stage is independent of any need to assess what dose is being injected. However the step of actually depressing the syringe can cause the user anxiety, and this is addressed in document A4 in which, when the user dials a dose, a spring is set. Upon release the spring automatically injects the dialled dose (hereafter "automatic" syringes).

14. Moreover not all pen syringes allow the user to cancel a set dose which if wrongly dialled has to be ejected and wasted. Document A10 addresses this problem by incorporating a release mechanism which can be actuated to release a unidirectional coupling between drive and dosing members and allow the set dose to be cancelled. However this suffers from two disadvantages: the release mechanism has to be actuated, and the syringe is manual rather than automatic.

15. The invention addresses these problems by incorporating, in an automatic syringe, a dose setting member which can be re-set, typically by simply turning it in the reverse direction.

16. Figure 1 of the patent is reproduced below. As shown, turning an end knob 40 rotates a graduated dose setting member 50. This has a threaded portion 53 which travels along a threaded plunger 30 moving the member 50 and a coupling member 60 to the right and thereby compressing a spring 70; a locking member 80 holding the plunger against rotation. The members 50 and 60 are coupled by a bi-directional coupling 54, 62 which allows the dose setting member 50 to be rotated back again to adjust the dose.

17. Upon release of the locking member 80, the plunger 30 is free to rotate, through engagement with an internal thread 21, and move to the left, driven by the spring 70. As it moves to the left, the plunger expels the dose



18. Claim 1 is the only independent claim. It reads:

A dose setting device for use in combination with a fluid filled reservoir, the dose setting device being adapted for repetitive injection of individually set doses of fluid from the reservoir, the dose setting device comprising:

- *a housing (10),*
- *a drive member (30) associated with the housing and adapted to expel a dose of fluid from the reservoir,*
- *a spring means (70) mounted in the housing,*
- *a dose setting assembly (40, 50, 60) mounted in the housing and connected to the spring means, the dose setting assembly composing a dose setting member (50) being moveable in a first direction to a selected set position against the bias of the spring means, wherein movement of the dose setting member is accompanied by straining of the spring,*
- *a releasable latch means (80, 90) associated with the housing and adapted to retain the dose setting member in the set position against the bias of the spring means, wherein release of the latch means causes the dose setting assembly to drive the drive member to thereby expel a set dose from a fluid filled reservoir when the dose setting device is used in combination therewith, the force for expelling the set dose being provided by the spring means,*

characterized in that

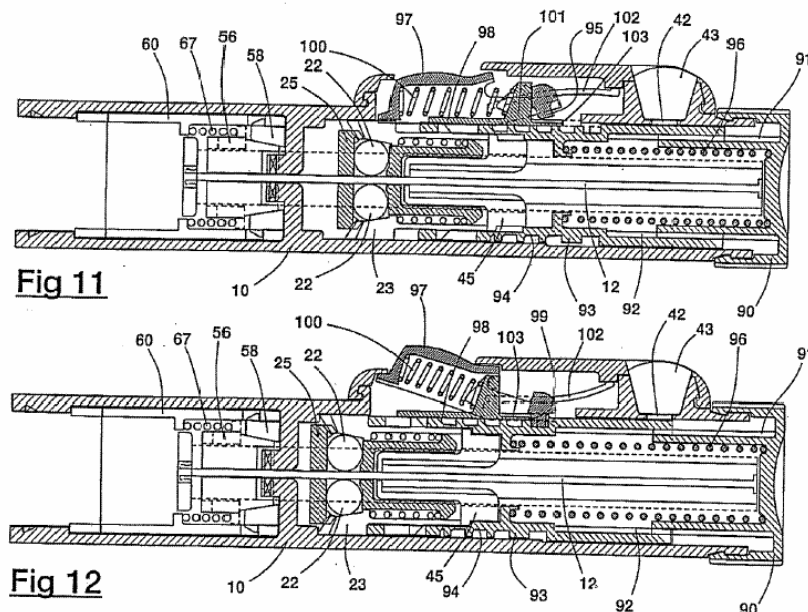
the dose setting member is moveable in a second direction to selectively adjust the set position.

NOVELTY

WO 01/72361 (document A1)

19. This document describes three embodiments of a syringe, in the third of which – shown in Figures 11 and 12 reproduced below - a spring automatically injects a pre-set dose as required by claim 1 of the patent. In the other two embodiments the dose is manually expressed.

20. As shown in Figures 11 and 12, turning an end cap 90 rotates a track member 93 which has a threaded portion 94 engaging a tooth 95. This moves the member 93 to the right to set the dose and compress a spring 96. Depressing a button 97 releases the tooth 95 and allows the spring 96 to move the track member 93 to the left. A one-way clutch mechanism (comprising two balls 22, a cone member 23 and a pressure component 25) couples the member 93 to a rod 12 which moves to the left to expel the dose. When the dose is being set and the member 93 moves to the right to compress the spring 96, the clutch mechanism 22, 23, 25 decouples the member 93 from the rod 12. The components of the syringe are contained in a tubular body 10.



WO 01/72361

10/11

PCT/GB01/01271

21. This syringe seems to me to have all of the features set out in the pre-characterising part of claim 1 of the patent – namely a housing 10, a drive member 12, spring means 96, a dose setting assembly 90, 93, a dose setting member 90 or 93, and a releasable latch 95, 97.

22. Regarding the characterising part of the claim, the description of the first embodiment of document A1 includes the following passage at page 10 lines 20 to 26:

“As the dose is being set, the cone member 23 rotates with respect to the pressure component 25, so lifting that component each time the teeth [on members 23 and 25] ride over each other...This also has the action of freeing the clutch between the set doses and thus there is no penalty in over-shooting the required dose and then winding the end-cap 14 in the opposite sense, from a larger dose to a lesser dose, since this will not significantly drive the rod 12 forwardly”

23. In other words, the dose setting member is rotatable in the reverse direction – or in the terms of the characterising part of claim 1 – “is moveable in a second direction to selectively adjust the set position”.

24. The only question that remains is whether the reversibility feature of the first embodiment, a manual syringe, is also to be found in the third embodiment, an automatic syringe. The passages at page 14 lines 12-15 and page 15 lines 15-18 state that the mechanism of the third embodiment is similar to that of the previous embodiments apart from the changes required to enable the dose to be automatically injected by the spring. I have carefully examined the description of the third embodiment and the related drawings, and it seems to me that there is nothing to support the view that the reversibility feature is in any way changed when moving from the first to the third embodiments; and I note that the patentee in its observations has made no argument to that effect. The standard of proof applicable here is that of the balance of probabilities, and I conclude on that basis that the third embodiment has all the features of claim 1; and that claim 1 is not new having regard to document A1.

25. The requester argues that claims 2 to 4 also lack novelty in the light of document A1.

26. Claim 2 reads:

A dose setting device as claimed in claim 1, further comprising a fluid filled reservoir having a foremost end adapted to cooperate with an injection needle and a rearmost end closed by a piston in sliding engagement with an internal surface of the reservoir, the drive member being in the form of a piston drive member adapted to engage the piston to thereby expel a dose of liquid as the drive member is moved forwardly by the spring means.

27. Figure 4 of document A1 shows a fluid-filled reservoir (ie a cartridge of medicament) with a piston (referenced 13) closing its rearmost end and engaged by the piston drive member 12. Although not illustrated in Figure 4 the foremost end of the reservoir cooperates with an injection needle (illustrated in Figure 3). I conclude that claim 2 is also not new having regard to document A1. In fact, on the basis of the documents submitted, it seems to me that the features of claim 2 are wholly conventional.

28. Claim 3 reads:

A dose setting device as defined in claim 1, wherein the dose setting assembly further comprises a coupling member (60) in displaceable engagement with the dose setting member, the spring means acting on the coupling member, the coupling member acting on the dose setting member (50).

29. The requester argues that document A1 shows a track member 93 which can be regarded as the coupling member of claim 3, a cap 90 which is displaceably engaged by member 93 and can be regarded as the dose setting member, and a spring 96 which acts on the member 93 and which in turn acts on the dose setting member or cap 90.

30. This analogy seems to me to fall down on the final feature in that, although the cap 90 and member 93 are connected by splines 91 and 92, the member 93 does not “act on” the cap 90 on a purposive construction of this term; rather the splines cause the member 93 to rotate when the cap 90 is rotated whilst allowing axial movement of the member 93 relative to the cap 90.

31. I conclude that claim 3 is novel over document A1. It follows that claim 4 which is dependent on claim 3 is also novel.

US 5320609 (document A2)

32. Document A2 also relates to a syringe in which a spring automatically injects a pre-set dose as required by claim 1 of the patent. As shown in Figures 2A and 3 reproduced below, the syringe has a main barrel 4 with an end cap 60 mounted at the top. Turning the cap 60 rotates a dose adjusting screw 158, which has external threads engaging internal threads on a piston driver 140. This causes the screw 158 to move axially relative to the driver 140 and compress an injection spring 174. Brake pads 194 are pressed by a sleeve 10 against the external surface of the driver 140 to hold it against axial movement. Pressing a release trigger 130 allows a second spring 106 to drive the lower part of the syringe assembly downwards. Once windows in the barrel 4 become aligned with the brake pads, the pads can disengage from the driver 140 which is then free to be driven by the spring 174 to dispense the dialled dose.

33. This syringe seems to me to have all of the features set out in the pre-characterising part of claim 1 of the patent – namely a housing 4, a drive member 140, spring means 174, a dose setting assembly 60, 158, a dose setting member 60 or 158, and a releasable latch 130.

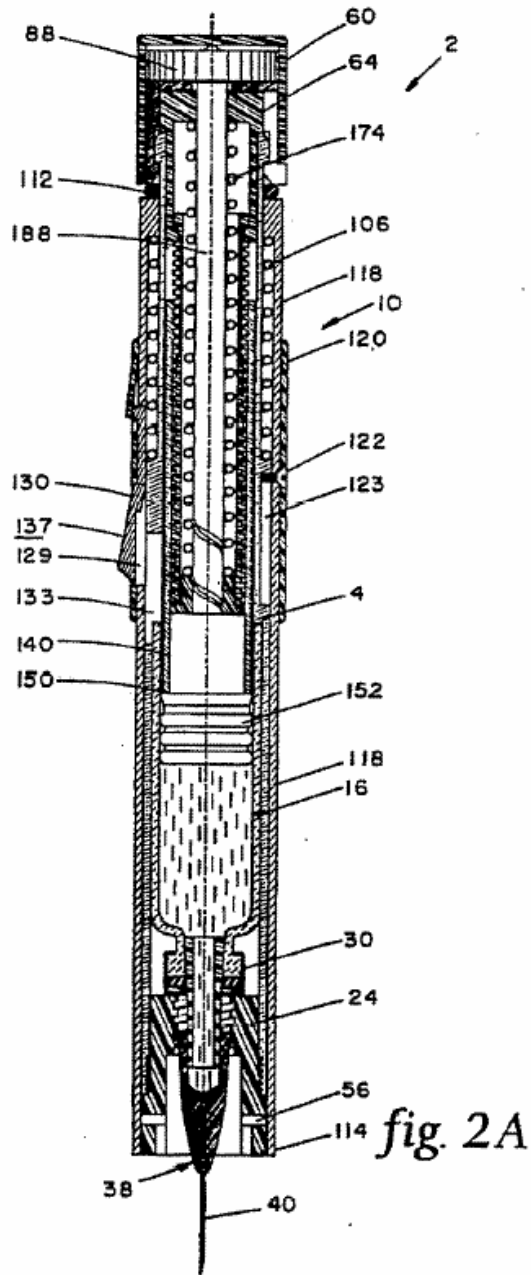
34. Regarding the characterising part of the claim, the description is silent on rotation of the dose setting member (ie the dose screw 158) in the reverse direction. However it seems to me that such reverse rotation would, through the engagement of the threads on the screw 158 and the driver 140 simply reverse the direction of relative axial movement between these two

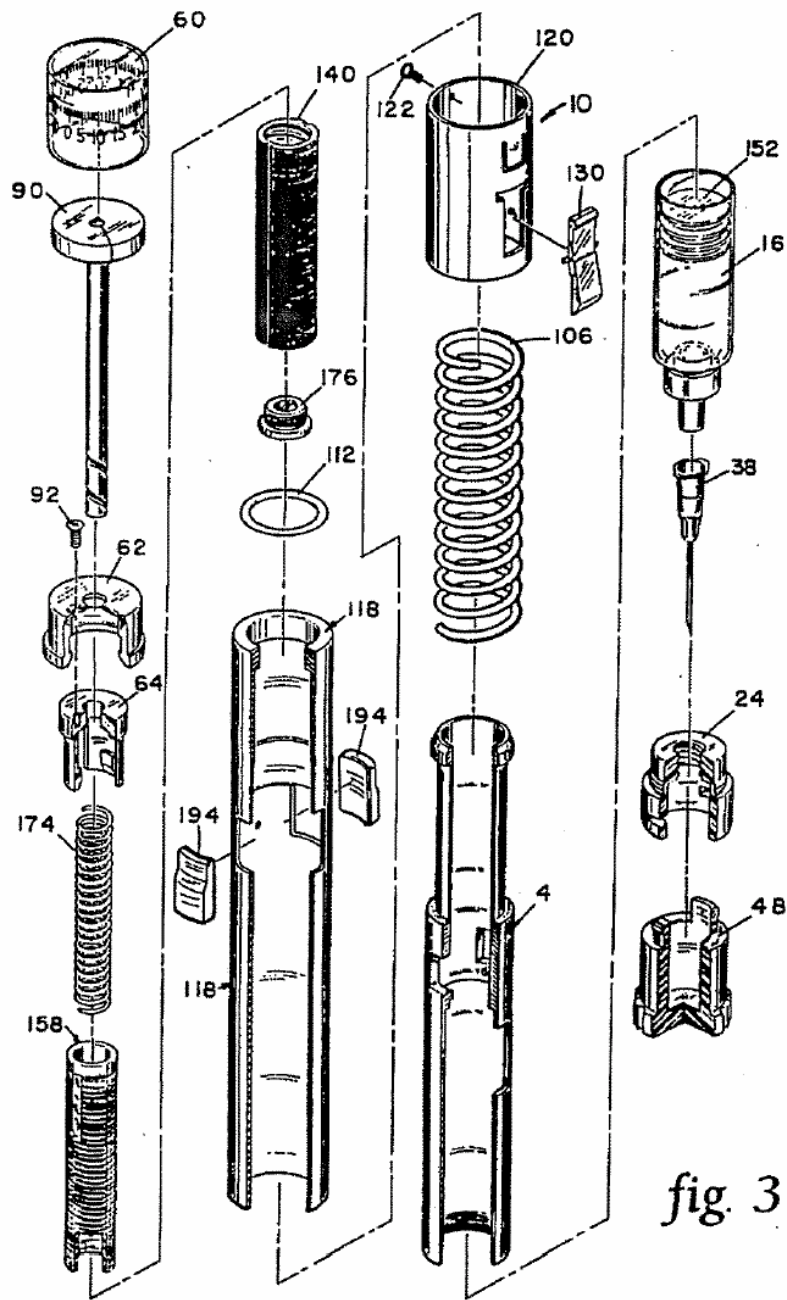
components and adjust the set dose. As pointed out by the requester, there is no description of any mechanism to prevent this, and again the patentee in its observations has advanced no argument on the point. On the balance of probabilities I conclude that document A2 has all the features of claim 1; and that the claim is not new having regard to that document.

35. I also conclude that claim 2 is not new having regard to document A2. This shows a fluid-filled reservoir 16 with a foremost end adapted to cooperate with an injection device 38, and a piston 152 closing its rearmost end and engaged by the piston drive member 140.

36. The requester argues that claim 3 and 4 also lack novelty over this document. However it seems to me that there is no coupling member between the dose adjusting screw 158 and the spring 174 and I conclude that claims 3 and 4 are novel over document A2.

37. The requester makes no case for lack of novelty against any of the remaining claims.





INVENTIVE STEP

38. The requester argues that claims 1-20 are not inventive in the light of the AUTOPEN document A4 taken in combination with various of documents

A5-A10 which describe manual injector pens with reversible dose setting mechanisms. The requester also argues that if document A2 is found not to destroy the novelty of claim 1 then it renders claim 1 obvious when taken in conjunction with other documents.

Claim 1

39. The patent acknowledges that automatic syringes are known, referring specifically to document A4, which relates to the AUTOPEN device. I take the inventive concept to be the incorporation in an automatic syringe, as set out in the pre-characterising part of claim 1, of a dose setting member which is "moveable in a second direction to selectively adjust the set position", as set out in the characterising part of claim 1.

40. I take the skilled addressee to be a person involved in the design of syringes, in particular of syringes where the user pre-sets a desired dose. Would it be obvious to such a person at the priority date (5 January 2001) that there was a problem with the automatic syringe of document A4 - namely that if a dose has been wrongly set, it cannot be cancelled and has to be wasted - and would it be obvious to try and solve it by adapting the syringe so that the dose setting member could be moved in a second direction or reversed?

41. The skilled addressee it seems to me would be well aware of the existence of this problem in syringes. The problem is addressed in each of documents A5 to A10, all of which were published between 1993 and 1997, well before the priority date of the patent (although I recognise that a number of these documents are from the same source). Moreover in all of these documents the problem is solved by allowing the dose setting member to be rotated in the reverse direction. Even in document A10, where, as described in the patent, a release mechanism has to be actuated first, once that is done the dose setting knob can be turned back to its initial position. Although the complex mechanisms involved in this type of syringe might require inventive ingenuity to adapt them, in my view the problem - and its solution in the broad terms set out in claim 1 - would be obvious to a person skilled in the art. Accordingly I conclude that claim 1 lacks an inventive step

42. Regarding document A2, if I am wrong in my assessment of novelty above and document A2 does not destroy the novelty of claim 1, then I think the above inventive step argument also applies if document A2 is taken as the starting point instead of A4.

43. Finally the requester also makes an obviousness attack on claim 1 from the opposite direction to that set out above, namely that it would be obvious to incorporate a drive spring into a known resettable, manual syringe and thereby obtain a resettable automatic syringe. Here however I think the argument fails. It is far from obvious in my view how a drive spring could be incorporated into such a manual syringe to provide an automatic syringe as set out in claim 1.

Claim 2

44. I have already concluded that the features of claim 2 appear to be wholly conventional. I therefore find that it too lacks an inventive step.

Claims 3 to 9

45. The requester argues that claim 3 is obvious in the light of document A4 and in the light of document A10. In document A4 a drive spring acts directly on a dose setting member rather than on a coupling member as required by claim 3; and document A10 relates to a manual syringe without the drive spring of the automatic syringe to which claim 3 relates. In neither document in my view is there anything to suggest incorporating a coupling member between a drive spring and a dose setting member as required by claim 3.

46. I conclude that claim 3 is inventive over these two documents. It follows that claims 4 to 9 which are dependant on claim 3 are also inventive.

Claims 10 to 19

47. Claim 10 reads:

A dose setting device as claimed in claim 1, further comprising a threaded member (20) fixed in the housing and comprising a first internal thread, the drive member being a longitudinal piston drive member (30) having an external thread (31) corresponding to the first internal thread, the threads being non-locking having a pitch angle whereby axial movement of the piston drive member is obtained by an axial force applied to the piston drive member by the spring means.

48. The requester argues that claim 10 is obvious in the light of documents A4 and A10. At column 8 of document A10 it is stated that “the internal thread of the nut member and the external thread of the spindle of the dose setting member have a pitch allowing transformation of an axial pressure to a rotation” which appears to be the same principle as that set out in the latter part of claim 10 of the patent. The requester argues that it would be obvious to provide the axial pressure through a drive spring as is done in document A4. However, in document A4 when the latch is released, the torque of a helical spring rotates a gear. This carries internally threaded drive tapers which cooperate with an external thread of a piston drive member to move the drive member axially. There is no axial force in the terms of claim 10 and it is far from obvious in my view how the spring of document A4 could be incorporated into the pen of document A10. I conclude that claim 10 is inventive over these two documents.

49. It follows that claims 11 to 19 which are dependant on claim 10 are also inventive.

Claim 20

50. Claim 20 reads:

A dose setting device as defined in any of the previous claims, wherein the latch means (80, 90) acts on the drive member.

51. The requester states that “Every automatic injection pen, eg A2 and A3, makes use of a latch means (trigger) which acts on the drive member. In the prior art devices, this action is indirect. However it would be obvious to the skilled person that the latch could act directly on the drive member rather than, for example, on the doing means”.

52. In document A2 (see Figures 2A and 3 above), the latch 130 acts on the barrel 4 rather than on the drive member 140. In respect of the argument concerning document A3 I turn to document A4 for reasons explained above. In document A4, a latch acts on a locking cage in engagement with a drive gear, rather than on the drive member. In neither case does it seem to me that it would be an obvious step to the skilled addressee to reconstruct the syringe so that the latch acts directly on the drive member. Accordingly I conclude that claim 20 is inventive over these two documents.

Opinion

53. I conclude that claims 1 and 2 are not new and do not involve an inventive step.

54. I also conclude that Claims 3 to 20 are new and inventive over the documents submitted by the requester.

Application for review

55. Under section 74B and rule 77H, the proprietor may within three months of the date of issue of this opinion, apply to the comptroller for a review of the opinion.

NOTE

This opinion is not based on the outcome of fully litigated proceedings. Rather, it is based on whatever material the persons requesting the opinion and filing observations have chosen to put before the Patent Office

Rebecca Villis
Examiner