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Datasheet for the decision of 9 November 2022

Case Number: T 0702/21 - 3.2.01

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Language of the proceedings: EN

Title of invention:
PREFILLED NEEDLE ASSISTED SYRINGE JET INJECTOR

Patent Proprietor:
Antares Pharma, Inc.

Opponent:
Bandpay & Greuter

Headword:

Relevant legal provisions:
EPC Art. 100(c), 100(b), 54, 56, 84

Keyword:
Added subject-matter - Main request (yes) - Auxiliary request II (no)
Novelty - Auxiliary request I (no) - Auxiliary request II (yes)
Insufficiency of disclosure (no)
Clarity - Auxiliary request II (yes)
Inventive step - Auxiliary request II (yes)

Decisions cited:

Catchword:

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Case Number: T 0702/21 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 9 November 2022

Appellant: (Patent Proprietor)	Antares Pharma, Inc. 13755 1st Avenue North Suite 100 Minneapolis, MN 55441 (US)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Appellant: (Opponent)	Bandpay & Greuter 30, rue Notre-Dame des Victoires 75002 Paris (FR)
Representative:	Bandpay & Greuter 30, rue Notre-Dame des Victoires 75002 Paris (FR)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 19 March 2021 concerning maintenance of the European Patent No. 1850892 in amended form.**

Composition of the Board:

Chairman	G. Pricolo
Members:	S. Mangin
	P. Guntz

Summary of Facts and Submissions

I. The appeals were filed by the appellant 1 (proprietor) and the appellant 2 (opponent) against the interlocutory decision of the opposition division finding that on the basis of auxiliary request II, the patent in suit (hereinafter "the patent") met the requirements of the EPC.

II. The Opposition Division held that:
- claim 1 of the main request extended beyond the content of the application as originally filed (Article 100(c) EPC),
- the subject-matter of claim 1 of auxiliary request I was not novel over D8 (WO 03/039634) (figures 23 and 24),
- auxiliary request II complied with Articles 123(2), 84, 54, 56 and Article 100(b) in conjunction with Article 83 EPC.

III. Oral proceedings were held via videoconference before the Board on 9 November 2022.

IV. Appellant 1 (proprietor) requested that the appealed decision be set aside and the patent be maintained on the basis of the main request or alternatively on the basis of auxiliary requests I-VI, all requests as filed with the statement of grounds of appeal.

Appellant 2 (opponent) requested the appealed decision to be set aside and the patent to be revoked.

V. Independent claim 1 of the main request reads as follows:

- **Feature 1**: A jet injector (10,86), comprising:
- **Feature 2**: a prefilled syringe (18,88) comprising:
- **Feature 2.1**: a container portion (20) defining a fluid chamber (22,106) containing a fluid medicament;
- **Feature 2.2**: an injection-assisting needle (24) disposed at a distal end of the fluid chamber (22,106), having an injecting tip (26) configured for piercing an insertion location, and defining a fluid pathway in fluid communication with the fluid chamber for injecting the fluid medicament from the fluid chamber (22,106) into an injection site;
- **Feature 2.3**: a plunger (28,104) movable within the fluid chamber (22,106); and
- **Feature 3**: a housing (12,108) that houses the prefilled syringe (18,88) and is configured for allowing insertion of the injection-assisting needle (24) at the insertion location to an insertion point that is at a penetration depth below a surface at the insertion location;
- **Feature 4**: a syringe support (16) supportively mounting the prefilled syringe (18,88) to the housing (12,108); and
- **Feature 5**: an energy source configured for biasing the plunger (28,104) with a force selected to produce an injecting pressure in the fluid medicament in the fluid chamber (22,106)
- **Feature 5.1**: that substantially remains between about 5,5 Bar (80 p.s.i.) and 68,9 Bar (1000 p.s.i.) during injection of the fluid medicament to jet inject the fluid medicament from the fluid chamber through the injection-assisting needle (24) to the injection site,

characterized in that

- **Feature 6**: the prefilled syringe (18,88) further comprises a syringe body (36,120) that includes a flange (34) and a wall (30) and a needle hub portion (32) of unitary construction, and the injection-

assisting needle (24) is mounted to the needle hub portion (32),
- Feature 6.1: wherein the prefilled syringe (18,88) has a distal end in which the injection-assisting needle (24) is located, and a proximal end opposite the distal end, wherein the flange (34) extends radially from the proximal end, and
- Feature 7: the syringe support (16) axially supports the flange at the proximal end of the prefilled syringe (18,88) during the jet injection of the medicament.

VI. Claim 1 of auxiliary request I is based on claim 1 of the main request with the following added feature:
- Feature 7.1: such that the distal portion of the prefilled syringe is substantially unsupported in an axial direction.

VII. Claim 1 of auxiliary request II is based on claim 1 of auxiliary request I with the following added feature:
- Feature 8: wherein the prefilled syringe (18, 88) remains stationary within the housing (12) and is fixed thereto.

VIII. The following documents are further referred in the present decision:
- D1: WO 03/070296
- D2: US 2004/220524
- D5: US 2001/049496
- D6: WO 97/41907
- D7: WO 00/24441
- D9: WO 03/068290
- D10: US 6102896
- D12: US 6391003
- D13: Pressure and stress transients in autoinjector devices, Veilleux & Shepherd, Drug Delivery and Translational Research (2018).

Reasons for the Decision

1. Main request - added subject-matter (Article 100(c) EPC)

The Board agrees with the finding of the opposition division that the following added feature 7 in claim 1 leads to an unallowable intermediate generalisation:
Feature 7: *"the syringe support (16) axially supports the flange at the proximal end of the prefilled syringe (18,88) during the jet injection of the medicament".*

1.1 Appellant 1 held that the distal end of the syringe did not need to be unsupported as described on page 6, lines 29 to 32 of the original application. From said disclosure the distal end of the prefilled syringe may be unsupported in the axial direction. The use of the term "may" implied that the feature was optional. Although it was apparent for the skilled person that it was better to have an unsupported syringe distal end, because then the syringe was only held at the flange site, it was not necessarily the case. The overall disclosure justified focusing only on the claimed subject matter of a prefilled syringe having at a proximal end a flange interacting with the syringe support.

1.2 The Board takes the view that throughout the application as filed (claim 9, page 3, lines 18-21, page 6, lines 29-32 and figures 2, 5, 8 and 9), the syringe support is disclosed as axially supporting the syringe flange during jet injection in combination with the distal portion of the syringe being substantially unsupported in an axial direction.

The passage on page 6, lines 29-32 of the application as filed reads:
"Thus, the entire support for the prefilled 20 can be provided on the syringe flange 34, while the distal end of the syringe 18 may itself be substantially unsupported in an axial direction".
While this cited passage uses the term "may", it does not mean that the distal end of the prefilled syringe 18 being unsupported in an axial direction is optional. The term "may" in this passage is to be read as a consequence of the entire support for the syringe being provided on the syringe flange 34. The support being unitary, only introducing its axial support to the syringe flange and omitting that the distal end of the syringe is axially unsupported leads to an unallowable intermediate generalisation as the features are structurally inextricably linked.

2. Auxiliary request I - Novelty over D8

The Board concurs with the Opposition Division's opinion that the subject-matter of claim 1 of auxiliary request I is not novel over D8.

2.1 Appellant 1 was of the opinion that D8 did not disclose:
(a)- a jet injector (feature 1)
(b)- a syringe support supportively mounting the prefilled syringe to the housing (feature 4)
(c)- a range of injecting pressure in the fluid medicament within the fluid chamber remaining between 5,5 and 68,9 Bar (feature 5.1)
(d)- the distal portion of the prefilled syringe being substantially unsupported in an axial direction (feature 7.1).

2.2 The Board does not agree with appellant 1 and confirms its preliminary opinion as expressed in the communication pursuant to Article 15(1) RPBA dated 9 June 2022:

(a) - The expression "jet injector" is to be understood having regard to the definition in paragraph [0036] of the patent as referring to an injector allowing an "*injection with sufficient velocity and force to drive the medicament to locations remote from the needle tip 26*". Furthermore, as mentioned by the Opposition Division, the injection pressures, the needle gauge and the medicament's viscosity in D8 and the patent overlap such that the auto-injector of D8 can be considered a jet injector.

(b) - Appellant 1, referring to figure 5 argued that: "Further, D8 does not disclose that the syringe support “mounts” the prefilled syringe to the housing. Although the respective rear end of the collapsible cartridge 219 may be seen as supporting the syringe, it does not mount it to the housing in the sense of the present invention".
However, figure 23 of D8 discloses a syringe support, the coil spring 282, supportively mounting the prefilled syringe (211) to the housing (body 12).

(c) - Appellant 1 was of the opinion that: "In D8, some pressure ranges may be described, but there is no clear and unambiguous disclosure whether these pressure ranges in combination with the specific viscosity of the medicament lead to a jet injection, which means an injection of the medicament so that the fluid does not leak out along the side of the needle."

The Board notes that neither the viscosity of the fluid nor the result to be achieved, namely that "the fluid does not leak out along the side of the needle" are defined in claim 1.

The pressure calculated by the Opposition Division dividing the injection force by the section of the fluid chamber arriving at an injection pressure between 14 and 336 Bar was not contested by the parties. This range largely overlaps with the range defined in the patent (5,5 - 68,9 Bar).

(d) - Appellant 1 was of the opinion that D8 (figures 19, 23, 24 and paragraph [0052]) discloses the distal portion of the prefilled syringe being substantially supported in an axial direction.
However, in line with the Opposition Division's opinion (point 3.5 on page 8 of the appealed decision), the distal portion of the prefilled syringe is substantially unsupported in an axial direction.

2.3 During oral proceedings, appellant 1 further argued that the below features 5 and 5.1 were not disclosed in D8.

- Feature 5: *"an energy source configured for biasing the plunger (28,104) with a force selected to produce an injecting pressure in the fluid medicament in the fluid chamber (22,106)*

- Feature 5.1: *that substantially remains between about 5,5 Bar (80 p.s.i.) and 68,9 Bar (1000 p.s.i.) during injection of the fluid medicament to jet inject the fluid medicament from the fluid chamber through the injection-assisting needle (24) to the injection site*"

Appellant 1 argued that the injection pressure in the fluid medicament in the fluid chamber that

substantially remains between about 5,5 Bar and 68,9 Bar meant that the pressure in the fluid chamber should not go below 5,5 Bar during injection. They referred to figure 6 of the patent representing the typical decrease of pressure in the fluid chamber containing the medicament during injection: a high pressure when the device is fired decreasing linearly to a low pressure when the injection is completed (paragraph [0037] of the patent).

D8 disclosed in paragraph [0066] that *"the injector of the present invention is preferably configured to generate injection forces ranging between about 5 lbs. and about 120 lbs"*, which corresponded to a pressure range between 14 and 336 Bar for a syringe's internal diameter of 4,5 mm (see paragraph [0065], line 7) as calculated by the Opposition Division. However according to appellant 1, this did not equate to a pressure remaining between 5,5 Bar and 68,9 Bar as the pressure in the syringe would drop and go below the 5,5 Bar.

Appellant 1 further argued that the possible integration of a pressure regulator or restrictor in the embodiment of figures 23 and 24 of D8 such as those already described in D8 (see paragraph [0062], lines 21-25) would be a combination of different embodiments, which is not permissible for novelty objections and would in any event not lead to the disclosure of the injecting pressure remaining within 5,5 Bars and 68,9 Bars.

2.4 The Board does not agree with appellant 1.

2.4.1 It is first to be noted that the *"energy source configured for biasing the plunger (28,104) with a force selected to produce an injecting pressure in the fluid medicament in the fluid chamber (22,106)"* in the

patent is a compressed spring with a linear spring constant. The use of a spring as energy source leads to a substantially linear drop when the spring expands as represented in figure 6 of the patent.

In D8, the energy source is a microcylinder of a pressurised gas (52). Paragraphs [0031] and [0032] of D8 disclose that the pressure produced in the pneumatic cylinder will decrease at least slightly as the piston moves through its stroke and the volume increases.

2.4.2 In view of the acknowledgement that at least a slight pressure drop occurs in the embodiments of D8 which do not comprise a restrictor or regulator, the disclosure of the injection forces ranging from about 5 lbs and about 120 lbs, corresponding to a pressure of 14 to 336 Bar can be assumed to take into account the pressure drop such that also at the end of the injection, the pressure remains above 14 Bar.

2.4.3 But even if the injection pressure between 14 and 336 Bar is to be understood as the initial injection pressure, paragraphs [0031] and [0032] of D8 teach that the decrease in pressure can be minimized by varying the pressure and the volume of the gas contained in the pressurised gas source 50 or by decreasing the volume of the pneumatic cylinder.

2.4.4 Furthermore paragraph [0062] discloses *"Though the injectors 10 illustrated in Fig. 23 and Fig.24 do not include a pressure regulator or a restrictor, if desired, injectors 10 including an integrated driver and dispenser 200 may be provided with a pressure regulator or restrictor, such as those already described".* Contrary to appellant 1's argument this disclosure is a direct and unambiguous disclosure of

the embodiments of figures 23 or 24 comprising a regulator or a restrictor. Regulators and restrictors enable a constant pressure in the pneumatic cylinder as disclosed in paragraph [0035], such that the pneumatic injector of figures 23 and 24 with a regulator or a restrictor will provide a constant injection force between 14 and 336 Bar.

3. Auxiliary request II

3.1 Added subject-matter

The subject-matter claimed in accordance with auxiliary request II does not extend beyond the content of the application as originally filed.

3.1.1 Appellant 2 is of the opinion that the subject-matter of claim 1 and in particular features 2.1, 6, 6.1 and 8 as well as the subject-matter of claims 2-3, 8 and 12 extend beyond the content of the application as originally filed.

3.1.2 The Board concurs with the Opposition Division that the "fluid medicament" (feature 2.1) finds basis in the application as originally filed in particular in the first paragraph under "summary of the invention", on page 2, lines 19-26.
"The invention is related to a jet injector. The preferred embodiment employs a prefilled syringe that is preferably prefilled with a medicament prior to the assembly of the device. The syringe has a container portion that defines a fluid chamber containing a medicament. An injection-assisting needle is disposed at the distal end of the chamber and has an injecting tip configured for piercing an insertion location. The needle defines a fluid pathway in fluid communication

with the chamber for injecting the fluid from the chamber into an injection site. The syringe also has a plunger that is movable within the fluid chamber".
This passage discloses that the syringe is prefilled with a medicament in the fluid chamber and the fluid is then injected from the chamber into an injection site. The medicament can thus be equated to a fluid medicament.

3.1.3 Furthermore, the addition of features 6 and 6.1 based on page 5, lines 18-22 of the application as filed does not lead to an unallowable intermediate generalisation. The below features referred to by appellant 2 are either already in claim 1 or are not inextricably linked to features 6 and 6.1:
(i) the needle hub portion 32 at the distal end of the fluid chamber 22;
(ii) the flange extending radially from the proximal end of the syringe wall 30;
(iii) the syringe cushion 38;
(iv) the syringe wall 30 comprising a tubular portion to define the fluid chamber;
(v) the needle 24 having an injecting tip 26 configured to penetrate the tissue of a patient;
(vi) the plunger 28 seals the medicament in the fluid chamber and is slidably received in the tubular portion.

Features 6 and 6.1 reciting:
- Feature 6: "*the prefilled syringe (18,88) further comprises a syringe body (36,120) that includes a flange (34) and a wall (30) and a needle hub portion (32) of unitary construction, and the injection-assisting needle (24) is mounted to the needle hub portion (32)*"

- Feature 6.1: "*wherein the prefilled syringe (18,88) has a distal end in which the injection-assisting needle (24) is located, and a proximal end opposite the distal end, wherein the flange (34) extends radially from the proximal end*",
imply that:
(i) the needle hub portion 32 is at the distal end of the fluid chamber 22;
(ii) the flange extends radially from the proximal end of the syringe wall 30;
(iv) the syringe wall 30 comprises a tubular portion to define the fluid chamber.
Indeed, the syringe has a typical construction, where the flange is at the proximal end of the tubular wall of the fluid chamber and the hub at the distal end of the fluid chamber.

Moreover, the syringe cushion is defined as optional:
- Under the summary of the invention of the application as filed: *"A syringe cushion can be provided in association with the syringe support and the prefilled syringe to compensate for shape irregularities of the pre-filled syringe and/or to cushion and provide shock absorption to the syringe during the device firing"*
and,
- in dependent claim 7:
"A syringe cushion can be provided in association with the syringe support and the prefilled syringe to compensate for shape irregularities of the pre-filled syringe"
The skilled person understands that the syringe cushion on page 5, lines 30 to page 6, line 2 and shown in figures 2, 4, 5 and 8 is not structurally and functionally linked to the flange or the support but is an additional optional element that can be added to

compensate for irregularities of the syringe and/or absorb shocks.

Feature 2.3 *"a plunger movable within the fluid chamber"* and features 5 and 5.1 *"an energy source configured for biasing the plunger (28,104) with a force selected to produce an injecting pressure in the fluid medicament in the fluid chamber (22,106) that substantially remains between about 5,5 Bar (80 p.s.i.) and 68,9 Bar (1000 p.s.i.) during injection of the fluid medicament to jet inject the fluid medicament from the fluid chamber through the injection-assisting needle(24) to the injection site"*, imply that the plunger 28 must seal the medicament in the fluid chamber and is slidably received in the tubular portion (point (vi)), otherwise the fluid medicament could not be injected with the defined pressure.

As to point (v), the skilled person is not presented with an additional information with the feature *"having an injecting tip (26) configured for piercing an insertion location "* having regard to the passage on page 5, lines 6-7: *"Needle 24 has an injecting tip 26 configured as known in the art to penetrate the tissue of a patient, preferably the skin"*. The tissue of a patient being undefined, the above-mentioned passage cannot be construed as implying any particular piercing capacity.

3.1.4 Finally, the basis for feature 8 of claim 1 can be found on page 8, lines 17-19. While the preceding paragraphs disclose the housing 12 having a needle guard 66 that is movable with respect to the outer housing 14, the guard is not inextricably linked to the fact that the syringe remains stationary within the housing and is fixed thereto. The needle guard protects

the needle tip 26. Therefore, the omission of the needle guard does not lead to an unallowable intermediate generalisation.

3.1.5 Appellant 2 is further of the opinion that the errors of conversion of the injection pressure in dependent claims 2 and 3 lead to added subject-matter.

3.1.6 The Board does not agree, the marginal rounding errors in the conversion from psi to Bar do not present the skilled person with new technical information especially as the pressure values in psi have been kept in bracket.

3.1.7 Appellant 2 is of the opinion that in dependent claim 8:
- the container portion being made of blown glass,
- the injection-assisting needle being adhered to the glass and
- the fluid chamber containing between 0.02 and 4 ml of the medicament
were not disclosed in combination originally as they originate from claims 10, 11 and 12 of the application as filed and claim 12 did not depend on claim 10 and 11 but directly on claim 1.

3.1.8 However, no new technical information is presented with the combination of the above 3 listed features in view of original claims 10, 11 and 12 and the description (page 3, lines 22-25).

3.1.9 Lastly appellant 2 is of the opinion that dependent claim 12 dependent on claim 1, which was based on original independent claim 18, without specifying the pressure and the penetration depth extends beyond the content of the application as originally filed.

3.1.10 The Board agrees with the Opposition Division (see point 2.2 of the appealed decision) and notes that claim 12 is dependent on claim 1, which defines an injection pressure between 5,5 Bar (80 psi) and 68,9 Bar (1000 psi).

3.2 Insufficiency of disclosure

The invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person.

3.2.1 Appellant 2 is of the opinion that the invention is not sufficiently disclosed for the following reasons:

- The patent does not disclose how to provide the claimed injecting pressure remaining between 5.5 and 68.9 Bar and does not indicate how to set or even to determine the injecting pressure. Appellant 2 refers to figure 21 of D13 which illustrates that the pressure in an autoinjector device varies in a complex manner over time during injection and depending on where it is measured. In view of the difficulty to measure, determine and control the actual injecting pressure in the fluid chamber, the patent does not disclose how the claimed injector must be designed in order to achieve the claimed pressure range during the whole injection.

- The skilled person wanting to implement the claimed invention would also be faced with the difficulty that claim 1 is directed to a "jet injector" comprising a needle, whereas a jet injector is in principle needleless and injects the medicament directly with a high pressure stream of liquid that penetrates the skin to deliver a medicament.

Assuming that the terms "jet injector" and "to jet inject" were interpreted as implying that the medicament is not delivered in the form of a bolus at the tip of the needle, this would lead to the conclusion that there is not enough information in the patent on how to implement this feature. The mere mention of the pressure range in the fluid chamber without the shape and size of the needle and the viscosity of the fluid medicament is not sufficient to characterise the presence of a jet especially at lower pressures. In the present case, the skilled person is unable to implement the invention over the entire range of injecting pressure which is claimed.

3.2.2 The Board does not agree. The jet injector of the present invention comprises a needle as defined in claim 1 and throughout the patent. The pressure remaining between 5,5 and 68,9 Bar is to be understood as an average pressure in the medicament in the fluid chamber. Document D13 referred to by appellant 2 shows how complex local pressures are in the fluid chamber and how unrealistic it would be to consider the local pressures for the range defined in claim 1 of the patent.
The patent gives information about the preferred size of the needles to be used in paragraphs [0038], [0042] and [0043], the preferred amount of medicament contained and injected from the fluid chamber in paragraph [0039] and the preferred injection rates in paragraph [0040]. Based on common general knowledge, the skilled person is able to select a spring with a stiffness providing the required pressure.
While it is correct that the skilled person cannot carry out the invention with a high viscous fluid pushed through a small needle at a pressure between 5,5 and 68,9 as mentioned by appellant 2, the skilled

person wishing to implement the invention will exclude any embodiment that is meaningless and inconsistent with the teaching of the application. Indeed, the skilled person will use his common general knowledge to supplement the information contained in the application and will realise that such an arrangement is not feasible.

3.3 Clarity - Article 84 EPC

Feature 8 of claim 1 is clear.

3.3.1 Appellant 2 is of the opinion that *"the prefilled syringe remain[ing] stationary within the housing"* is unclear as to whether this limitation requires the syringe to remain stationary during jet injection or more broadly at all times, including before, after, and during jet injection.

3.3.2 The Board notes that the feature reads: *"the prefilled syringe (18, 88) remains stationary within the housing (12) and is fixed thereto".* The last part of the feature emphasises that the prefilled syringe being fixed to the housing will remain stationary at all times. There is no reason to consider that this feature would be limited to the injection phase especially in view of the description where the embodiments described no relative movement between the prefilled syringe and the housing at any time.

3.4 Novelty

The subject-matter of claim 1 is novel over D8 as it does not disclose feature 8, namely that *"the prefilled syringe remains stationary within the housing and is fixed thereto".*

3.4.1 According to appellant 2 feature 8 only implied that the syringe was stationary within the housing and fixed during the injection of the medicament (i.e., the needle does not need to be always stationary).
In the embodiments of figures 23 and 24 of D8 the syringe moves relative to the body 12 before injection starts, but then remains stationary and fixed relative to the housing at a distal position during injection thereby anticipating feature 8 of claim 1.

Alternatively appellant 2 argued that if feature 8 were to be interpreted in a narrower manner as requiring that the syringe stays stationary within the housing at all times, a different claim mapping could be made with respect to the embodiment of figures 18-19 of D8. In this embodiment, the casing 219 comprises a collapsible portion 290 and a fixed portion 292. The syringe moves relative to the fixed portion 292 but always remains stationary relative to the collapsible portion 290, as shown by the comparison between Fig.18 and Fig.19. The collapsible portion 290 can be considered as a housing as recited in claim 1 of the patent, since it surrounds and therefore houses the prefilled syringe. Appellant 2 noted that housing should be interpreted in a broad sense since there was no general definition of a "housing". For example, D7, page 7, lines 30-32 defined the housing as *"a point of reference for positional and directional statements for other parts and components"*. Therefore, with this claim mapping, all features were disclosed in figures 18 and 19 of D8.

3.4.2 The Board does not share the broad interpretation of feature 8 made by appellant 2 as explained above in connection with the clarity issue. In figure 23 of D8, the prefilled syringe 211 moves relative to the housing

12 so that the needle 250 can be inserted in the patient's skin. Feature 8 is thus not anticipated by the embodiments of figures 23 and 24.

Furthermore, the Board follows the opinion of the Opposition Division that the "housing that houses the prefilled syringe" is the body 12 (not shown in figure 18 and 19 but in figure 5) or possibly the casing 219 but cannot be considered as the collapsible portion 290 of the casing 219, which only surrounds part of the syringe.
According to paragraphs [0055] and [0056] of D8, the collapsing portion 290 is a hollow cylinder shaped and sized to receive the coil spring which extends only over a part of the syringe and moves with the syringe as an insertion force is applied on the piston. Thus, the size and the function of the collapsible portion 290 in D8 cannot be regarded as a "housing that houses the prefilled syringe".

3.5 Inventive step starting from D2, D1 or D11

3.5.1 Starting from D2 in combination with common general knowledge, D5, figure 1a, D6, figure 10, D7, figures 2A-2B or D11 figures 1-2.

(a) Appellant 2 was of the opinion that the subject-matter of claim 1 differed from D2 in that the syringe comprises a flange extending radially from the proximal end (part of features 6 and 6.1) and in that the flange is axially supported by the syringe support during injection (feature 7). This was not contested.

Appellant 2 defined the objective problem in providing an alternative injector and argued that

it is common general knowledge to use "standard prefilled syringes", which generally have a radial flange. Then the skilled person would just have to add a supporting piece for holding the syringe flange and then connect the supporting piece to the housing instead of threadably connecting the syringe to the housing. Paragraph [0057] of D2 indicates that the threaded connection between nozzle assembly 12 and housing 14 can be replaced by other connections.

During oral proceedings Appellant 2 referred in particular to the combination with D7 which is directed to an autoinjector and acknowledges the *"need for autoinjector designs better adapted for use with greater variation in syringe size and type"* (page 5, lines 4-6). Furthermore, the paragraph bridging pages 7 and 8 discloses that replacement of containers may be facilitated by any known separation or openable arrangement e.g., threaded, or hinged parts. The skilled person would therefore combine D2 with D7 and arrive at the subject-matter of claim 1.

(b) The Board does not agree. D2 discloses the use of an injection assisting needle (20) with a particular structure (see figures 2 and 3) to enable delivery of medicament quickly under low pressure (see paragraph [0010]). Therefore, starting from D2 there is no incentive for the skilled person to use a conventional syringe and to add a syringe support according to claim 1.

The combination of D2 with D7 is based on an ex post facto analysis. It is not because in D2 it is disclosed that the threaded connection between

nozzle assembly 12 and housing 14 can be replaced by other connections that the skilled person would be hinted to change the entire nozzle with its special design for a conventional syringe with a flange extending radially as disclosed in D7. Furthermore, the combination of the teachings of D2 with D7 would still not enable the skilled person to arrive at the subject-matter of claim 1. The skilled person would still need to add a support such that the flange is axially supported by the flange. Appellant 2 argues that the skilled person would add such a support, but this is again based on hindsight as there is no incentive to add such a support in particular.

3.5.2 Starting from D1

(a) Appellant 2 is of the opinion that the subject-matter of claim 1 differs from D1 in that the syringe comprises a flange extending radially from the proximal end (part of features 6 and 6.1) and in that the flange is axially supported by the syringe support during injection (feature 7).

The objective technical problem therefore consists in providing an alternative injector.

The skilled person faced with this objective technical problem would contemplate modifying the injector of D1 to adapt it to syringes having a proximal flange, because those are extremely common (see for instance D8 and D7 as above for the combination with D2).

(b) The Board takes the view that the skilled person starting from D1 has no incentive to use a

conventional syringe. Indeed, the invention in D1 relates to an injector with a bypass channel that can be closed or opened to feed a fluid to be injected from a container 42 to an injection conduit.

3.5.3 Starting from D11

(a) Appellant 2 is of the opinion that claim 1 differs from the teaching of D11, at best, in that D11 does not explicitly disclose feature 5.1 (injecting pressure that substantially remains between about 5,5 Bar and 68,9 Bar during injection, to jet inject the fluid medicament from the fluid chamber through the injection-assisting needle to the injection site).

The objective technical problem consists in finding an appropriate injection pressure for the injector of D11.

The skilled person confronted with the technical problem of finding an appropriate injection pressure for the injector of D11 would do so based on routine experiments. If necessary, Dl, D2 (or its equivalent D12), D8, D9 and D10 provide exemplary pressure values falling within the claimed range.

(b) D11 discloses an auto-injector with a standard needle. In the Board's view, the skilled person would a priori not start from such an embodiment and use an injection pressure ranged between 5,5 Bar and 68,9 Bar with such needles.
Nor would the reference to D1, D2 (or D12), D8, D9 and D10 help, as even if these documents may

disclose injection pressures in the range defined by claim 1, they disclose syringes with a special structure or comprising small needles (for example D8, paragraphs [0065] and [0077] disclose 0,5 inch (1,27 cm) needles) which do not appear suitable for the design of D11.

4. The Board thus concludes that none of the objections raised by appellant 2 prejudice the maintenance of the patent on the basis of auxiliary request II, which corresponds to the patent in the form allowed by the Opposition Division .

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

A. Voyé G. Pricolo

Decision electronically authenticated