UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WEST PHARMACEUTICAL SERVICES, INC.
Petitioner

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH
Patent Owner

PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 9,586,011

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I. Introduction

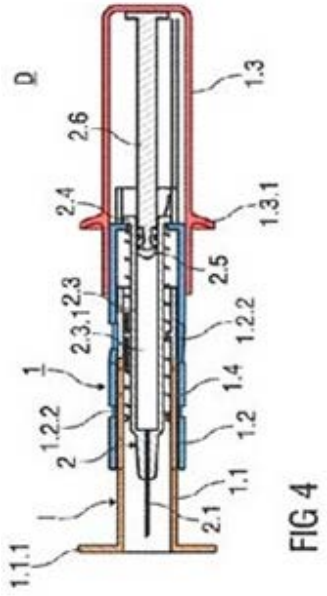
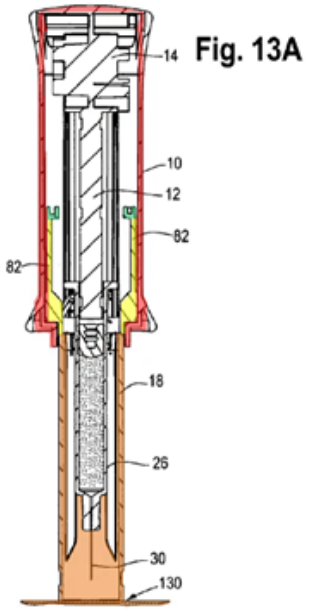
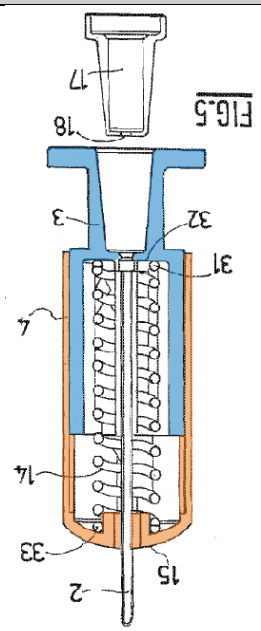
Petitioner West Pharmaceutical Services, Inc. ("Petitioner" or "West") requests *inter partes* review of claims 1-13, 18, and 20 of U.S. Patent No. 9,586,011 (Ex. 1001 or the "'011 Patent"), assigned to Sanofi-Aventis Deutschland GMBH ("Sanofi"), because they are obvious over the prior art.

The challenged claims are directed to a needle safety device for a pre-filled syringe having a hypodermic needle. The needle protection portion of Sanofi's claimed device has three main components which cooperate to protect the needle and avoid accidental needle sticks during use: (1) a "*hollow support body*" that retains the prefilled syringe, (2) a "*hollow needle shield*," and (3) a "*guiding mechanism to guide the movement of the needle shield relative to the support body*." The challenged claims also require a handle or outer body. The Office should never have granted the challenged claims because at the time the application was filed in mid-2010, the challenged claims would have been obvious over prior art needle safety devices for pre-filled syringes from companies like Becton Dickinson & Co. ("BD") and Bristol-Myers Squibb Co. ("BMS"). The Board should thus institute review and cancel the challenged claims of the '011 Patent.

Specifically, by at least 2005 and long before the priority date of the challenged claims, BD had designed a needle safety device intended to cover the

needle to protect patients and users from any risk of needle-stick injury at the end of the injection, when the device has the greatest potential for contaminating others. BD's device had every feature of the challenged '011 Patent claims necessary to achieve the desired needle safety – (1) the hollow support body, (2) the hollow needle shield, and (3) the guide mechanism that guides the needle shield before and after injection to prevent accidental needle sticks. The only thing BD's device lacked, to anticipate the challenged claims, was a handle that was slidable on the hollow support body. In view of that need, BMS designed a similar device, but with a handle that is slidable on the hollow support body. Like BD's device, BMS's device has almost every feature of the challenged Sanofi patent claims, *and* it employs a slidable handle to improve performance and assist users with limited dexterity.

BD's device is described in U.S. Patent Pub. No. 2009/0024093 to Carrel et al. (Ex. 1005 or "Carrel"), and BMS's device is set forth in U.S. Patent Publication No. 2008/0228147 to David-Hegerich et al. (Ex. 1006 or "David-Hegerich"). Exemplary embodiments of these needle safety devices are set forth below:

’011 Patent	David-Hegerich	Carrel
 Ex. 1001, ’011 Patent, FIG. 4 (annotated).	 Ex. 1006, David-Hegerich, FIG. 13A (annotated).	 Ex. 1005, Carrel, FIG. 5 (annotated).

Neither Carrel nor David-Hegerich were substantively considered by the examiner during prosecution. And a person of ordinary skill in the art (a “POSA”) would have been motivated to modify Carrel to include David-Hegerich’s slidable handle based on David-Hegerich’s express disclosure of the handle’s benefits. Moreover, a person of ordinary skill in the art would have recognized the benefits of using a sliding handle and would have been motivated to include such a handle on the device described by Carrel.

Petitioner West will thus prove in detail below that independent claims 1 and 20 of the ’011 Patent are unpatentable over Carrel in view of David-Hegerich. The same is true for at least dependent claims 2-13 and 18—they merely recite well-

known aspects of needle safety devices for pre-filled syringes. The challenged claims should, thus, be canceled because they should never have been issued.

II. Statement of Unpatentability Grounds for Claims 1-13, 18 and 20 of the '011 Patent

Petitioner requests *inter partes* review of claims 1-13, 18, and 20 of the '011 Patent, and a final determination that those claims are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent Pub. No. 2009/0024093 to Carrel et al. (Ex. 1005) in view of U.S. Patent Publication No. 2008/0228147 to David-Hegerich et al. (Ex. 1006). The '011 Patent issued from an application filed June 21, 2011, and was thus filed before the enactment of the America Invents Act ("AIA"). Accordingly this petition applies the pre-AIA versions of 35 U.S.C. §§ 102, 103, 112.

The earliest possible priority date of the '011 Patent is July 2, 2010. The prior art references cited for the ground above thus each qualifies as prior art to the '011 Patent under 35 U.S.C. § 102(b). Specifically, Carrel (Ex. 1005) qualifies as prior art under 35 U.S.C. § 102(b) at least because its publication date is January 22, 2009, which is more than one year before July 2, 2010. David-Hegerich (Ex. 1006) qualifies as prior art under 35 U.S.C. § 102(b) at least because its publication date is September 18, 2008, which is also more than one year before July 2, 2010.

In addition to Carrel and David-Hegerich, Petitioner also relies on the expert opinions of Mr. Charles E. Clemens (Ex. 1003) to prove that the challenged claims would have been obvious to a POSA by July 2010. Mr. Clemens is a seasoned

engineering professional with over 35 years of product development experience in the health care and biomedical industries, including needle-based drug delivery devices and systems. Mr. Clemens's qualifications are listed in his CV (Ex. 1004).

III. Level of Ordinary Skill in the Art

Patent claims must be analyzed from the perspective of a POSA at the time the claimed invention was allegedly invented by the patentee. If given the benefit of the earliest possible priority date on the face of the '011 Patent, this appears to be the time period shortly before July 2, 2010.

Further, in ascertaining the appropriate level of ordinary skill in the art of a patent, several factors should be considered including: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of workers in the field of the patent. Moreover, a POSA is presumed to be aware of the pertinent art, thinks along the line of conventional wisdom in the art, and is a person of ordinary creativity.

In view of these factors, a POSA with respect to the '099 Patent disclosure, would be a person with an undergraduate degree in mechanical engineering, and 3-5 years of experience designing needle safety or injectable drug delivery devices beyond the completion of their degree. Ex. 1003, Clemens Decl., ¶¶17-22.

IV. Claim Construction

The application of Carrel and David-Hegerich to the purported invention of the ’011 Patent is clear and straightforward. At this early stage of the IPR proceeding, Petitioner does not believe that any term of the ’011 Patent requires an express claim construction for the Board to understand the applicability of the cited art. Nor does the Petitioner believe that the ground of unpatentability would turn on the construction of any particular claim term or phrase. Accordingly, at this stage, Petitioner asks that all terms and phrases in the ’011 Patent be accorded their ordinary and customary meaning, in view of the ’011 Patent specification, and as understood by a POSA.

V. The ’011 Patent

The safety device claimed in the ’011 Patent use a simple mechanical approach to prevent accidental needle pricks. Ex. 1001, 1:45-48.

A. Overview of the ’011 Patent

The ’011 Patent is directed to “safety devices for pre-filled syringes.” *Id*., 1:17-19. More specifically, the ’011 Patent is “adapted to avoid accidental needle pricks and needle injuries before, during and after an injection of a medication or drug contained in the pre-filled syringe.” *Id*., 1:19-22. The primary way the device claimed by Sanofi achieves this is using three main components: (1) a “*hollow support body*” to retain the pre-filled syringe, (2) a “*hollow needle shield*” to cover

the needle before and after injection and (3) a "*guiding mechanism to guide the movement of the needle shield relative to the support body*" before and after injection. A handle is added to the proximal end to presumably make the needle safety device easier to grasp and use, but the claims do not otherwise require that the handle cooperate with the hollow support body, needle shield or guiding mechanism to aid in protecting the needle to avoid accidental needle sticks in the challenged claims. These basic features are illustrated in Figure 1, set forth below:

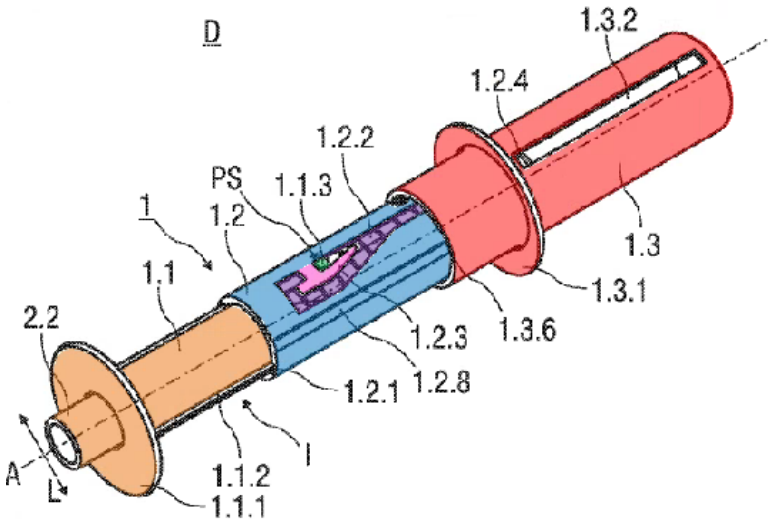


FIG 1

Id., FIG. 1 (annotated). The hollow needle shield is element **1.1** (shaded in orange). The hollow support body that holds the needle is element **1.2** (shaded in blue). The guiding mechanism comprises the claimed guide track (element **1.2.2**, shaded in purple), disposed on the hollow support body **1.2,** a "deflectable flexible arm [1.1.4] with a guide pin [1.1.3] radially extending therefrom." *Id.*, 14:13-14. The

guide pin (shaded in green) on the deflectable flexible arm (shaded in yellow) follows the guide track as the needle shield **1.1** moves relative to the support body **1.2**. Figures 2 and 3 are illustrative.

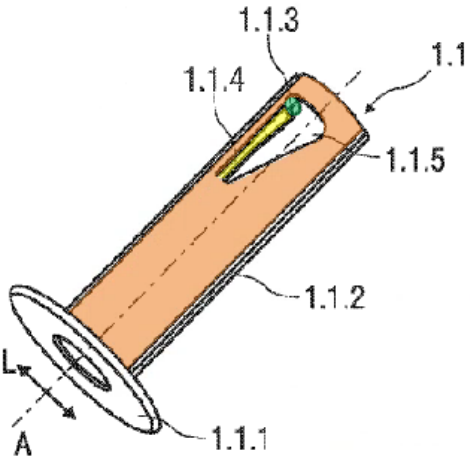


FIG 2

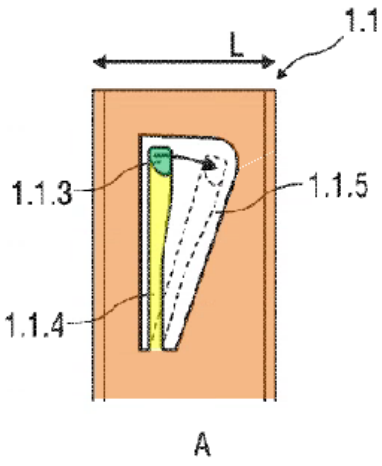
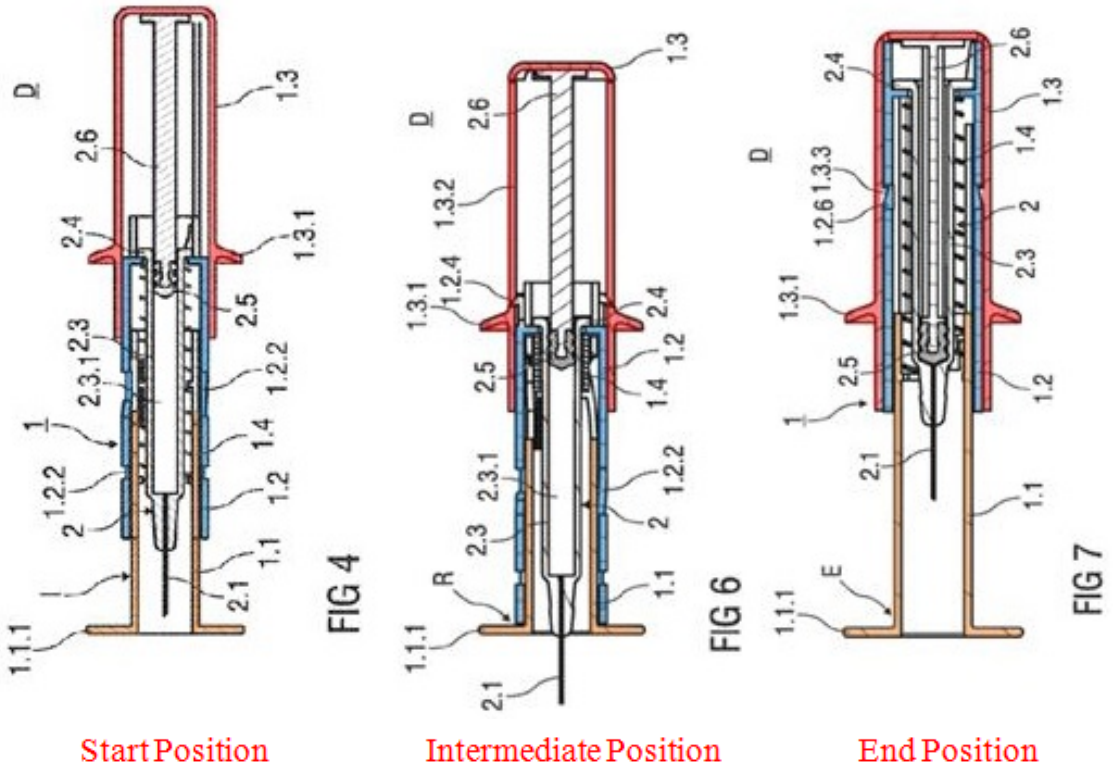


FIG 3

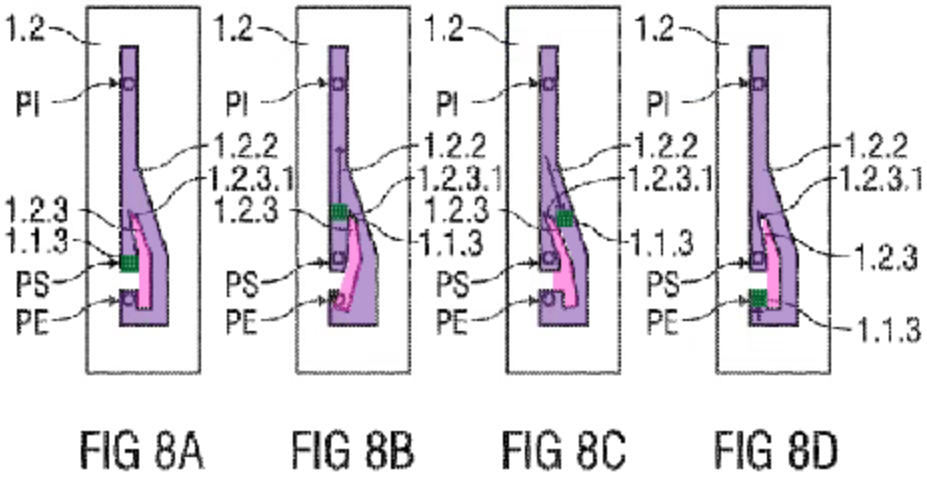
Id., FIGS. 2 and 3 (annotated). A hollow outer body 1.3 (shaded in red in annotated Figure 1 above) is added and slides over the hollow support body, but does not connect to the other components of the needle safety device of the challenged claims.

The claimed invention transitions between three positions. Initially, in a start or storage position, the needle shield is extended over the needle, as illustrated in Figure 4. At an intermediate position, the device is pressed against an object (i.e., a patient's skin), the needle shield 1.1 is retracted, relative to the support body 1.2 and allows the needle to be exposed for injection, as illustrated in Figure 6. At the

advanced or end position, the needle shield 1.1 is again extended over needle 2.1, as depicted in Figure 7.



Id., FIGS. 4, 6, and 7 (annotated). The transition between the three positions correlates with the movement of the guide pin through the track. The guide pin movement is illustrated by Figures 8A-8D below:



Id., FIGS. 8A-8D (annotated).

The starting position PS corresponds to state of the device in its start position, before injection. *See id*., 9:28-32. As the injection stroke begins, the guide pin 1.1.3 moves past a flexing gate element 1.2.3 (shaded in pink) and slides up to an intermediate position PI and the needle is inserted into the skin (or other object). After the injection stroke is completed and the needle is extracted, the guide pin travels back down the guide track where it is deflected by flexing gate element 1.2.3 and guided by the track away from the starting position PS, and towards the end position PE.

The safety device claimed by the challenged claims of the ’011 Patent, thus, has simple mechanical structures and interfaces to protect the needle and prevent accidental needle sticks. *Id*., 1:45-48. Such a mechanism can be found in an age-old mechanism of a retractable ball point pen. It also has been utilized in needle safety devices, such as in the prior art Carrel and David-Hegerich references.

Claim 1 of the ’011 Patent is illustrative:

[1.P] A safety device for a pre-filled syringe, comprising:

[1.1] an outer body;

[1.2] a hollow support body to retain the pre-filled syringe therein, wherein the hollow support body is received in the outer body and slidably arranged relative to the outer body to perform an injection stroke;

[1.3] a hollow needle shield slidable relative to the support body; and

[1.4] a guiding mechanism to guide the movement of the needle shield relative to the support body, the guiding mechanism comprising

[1.5] a deflectable flexible arm with a guide pin radially extending therefrom, the flexible arm extending essentially parallel to a central axis of the safety device, and

[1.6] a guide track configured to guide the guide pin within and along the guide track so that the guide pin follows the guide track when the needle shield is slid relative to the support body,

[1.7] wherein the flexible arm is configured to be laterally deflected as the guide pin follows the guide track, and

[1.8] wherein the flexible arm is connected to or is integrally formed to the needle shield or the support body, and the guide track is formed into the other of the needle shield or the support body.

The challenged dependent claims add well-known features that further define the mechanical characteristics of the device such as the "flexible arm," the "guide track," and their relationship with the rest of the device.

B. The Prosecution History

During prosecution, the examiner rejected the original claims as being anticipated by U.S. Pub. Pat. Appln. No. 2009/0259178 to Brechbuehler et al. Ex. 1002, '011 File History, p. 89-100. To address the rejection and avoid Brechbuehler, the applicant requested an interview with the Examiner (*id*., 76, 69), and then filed an amendment and reply addressing the rejection. Specifically, the applicant amended independent claim 1 to clarify that the "hollow support body" is "slidably arranged relative to the outer body to perform an injection stroke." *Id*., 77. This avoided Brechbuehler, the applicant argued, because Brechbuehler's needle holder (i.e., support body) is connected to an outer housing (i.e., handle) such that the two parts could not move axially relative to each other. *Id*., 83, 69.

After an additional search, the Examiner ultimately allowed the amended claims for the same reason applicant argued in its amendment and reply. *Compare id*., 83 *with id*., 28-29. The Examiner wrongly agreed that the claims avoided the prior art by arguing that it did not disclose an outer body (i.e., a handle) that is slidably arranged with the support body (i.e., the needle holder) to perform an injection stroke.

But that very feature is disclosed in the prior art. Specifically, Carrel describes all of the features of the claims except an outer body that is slidable relative to the hollow support body. David-Hegerich (Ex. 1006) shows the same slidable outer body arrangement as in the challenged claims, and expressly explains why a POSA would have modified a device like Carrel (Ex. 1005) to include the David-Hegerich outer handle.

VI. Overview of the Prior Art

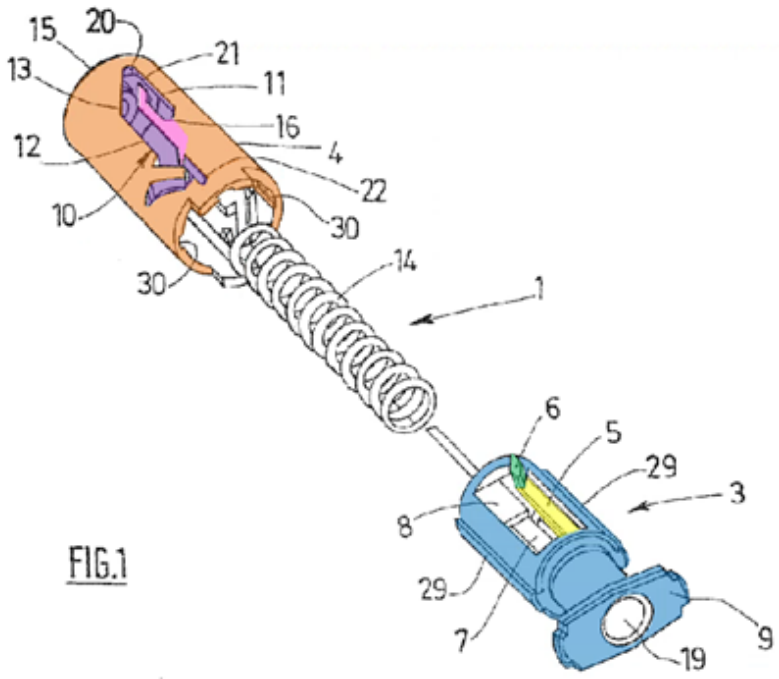
The sole ground of unpatentability under 35 U.S.C. § 103 relies on Carrel (Ex. 1005) in view of David-Hegerich (Ex. 1006). Carrel discloses and teaches the needle safety features of the challenged claims – the hollow support body, hollow needle shield, guide mechanism and a handle – except an outer body (i.e., a handle) that is slidably arranged on the hollow support body. For that feature, Petitioner relies on David-Hegerich and proves below that a POSA would have found it obvious to combine David-Hegerich's slidable outer handle with the Carrel device and result in each and every feature of the challenged claims. Moreover, the prior art David-Hegerich reference discloses the very feature that Sanofi added to the claims during prosecution to obtain the challenged '011 Patent claims. And David-Hegerich itself expressly teaches why incorporating a slidable outer handle on a needle safety device, such as that described in Carrel, would have been both useful and beneficial.

Like Carrel, David-Hegerich discloses a needle safety device. And like Carrel, David-Hegerich teaches the same basic guide and pin mechanism for protecting the needle before and after the injection as does Carrel and claimed in the ’011 Patent. For example, David-Hegerich discloses a very similar “guiding mechanism” that relies on a guide track that maneuvers a deflectable flexible arm to control the motion of a needle shield relative to the needle support body.

A. Carrel

Carrel is the base reference that discloses most of the features set forth in the challenged claims. Carrel is directed to a “protection device (1) intended to at least partially cover the needle (2) of an injection device.” Ex. 1005, Abstract. More specifically, like the ’011 Patent, Carrel is adapted to protect patients and users “from any risk of needlestick injury.” *Id*., [0003].

Carrel discloses three basic parts for protecting a hypodermic needle: (1) a *hollow support body* (support 3, shaded in blue) that retains the prefilled syringe; (2) a *hollow needle shield* (sleeve 4, shaded in orange), and (3) a *guiding mechanism to guide the movement of the needle shield relative to the support body* (comprising a pin 6 (in green) on a flexible arm 5 (in yellow) that travels in a guide track or passageway 10 (in purple)). These basic features are illustrated in Figure 1, set forth below:

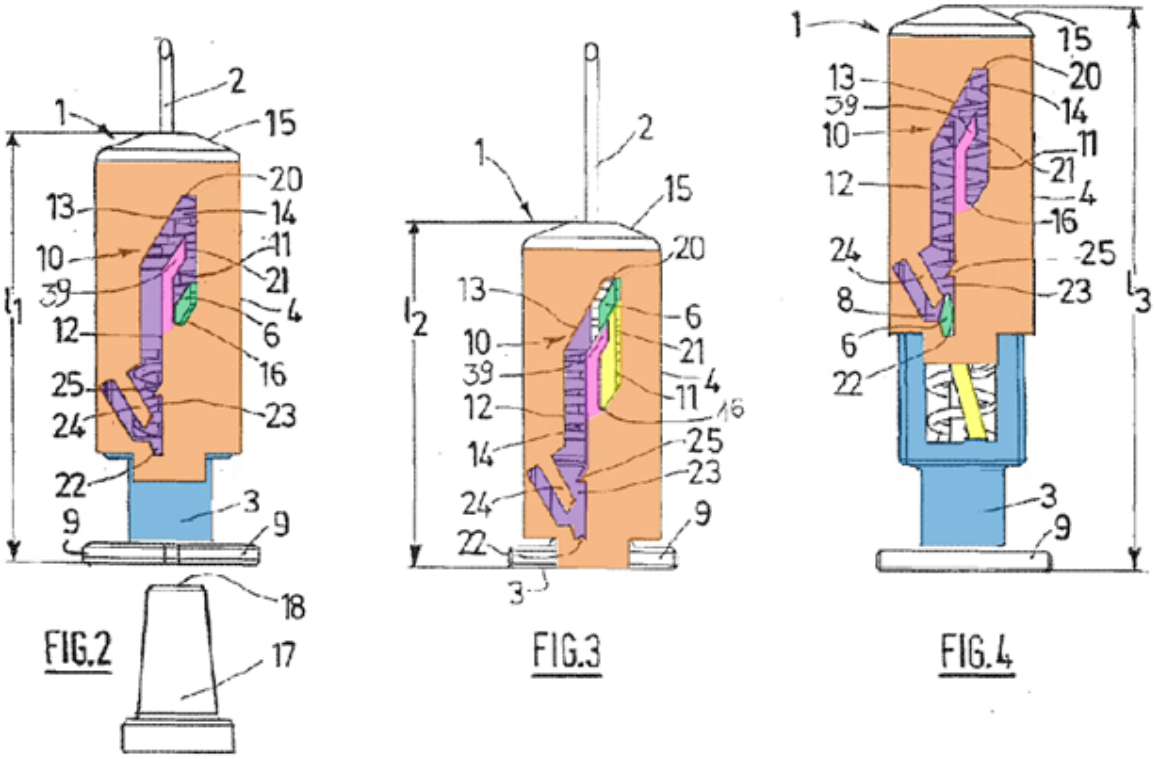


Id., FIG. 1 (annotated).

The guide track (passageway 10) works in conjunction with a deflectable flexible arm (flexible tab **5**, shaded in yellow) with a guide pin (peg **6**, shaded in green) radially extending therefrom. *Id*., [0053]. More specifically, Carrel teaches that "support 3 comprises a flexible tab 5 which runs longitudinally from the proximal part of the support 3 in the distal direction. This flexible tab 5 at its distal end comprises a peg 6." *Id*.

As illustrated above, Carrel's passageway 10 is defined by "first and second sections" that "are joined together by a first narrowed region defined by a flexible tongue at least partially defining the said first safety means." *Id*., [0025]; *see also id.*, FIGS. 1-4. Carrel further teaches that its "sleeve 4 comprises *a running passageway 10* forming a U, made in the wall of the sleeve 4 and arranged in such

a way as to *collaborate with the peg 6 over the entire travel of the sleeve*, as will be apparent from FIGS. 2-4." *Id*., [0055] (emphasis added).[1]



Id., FIGS. 2-4 (annotated). Carrel's starting position corresponds to a state of the device before delivery of the injectable medicine. As the injection stroke begins, the guide pin (peg 6, shaded in green) moves past the flexing gate element (flexible tongue 39, shaded in pink) as sleeve 4 is retracted and the guide pin slides up to intermediate position (as the needle is inserted into the skin or other object). Then, after the injection stroke and as the needle is extracted, sleeve 4 slides over the

[1] Unless otherwise noted, any emphasis in a citation has been added.

needle and the guide pin travels back down the guide track (passageway 10) where the guide pin (peg 6) is deflected away from the starting position, and towards the ultimate ending position (protection position).

Carrel's protection device teaches simple mechanical techniques "for protecting a needle so as to protect the patient and/or the user from the risk of needlestick injury." *Id*., [0001].

B. David-Hegerich

Like Carrel, David-Hegerich is directed to "[a]n injection device for use with a pre-filled syringe." Ex. 1006, Abstract. David-Hegerich's device "features a track and track follower engagement which facilitates locking a protective needle guard over the tip of the needle at the conclusion of the injection." *Id*.

The David-Hegerich device comprises at least three basic elements also described in Carrel and claimed in the challenged ’011 patent claims: (1) a *hollow needle shield* (hollow tubular needle guard 18), (2) a *guiding mechanism to guide the movement of the needle shield relative to the outer body* (tracks 42 and track followers 82) in a middle section, and (3) an outer body (handle 10) which functions as a handle and a hollow support body and supports the guide mechanism (tracks 42 and track followers 82). These basic features are illustrated in Figure 13A.

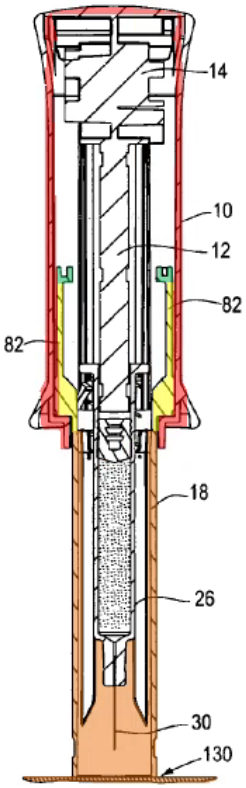


Fig. 13A

The hollow needle shield is hollow tubular needle guard **18** (shaded in orange). The outer body or handle is handle **10** (shaded in red). With respect to the guiding mechanism, a portion of the mechanism is illustrated as track followers **82** (shaded in yellow and green) follows the channels of track features that run along the surface of the plunger top 14.

The David-Hegerich device includes “a hollow tubular handle 10 which is grasped by the user to make an injection” and includes “an interior region receiving the needle guard 18 and syringe 26.” *Id*., [0046] and [0137]. David-Hegerich further teaches that its “plunger 12 includes a top portion 14 which is

attached to the open proximal end of the generally cylindrically-shaped handle 10." *Id*., [0049]. David-Hegerich explains that handle 10 is used to drive the plunger 12 and dispense the medicament from the syringe: *"As the handle 10 is moved towards the injection site* during an injection (as will be explained more fully below in conjunction with FIGS. 14-16), *the handle moves the plunger 12 tip 15 through the interior of the pre-filled syringe 26 to expel medicament* from the pre-filled syringe through the needle 30." *Id*., [0049]. After the device is removed, the needle guard 18 extends to cover the needle tip:

> At the completion of the injection and as the device is removed from the injection site, the needle guard 18 is moved distally by a spring 16 and locked into a position to cover the tip of the syringe needle 30 to prevent an accidental needle stick (FIG. 18).

Id. David-Hegerich thus discloses the slidable handle missing from Carrel. David-Hegerich also expressly explains the advantages of employing a slidable handle, including facilitating use for persons having low dexterity:

> [I]t provides an ergonomic, easy-to-use device that is particularly suitable for self administration of injections by patients with dexterity limitations, including the elderly and persons suffering from arthritis in the hands or fingers. The handle 10 is preferably designed without sharp edges or surfaces that would generate pressure points during use. No squeezing is required. The wide tubular structure of the handle allows for ease of grip by the user, in a variety of different

> hand positions. The injector handle 10 is designed to provide a stable hand grip.

Id., [0050] and [0020].

David-Hegerich's device thus discloses simple mechanical technique to advance the needle shield "beyond the tip of the needle to prevent against an accidental needle stick." *Id*., [0037].

VII. Ground 1: The Combination of Carel and David-Hegerich Renders Obvious Claims 1-13, 18, and 20 of the '011 Patent

A. Motivation to combine

A POSA would have known of and been motivated to combine Carrel and David-Hegerich and the resulting combination would have been each and every feature of the challenged claims. Both are directed to needle safety devices for pre-filled syringes. And both similarly solve the problem of protecting the needle of a pre-filled to needle sticks, as described in Sections VI.A and B above. Ex. 1003, ¶¶66-78.

Moreover, a POSA specifically would have been motivated to modify Carrel with the slidable handle disclosed in David-Hegerich because David-Hegerich teaches that its handle makes needle safety systems easier to use. *Id*. A POSA would further have been motivated to incorporate the slidability taught by David-Hegerich onto the hollow support body because this person would have sought to reduce the overall length of the device to reduce the size and facilitate a smoother

injection, and provide tamper resistance. *Id*. Each of the foregoing modifications would have been obvious to a POSA. *Id*. And after the combination, each feature would continue to function as intended. *See KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

To be more specific, a POSA would have enhanced Carrel's device with David-Hegerich's slidable handle. *First*, a POSA would have recognized the advantages of David-Hegerich's "handle" for improving handling for low dexterity users. Ex. 1006, [0050]; Ex. 1003, ¶¶68-71. According to David-Hegerich, "the injection device 8…provides an ergonomic, easy-to-use device that is particularly suitable for self-administration of injections by patients with dexterity limitations." Ex. 1006, [0050]. David-Hegerich further states that "[n]o squeezing is required [and that t]he wide tubular structure of the handle allows for ease of grip by the user, in a variety of different hand positions." *Id.* So David-Hegerich's outer, hollow "injector handle 10 is designed to provide a stable hand grip." *Id*. *Second*, a POSA would have recognized the advantages of advancing David-Hegerich's handle down (and over) the needle guard, gradually bringing their proximal ends into closer proximity for an improved injection stroke by transmitting the force on the handle through the plunger. *See* Ex. 1006, [0061]; Ex. 1003, ¶¶68-71.

David-Hegerich thus expressly teaches numerous benefits of employing an outer, slidable handle on a needle safety device for a pre-filled syringe. The

benefits of employing an outer handle like David-Hegerich's handle would have thus been predictable to a person of ordinary skill in the art. *KSR*, 550 U.S. at 417; Ex. 1003, ¶70.

Carrel's needle safety device would have benefited from David-Hegerich's outer handle in much the same way as David-Hegerich itself describes. For example, Carrel's device appears to be a relatively small device, and as described, Carrel's sleeve 4 is configured to retain a pre-filled syringe therein. Ex. 1005, [0061]. Accordingly, a POSA would have understood that Carrel's device would be difficult to use. Ex. 1003, ¶71. For example, because Carrel's device is small, it would be difficult for an elderly person or a person with limited dexterity to use the device. *Id.* Thus, Carrel would benefit from a larger easy-to-use handle with a stable hand grip, as taught in David-Hegerich. Ex. 1006 [0050]; Ex. 1003, ¶¶71-74.

Further, Carrel's sleeve 4 is configured to retain a pre-filled syringe therein. Ex. 1005, [0061]. Carrel's Figures 1-4 illustrate a method for attaching a pre-filled syringe within sleeve 4 that would require a patient (or caregiver) to apply force to the syringe's plunger relatively far away from the injection site. Ex. 1003, ¶¶74-75. A POSA would have understood that as the distance between the proximal end of a syringe plunger and the injection site increases, so would the likelihood of a flawed or dangerous injection stroke. *Id*. For example, applying a force to the proximal end of the syringe plunger becomes more difficult the further it is from the

injection site, thereby increasing the force required to deliver the injection and the likelihood that the plunger will bind during injection. *Id.*

Thus, given the nature of an injection and the importance of administering the medication in a safe and efficient manner, a POSA would have recognized the advantages of a shorter device over a longer one provided by the slidable handle, because the injection force is applied closer to the injection site, as taught by David-Hegerich. *Id.*, ¶76. A POSA would have recognized the advantages of advancing, or sliding, David-Hegerich's handle down (and over) the needle guard, gradually bringing their proximal ends into closer proximity for an improved injection stroke by transmitting the force on the handle through the plunger and closer to the injection site. *See* Ex. 1006, [0061]; Ex. 1003, ¶76.

Finally, a POSA would have had a reasonable expectation of success in implementing David-Hegerich's slidable outer handle onto Carrel's device. Ex. 1003, ¶77. As Mr. Clemens explains, such a modification would have been a routine matter for a POSA. *Id*. A POSA could have easily added the slidable handle of David-Hegerich to Carrel's device support body to aid in applying the force to the proximal syringe plunger during injection. *Id*. A POSA would have understood that the depicted combination is only one of the at least two or more obvious design approaches to combine Carrel and David-Hegerich. *Id*. Indeed, the challenged claims only require that the handle slide on the hollow support body,

and not otherwise cooperate with the hollow support body, needle shield or guide mechanism. *Id*.

* * *

For at least the foregoing reasons, a POSA would have been motivated to modify Carrel's device to include a David-Hegerich-style slidable outer handle, and to arrive at the safety device for a pre-filled syringe the challenged '011 Patent claims. Ex. 1003, ¶¶66-78.

B. Independent Claim 1

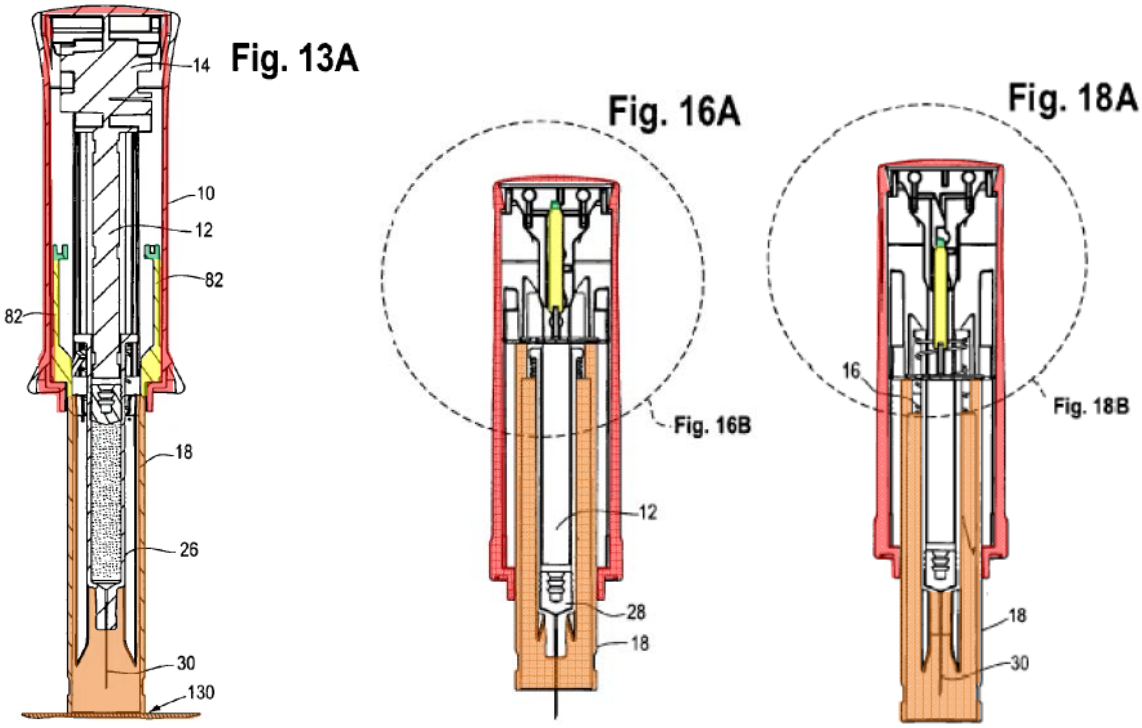
1) [1.P]: "[a] safety device for a pre-filled syringe"

Carrel is directed to a *protection device* 1 (i.e., safety device) for safety device to at least partially cover the device's needle. Ex. 1005, Abstract. Carrel teaches that its "protection device 1" is configured to accept and retain "the syringe body 17, partially depicted in FIG. 2, *prefilled with the medicinal product* to be injected into the injection site." Ex. 1005, [0061]. Thus, Carrel teaches a safety device for a pre-filled syringe. Ex 1003, ¶¶81-82.

Although Carrel is the primary reference, David-Hegerich is also directed to a safety device for a pre-filled syringe. *See* Ex. 1006, Abstract ("An injection device for use with a pre-filled syringe... [having] a protective needle guard over the tip of the needle at the conclusion of the injection").

2) [1.1]: "an outer body"

Carrel teaches a handle (fixing means 9). David-Hegerich teaches a handle (i.e., outer body) that is slidable. Ex. 1003, ¶83-84. For example, as illustrated in Figures 13A, 16A, and 18A, the David-Hegerich device discloses "a *hollow tubular handle 10* which is grasped by the user to make an injection." Ex. 1006, [0046]; *see also id.*, [0137] ("a hollow tubular handle 10 having an interior region receiving the needle guard 18 and syringe 26").



Id., FIGS. 13A, 16A, and 18A (annotated).

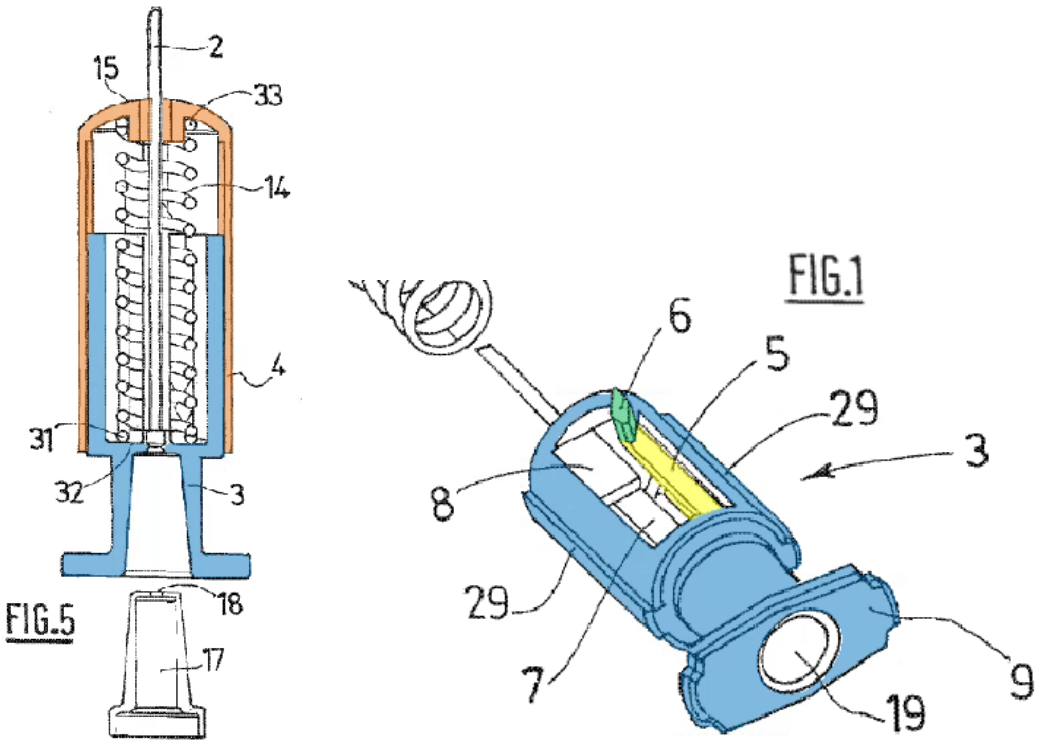
A POSA would have understood that the David-Hegerich hollow tubular handle (shaded in red) is an outer body, as claimed. Ex. 1003, ¶83.

Further, Carrel would benefit from a larger easy-to-use handle with a stable hand grip, as taught in David-Hegerich. *Id*., ¶84; *see* Ex. 1006, [0050]. Thus, a POSA would have been motivated to enhance Carrel with David-Hegerich's outer handle. *See supra* Section VII.A (describing at least three reasons for enhancing Carrel's needle safety device with David-Hegerich's handle); Ex. 1003, ¶¶66-78, 86. The combination of Carrel and David-Hegerich thus teaches this limitation. Ex. 1003, ¶¶83-84.

3) [1.2]: "a hollow support body to retain the pre-filled syringe therein, wherein the hollow support body is received in the outer body and slidably arranged relative to the outer body to perform an injection stroke"

Carrel teaches a hollow support (support 3) that retains the pre-filled syringe (syringe body prefilled with the medicinal product). Ex. 1005, [0002] and [0061]; Ex. 1003, ¶¶85-93.

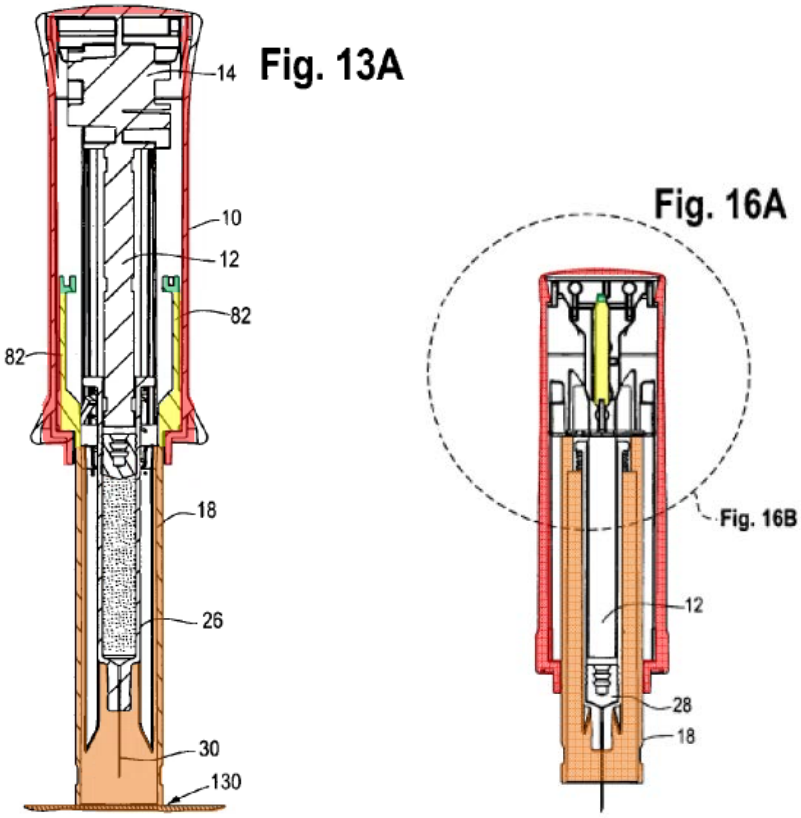
Figures 1 and 5 illustrate how Carrel's support body 3 is configured to retain the syringe body 17 prefilled with the medicinal product.



Ex. 1005, FIGS. 1 and 5 (annotated).

David-Hegerich teaches a hollow support body that is received into an outer body handle that is slidably arranged relative to the outer body to perform an injection stroke feature, and a POSA would have found it obvious to modify Carrel to incorporate David-Hegerich's outer handle into Carrel's device. Ex. 1003, ¶66-78, 89.

As provided in Section VI.B.2 with respect to limitation [1.1], and illustrated in Figures 13A and 16A, David-Hegerich teaches a "*hollow tubular handle 10* which is grasped by the user *to make an injection*." Ex. 1006, [0046].



Id., FIGS. 13A and 16A (annotated). David-Hegerich further teaches that its "plunger 12 includes a top portion 14 which is attached to the open proximal end of the generally cylindrically-shaped handle 10." *Id*., [0049]. David-Hegerich continues:

> As the handle 10 is moved towards the injection site during an injection (as will be explained more fully below in conjunction with FIGS. 14-16), the handle moves the plunger 12 tip 15 through the interior of the pre-filled syringe 26 to expel medicament from the pre-filled syringe through the needle 30. At the completion of the injection and as the device is removed from the injection site, the needle guard 18 is moved distally by a spring 16 and locked into a position to cover

> the tip of the syringe needle 30 to prevent an accidental needle stick (FIG. 18).

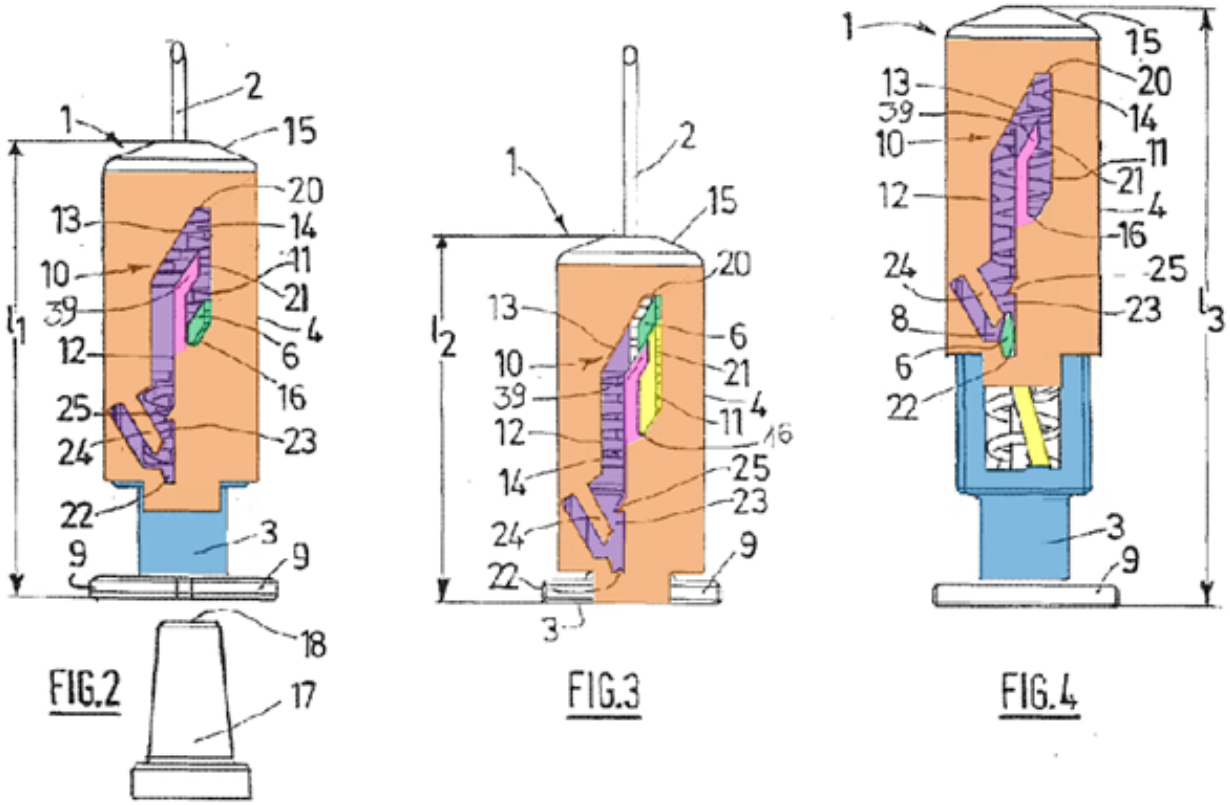
Id., [0049].

As provided above, because the Carrel device is small, it would be difficult for an elderly person or a person with limited dexterity to use Carrel's device. *See supra*, Section VII.A.; Ex. 1003, ¶92. Thus, Carrel would benefit from the addition of a large, easy-to-use, outer handle with a stable hand grip, as taught in David-Hegerich. Ex. 1006, [0050]; Ex. 1003, ¶92. For the reasons set forth above in Section VII.A, a POSA would have been motivated to enhance Carrel's device with the addition of a David-Hegerich-like handle 10. Ex. 1003, ¶¶66-78, 92.

Based on the foregoing, and as provided in Section VII.A above, a POSA would have thus modified Carrel, in view of David-Hegerich, to construct a device having this limitation, and would have had a reasonable expectation of success in performing what would have been a routine engineering exercise to a POSA. *Id*., ¶¶66-78, 93.

4) [1.3]: "a hollow needle shield slidable relative to the support body"

Carrel teaches a hollow needle shield (sleeve 4) that is slidable (in translation) relative to the support body (support 3), *Id*., ¶94, as shown in Figures 2-4, included below:



Ex. 1005, FIGS. 2-4 (annotated).

As illustrated above, Carrel discloses that its sleeve 4 that is slidable relative to the support body 3 in various positions to expose or protect the needle before, during, and after delivering the injection:

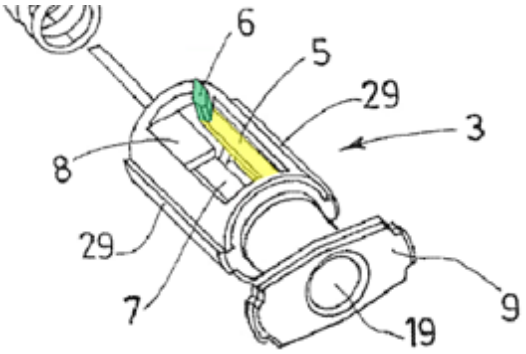
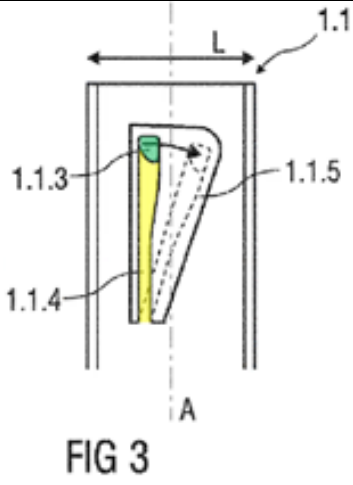
> This protection device 1 comprises a support 3 for a needle 2 and a sleeve 4 arranged in such a way as to accept the support 3. *This sleeve 4 can be moved in translation with respect to the support 3, from a storage position* depicted in FIG. 2 *towards a second position*, the injection position, depicted in FIG. 3 *and towards a third position*, the protection position, depicted in FIG. 4.

Id., [0051]. A POSA would have understood that sleeve 4 moves, by sliding relative to support 3, from the start or storage position, towards a second, intermediate position, and towards a third or final position. Ex. 1003, ¶95. Thus, Carrel teaches this limitation. *Id*.

Although Carrel is the base reference, David-Hegerich also discloses a hollow needle shield. More specifically, David-Hegerich teaches a hollow tubular needle guard 18 that is slidable relative to its pre-filled syringe 26. *See* Ex. 1006, [0048]; Ex. 1003, ¶96.

5) [1.4]: "a guiding mechanism to guide the movement of the needle shield relative to the support body, the guiding mechanism comprising a deflectable flexible arm with a guide pin radially extending therefrom, the flexible arm extending essentially parallel to a central axis of the safety device"

Carrel discloses the guide mechanism of the challenged claims. Carrel teaches that "support 3 comprises a flexible tab 5 which runs longitudinally from the proximal part of the support 3 in the distal direction. This flexible tab 5 at its distal end comprises a peg 6." Ex. 1005, [0053]. Carrel's "flexible tab 5 is able to deflect laterally between a normal position and at least one stressed deflected position." *Id*. The below table shows the structural similarities between Carrel's flexible tab 5 and peg 6 and the recited flexible arm and guide pin of the '011 Patent.

Carrel	The flexible arm and guide pin of the ’011 Patent
 Ex. 1005, Carrel, FIG. 1 (annotated).	 FIG 3 Ex. 1001, FIG. 3 (annotated).

Like the challenged ’011 Patent claims, Carrel’s flexible tab 5 and peg 6 form, in part, the recited guiding mechanism:

> As the sleeve 4 deploys, when the *peg 6 can follow the path marked* out by the intermediate section 13 and the second longitudinal section 12 of the running passageway 10 *by virtue of the ability of the tab 5 to deflect tangentially* under stress.

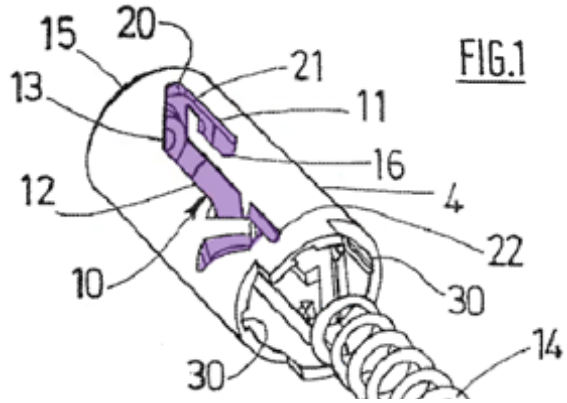
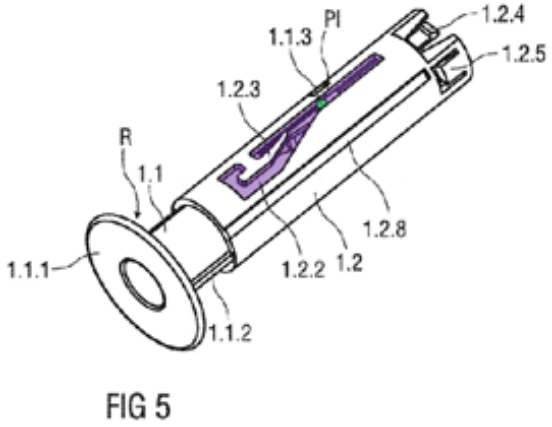
Ex. 1005, [0067]. In view of the foregoing, a POSA would have understood that Carrel’s flexible tab 5 and peg 6 together teach the pin and essentially parallel flexible arm of the guiding mechanism of the challenged claims to guide the movement of the needle shield relative to the support body. Ex. 1003, ¶¶97-99. Thus, Carrel teaches this limitation. *Id*.

Although Carrel is the base reference, David-Hegerich also discloses a similar guide mechanism having an essentially parallel flexible arm and pin attached thereto for guiding the movement of a needle shield to a support body. For example, its track followers 82 act as a deflectable flexible arm with a guide pin (hooked end) that guides the movement of the needle shield, the flexible arm extending essentially parallel to a central axis of the safety device. *See* Ex 1006, FIGS. 15-18, [0065]-[0068]; Ex. 1003, ¶100.

6) [1.5]: "a guide track configured to guide the guide pin within and along the guide track so that the guide pin follows the guide track when the needle shield is slid relative to the support body"

Carrel teaches a running passageway 10 configured to guide peg 6 within and along the passageway when sleeve 4 is slid relative to support 3. Ex. 1003, ¶¶101-106. Carrel's passageway is defined by "first and second sections" that "are joined together by a first narrowed region defined (21,36) by a flexible tongue at least partially defining the said first safety means." Ex. 1005, [0025], Figures 1-4. Carrel further teaches that "*running passageway 10* form[s] a U, [is] made in the wall of the sleeve 4 and [is] arranged in such a way as to *collaborate with the peg 6 over the entire travel of the sleeve*, as [is] apparent from FIGS. 2-4." *Id*., [0055].

The structural similarity between Carrel's guide track and guide track 1.2.2. of the challenged '011 Patent claims are illustrated in the below table:

Carrel	The guide track of the '011 Patent
	 FIG 5
Ex. 1005, Carrel, FIG. 1 (annotated).	Ex. 1001, FIG. 5 (annotated).

Based on the foregoing, a POSA would have understood that Carrel teaches this limitation. Ex. 1003, ¶¶104-105. While the images are very similar, the two main differences between the figures include the shape of the guide tracks and the location of the guide track – neither of which is an element of the challenged claims. *Id*.

David-Hegerich also discloses a similar guide track. Its tracks 42 guided the movement of the deflectable flexible arm (track followers 82) so that the guide pin follows the guide track. *See* Ex. 1006, FIGS. 15-18, [0065]-[0068].

7) [1.6]: "wherein the flexible arm is configured to be laterally deflected as the guide pin follows the guide track"

Carrel teaches that its flexible tab 5 is configured to be laterally deflected as peg 6 follows running passageway 10. *See supra* Section VII.B.5; Ex. 1003, ¶¶107-110. To reiterate, Carrel's "support 3 comprises a flexible tab 5 which runs

longitudinally from the proximal part of the support 3 in the distal direction." Ex. 1005, [0053]. Carrel further teaches that its "flexible tab 5 at its distal end comprises a peg 6" and that the "*flexible tab 5 is able to deflect laterally* between a normal position and at least one stressed deflected position (see FIG. 4)." *Id*., [0053].

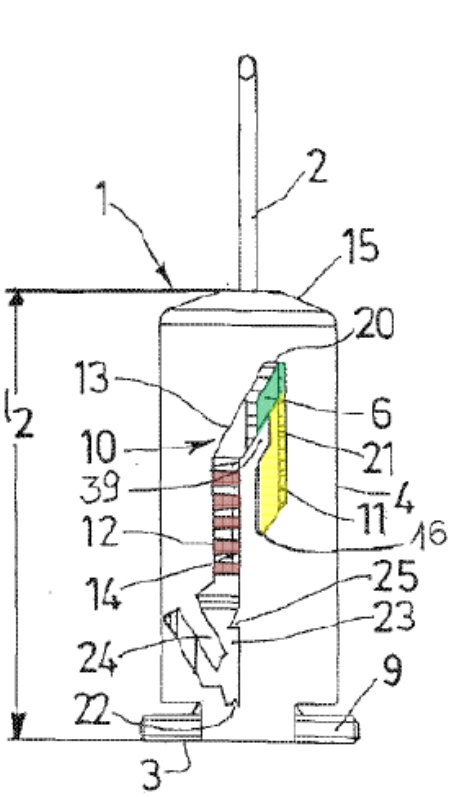


FIG.3

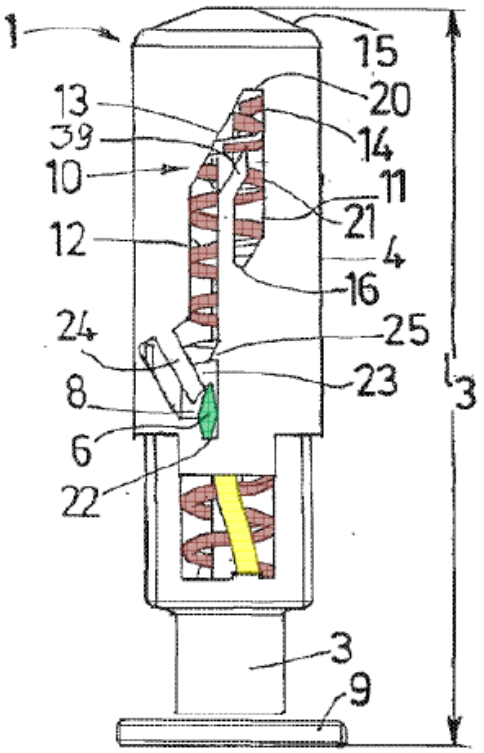


FIG.4

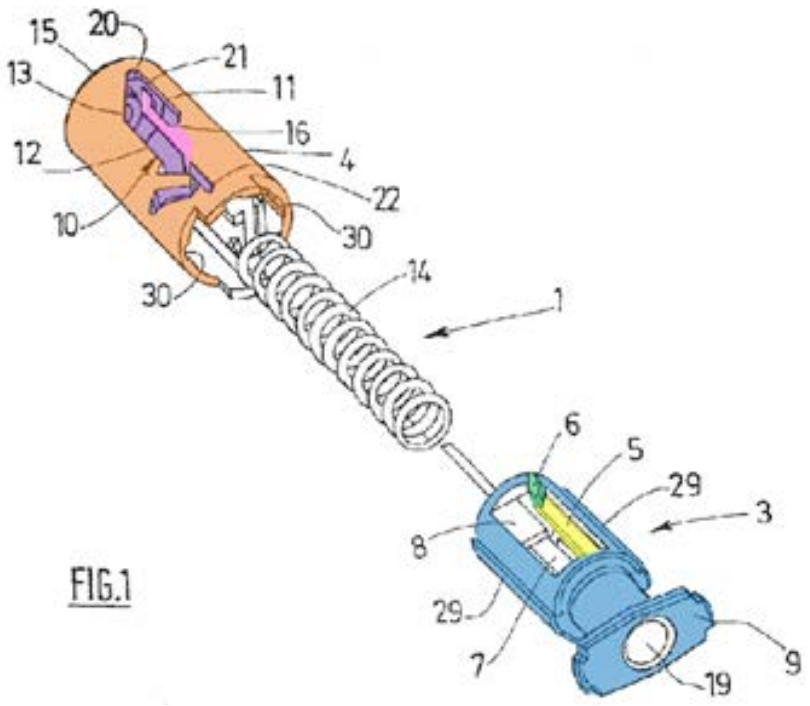
Id., FIGS. 3-4 (annotated). As illustrated above in Figures 3 and 4, as peg 6 (green) takes the path of the first longitudinal section 11, the intermediate section 13, and the second longitudinal section 12 of passageway 10, flexible tab (yellow) is deflected laterally (as shown in FIG. 4). *See id*., FIGS. 2-4; Ex. 1003, ¶108.

Further, in Figure 1, Carrel's flexible tab 5 is "depicted in its normal position," but tab 5 "is able to move from its normal position to its stressed deflected position within a window 7 cut into the wall of the support 3." Ex. 1005, [0053]. Thus, Carrel teaches this limitation. Ex. 1003, ¶109.

David-Hegerich also discloses a similar structure. David-Hegerich's track follower is configured to be laterally deflected as it follows the guide tracks 42. *See* Ex. 1006, FIGS. 15-18, [0065]-[0068].

8) [1.7]: "wherein the flexible arm is connected to or is integrally formed to the needle shield *or* the support body, and the guide track is formed into *the other of* the needle shield or the support body"

Carrel discloses a flexible arm integrally formed in the needle shield and the guide track in Carrel is in the support body. *See supra* Section VII.B.3; *see also* Ex. 1005, FIG. 1. Carrel's "*support 3 comprises a flexible tab 5* which runs longitudinally from the proximal part of the support 3 in the distal direction." *Id*., [0053]. Thus, Carrel's flexible tab 5 (in yellow) is connected to or is integrally formed to the support body, support 3. Ex. 1003, ¶111-112.



Ex. 1005, FIG. 1 (annotated).

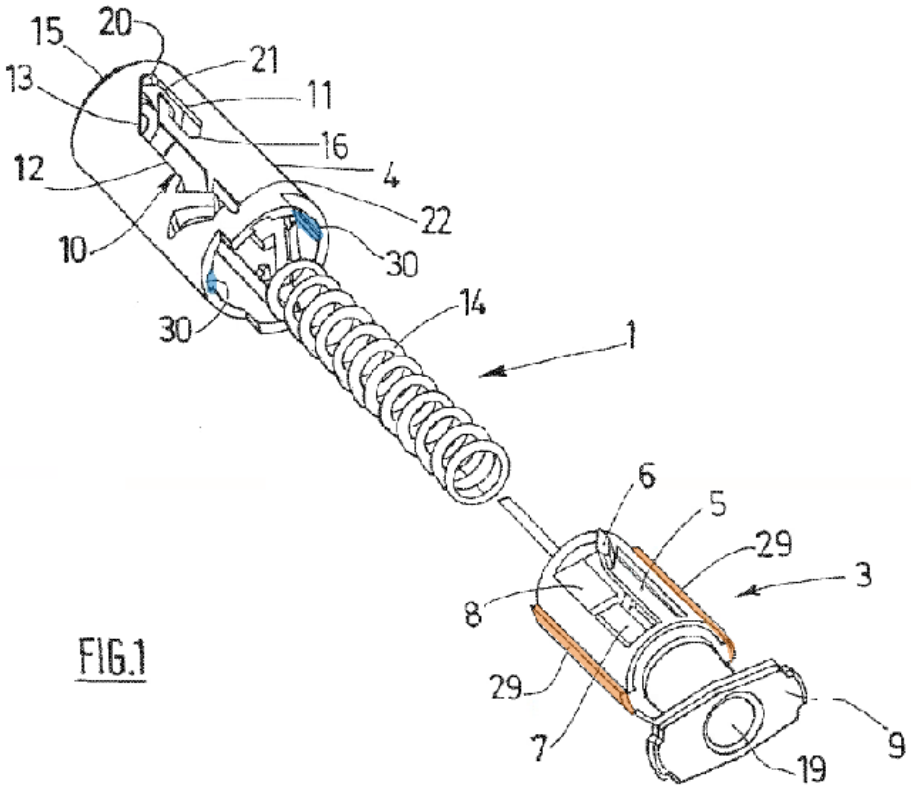
As explained in Section VII.B.4, Carrel's sleeve 4 is the claimed needle shield. *See id*., [0051]. And as explained in Section VII.B.6, Carrel's running passageway 10 is the claimed guide track. Carrel's running passageway 10 or guide track is formed in sleeve 4 or needle shield. *See id*., FIG. 1. As illustrated, Carrel's "*sleeve 4 comprises a running passageway 10* forming a U, made in the wall of the sleeve 4 and arranged in such a way as to collaborate with the peg 6 over the entire travel of the sleeve, as will be apparent from FIGS. 2-4." *Id*., [0055]. Thus, Carrel teaches this limitation. Ex. 1003, ¶112.

C. Claim 2: "The safety device according to claim 1, wherein the guiding mechanism further comprises a longitudinal tongue configured to be received in a longitudinal groove to inhibit relative rotation of the needle shield and the support body when the needle shield is moved with respect to the support body in a distal direction.

Carrel teaches an axial guidance means (29, 30) for preventing the sleeve 4 from rotating with respect to support 3:

> In the example depicted, the support 3 and the sleeve 4 each comprise *means for the guidance* and axial translation of the support 3 with respect to the sleeve 4: in FIG. 1, these guide means are in the form of diametrically opposed *longitudinal bulges 29 situated on the external wall of the support 3*, these longitudinal bulges 29 collaborating with diametrically opposed *slideways 30 situated on the internal wall of the sleeve 4*, facing the said bulges 29.

Ex. 1005, [0052].



Id., FIG. 1 (annotated). As illustrated, one of Carrel's longitudinal bulges 29 (shaded in orange) is the claimed longitudinal tongue, and one of Carrel's slideways 30 (shaded in blue) is the claimed longitudinal groove. Ex. 1003, ¶114.

Longitudinal bulges 29 and corresponding slideways 30 prevent the needle shield (sleeve 4) from rotating, with respect to the support body (support 3) when the needle shield is moved with respect to the support body in a distal direction: "axial guidance means (29, 30) for guiding the said sleeve (4), [is] arranged in such away as to prevent it from pivoting axially as it moves axially with respect to the said support (3) at least from its injection position to its protection position." Ex.

1005, Claim 2; Ex. 1003, ¶113-116. Thus, the Carrel teaches this feature of claim. Ex. 1003, ¶¶113-116.

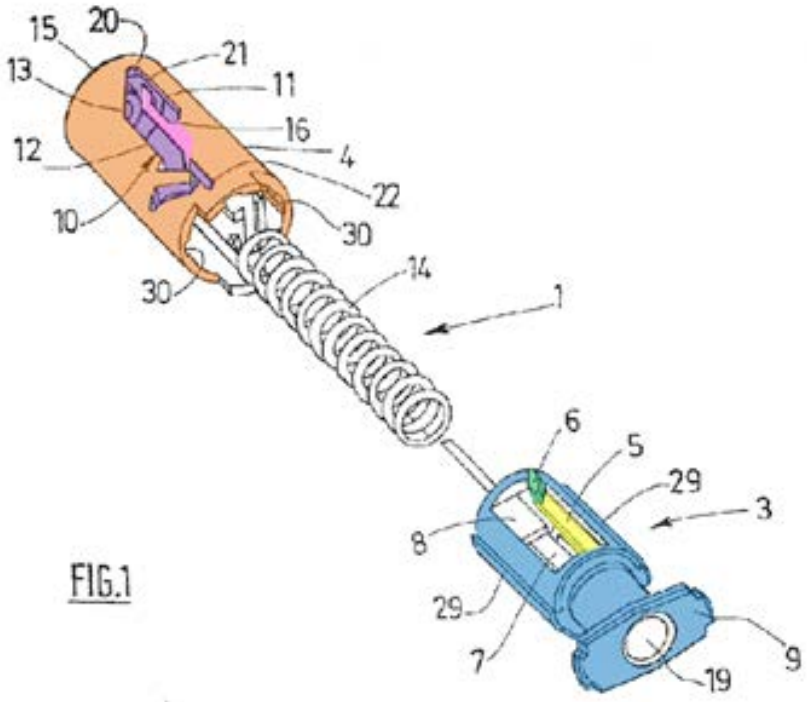
D. Claim 3: "The safety device according to claim 1, wherein the flexible arm is connected to or is integrally formed to the needle shield and the guide track is formed into the support body."

As described in Sections VII.B.5-8 and illustrated in Figure 1, Carrel's preferred embodiment has its flexible arm (flexible tab 5) connected to or integrally formed in the support body (support 3), and Carrel's guide track (passageway 10) is formed into the needle shield (sleeve 4). *Id*., ¶¶117-119. But Carrel also teaches an alternate embodiment with the opposite configuration. Specifically, Carrel teaches that in an "undepicted embodiment of the invention, the *flexible tab 5 is arranged on the sleeve 4* and the *running passageway 10 is formed within the wall of the support 3*." Ex. 1005, [0073]. A POSA would have understood that there were no advantages for using the embodiment depicted in Figure 1 over the undepicted embodiment and that implementing one disclosed embodiment or the other disclosed embodiment would have been merely a design choice. Ex. 1003, ¶¶117-119.

Thus, the combination of Carrel and David-Hegerich teaches this claim. *Id*.

E. Claim 4: "The safety device according to claim 1, wherein the flexible arm is connected to or is integrally formed to the support body and the guide track is formed into the needle shield.

Claim 4 describes Carrel's preferred embodiment, as explained in Section VII.B.5-8 above and illustrated in Figure 1, included below.



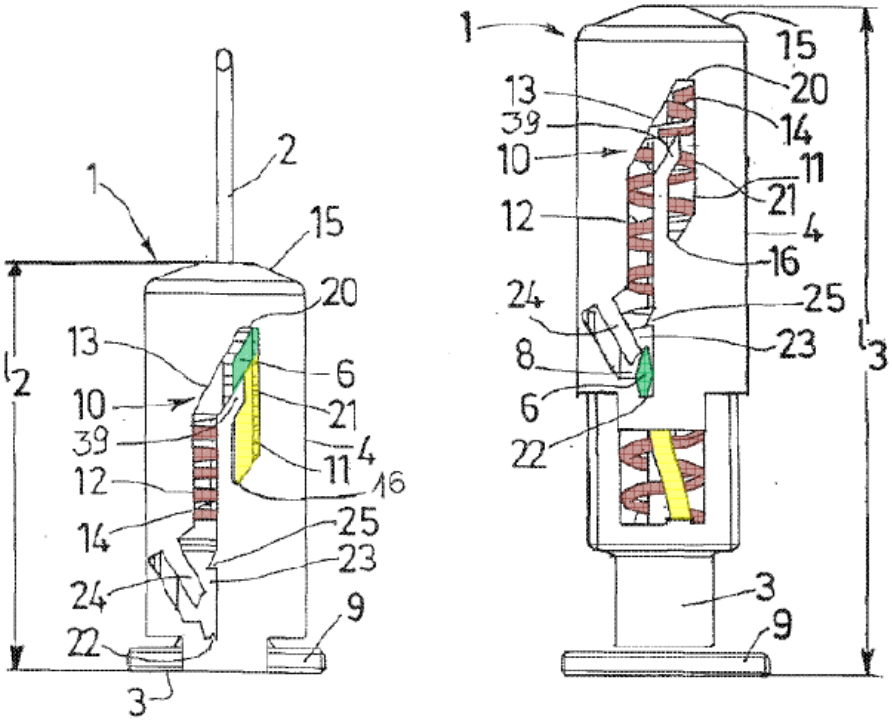
Ex. 1005, FIG. 1 (annotated).

As illustrated, Carrel's "*support 3 comprises a flexible tab 5* which runs longitudinally from the proximal part of the support 3 in the distal direction." Ex. 1005, FIG. 1, [0053]. Thus, Carrel teaches a flexible arm that is connected to or is integrally formed to the support body. Ex. 1003, ¶¶121-122. Further, Carrel's "sleeve 4 comprises a running passageway 10 forming a U, *made in the wall of the sleeve 4* and arranged in such a way as to collaborate with the peg 6 over the entire

travel of the sleeve, as will be apparent from FIGS. 2-4." Ex. 1005, FIG. 1, [0055]. Thus, Carrel teaches a guide track formed into the needle shield. Ex. 1003, ¶122. The combination of Carrel and David-Hegerich teaches this claim. *Id*.

F. Claim 5: "The safety device according to claim 1, wherein the flexible arm is deflectable and energizable by the action of a relaxing spring."

Carrel's protection device also inlcudes a helical spring 14 located between internal flange 32 of the proximal part of the support 3 and the internal face of the radial distal wall 15 of sleeve 4. *See* Ex. 1005, [0057]. These features are set forth in Figures 3-4, below:



Ex. 1005, FIGS. 3-4 (annotated).

In a storage position, Carrel's "*flexible tab 5* (partly concealed by the sleeve 4 in FIG. 2) *is in the normal position* and the peg 6 is kept in abutment against the proximal end 16 of the first longitudinal section 11 of the running passageway 10 *by the action of the spring 14* which is partially compressed between the sleeve 4 and the support 3, as can be seen in FIG. 5." *Id*., [0060]. As depcited in Figure 3, "the spring 14 is in the compressed state and the needle 2 is exposed," while Figure 4 illustrates spring 14 in a "relaxed position" at the end of the injection. *Id*., [0063] and [0065]. Accordingly, Carrel's flexible tab is deflectable and energizable by the action of spring 14 (shaded in brown). Ex. 1003, ¶¶123-125. Thus, the combination of Carrel and David-Hegerich teaches this claim. *Id*.

G. Claim 6: "The safety device according to claim 5, wherein: the needle shield is arranged to protrude from the support body in an initial position, and the spring is configured to be in a partially energized state when the needle shield is in the initial position."

Carrel teaches a needle shield (sleeve 4) arranged to protrude from the support body (support 3) in an initial position (storage position). Ex. 1005, [0060]. More specifically, Carrel teaches "[i]n this *storage position*, the flexible tab 5 (partly concealed by the sleeve 4 in FIG. 2) is in the normal position and the peg 6 is kept in abutment against the proximal end 16 of the first longitudinal section 11 of the running passageway 10 by the *action of the spring 14 which is partially compressed* between the sleeve 4 and the support 3, as can be seen in FIG. 5." *Id*. These features are set forth in Figures 2 and 5, below.

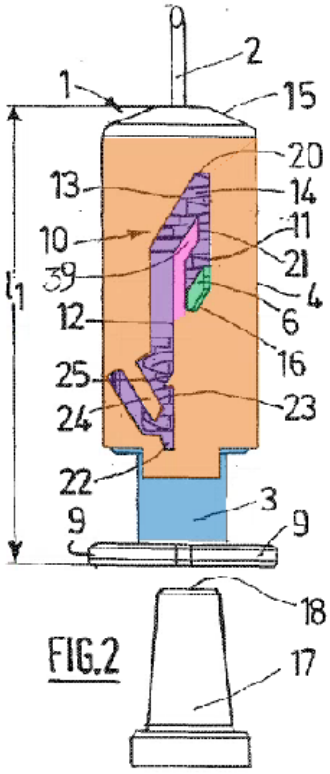


FIG.2

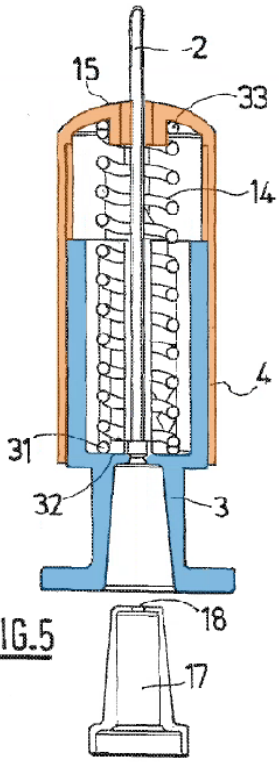


FIG.5

Id., FIGS. 2 and 5 (annotated).

As illustrated, Carrel's spring is in a partially energized (partially compressed state) and the needle shield (sleeve 4) protrudes from the support body (support 3) when Carrel's device is in the initial position (storage position). Ex. 1003, ¶¶126-127. Thus, the combination of Carrel and David-Hegerich teaches this claim. *Id*.

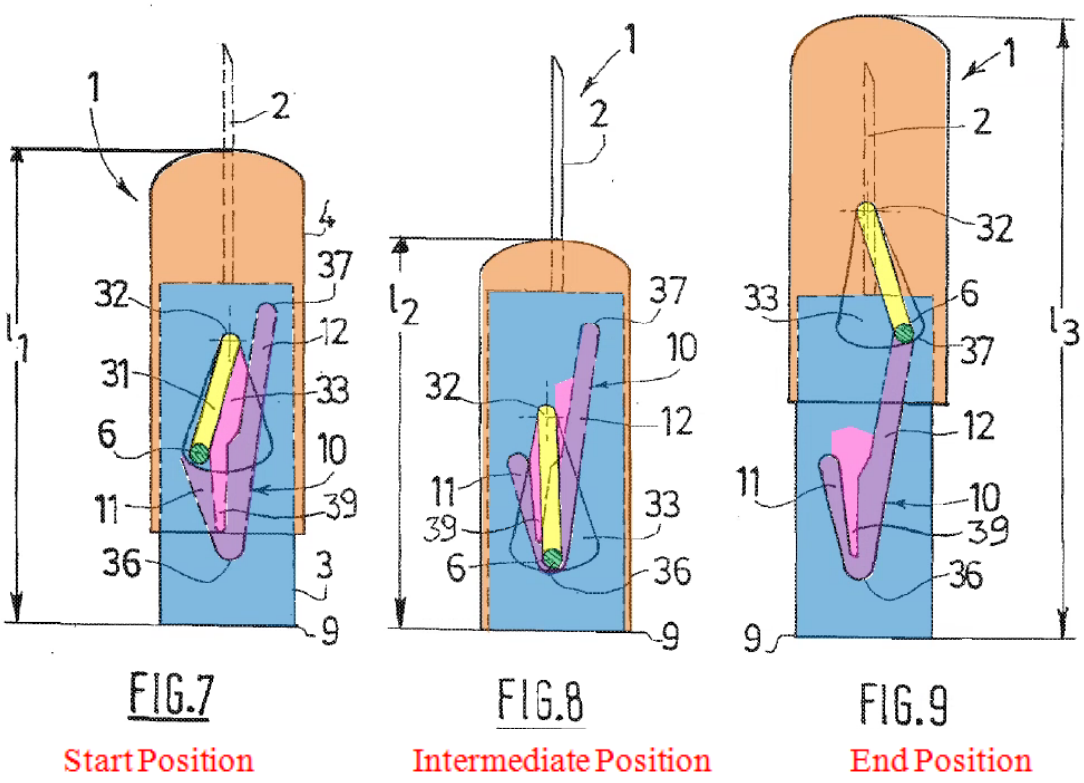
H. Claim 7: "The safety device according to claim 1 wherein…"

1) [7.1]: "the guide pin is arranged to be located in an intermediate position in proximity of a proximal end of the guide track when the needle shield is in a retracted position"

Carrel teaches that its guide pin (peg 6) is arranged to be located in an intermediate position in proximity of the proximal end of the guide track (the vertex 36 of the U) when the needle shield is in a retracted position. Ex. 1005, FIG. 8 and [0077]; Ex. 1003, ¶¶128-132.

In one embodiment, Carrel's initial/storage position is depicted in Figure 7, where "the peg 6 of the pivoting tab 31 is blocked in the distal end of the first longitudinal section 11 of the U forming the running passageway 10." Ex. 1005, [0077]. Upon activating the device, between Carrel's storage position and the injection position "peg 6 is displaced along the first longitudinal section 11 where it presses against the flexible tongue 39 and bends it to reach the vertex 36 of the U." *Id*. In Carrel's injection/intermediate position, as depicted in Figure 8, "the pivoting tab 31 has pivoted and the peg 6 is blocked in the vertex 36 of the U that forms the running passageway 10." *Id*.

These configurations are set forth in Figures 7-9, below.



Id., FIGS. 7-9 (annotated).

Figures 7-9 illustrate a running passageway 10 that has a different shape than that of the running passageway 10 depicted in Figures 2-4. More specifically, Figures 7-9 depict "a second alternative form of embodiment of the protection device according to the invention in the storage position, the injection position and the protection position respectively." *Id.*, [0048]. Though the shape of passageway 10 differs between the embodiments, it would not affect the way the device would be used by a patient or caregiver and it would still implement the safety features described with respect to the embodiment of Figures 2-4. Ex. 1003, ¶ ¶131-132. A POSA would have understood that there were no advantages for using the passageway 10 illustrated in Figures 2-4 over that depicted in Figures 7-9 and that

implementing one disclosed embodiment or the other disclosed embodiment would have been merely a design choice. *Id*.

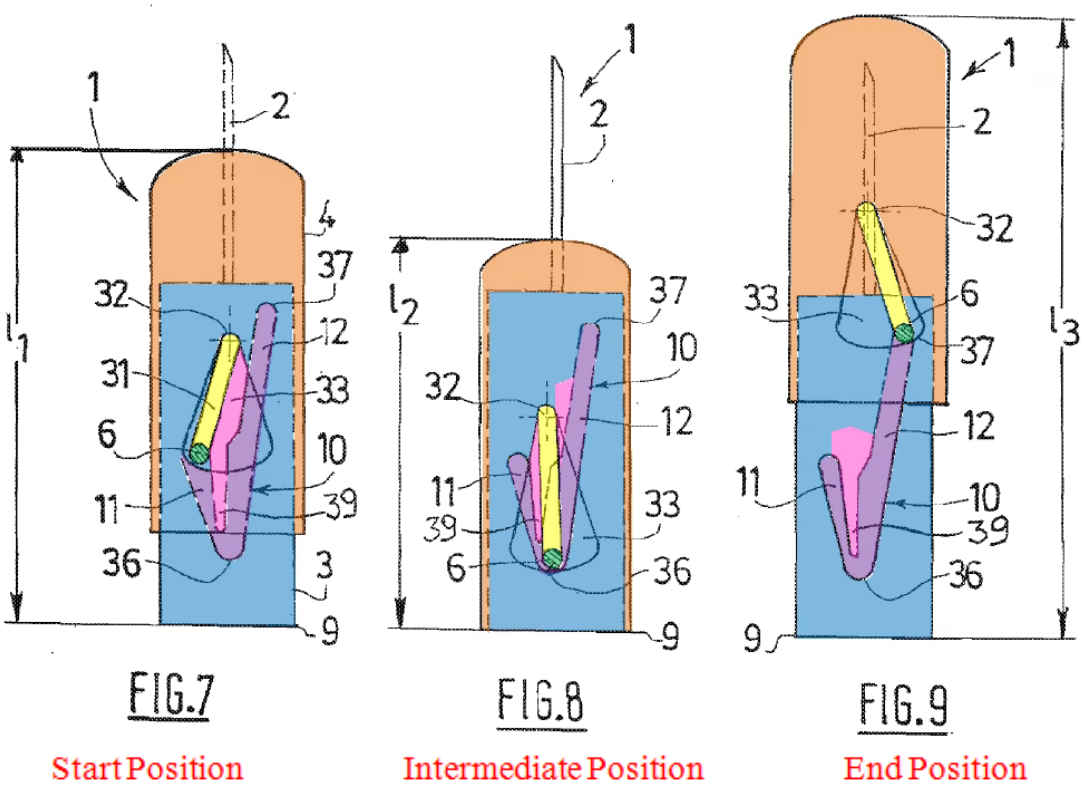
Thus, the combination of Carrel and David-Hegerich teaches this limitation. *Id*., ¶132.

2) [7.2]: "wherein… the guide pin arranged to be located in an end position in proximity of a distal end of the guide track when the needle shield is an advanced position"

Carrel teaches that its guide pin (peg 6) is arranged to be located in an end position in proximity of a distal end of the guide track (second longitudinal section 12) when the needle is an advanced position (protection position.) Ex. 1005, [0077], FIG. 9; Ex. 1003, ¶¶133-136.

In the embodiment set forth in Figure 9, Carrel's protection position shows how "pivoting tab 31 has continued to pivot about the pivot connection 32 and the peg 6 is blocked in the second longitudinal section 12 of the U that forms the running passageway 10 by a narrowed region, not depicted." Ex. 1005, [0077].

Again, the configurations of this embodiment are set forth in Figures 7-9, below.

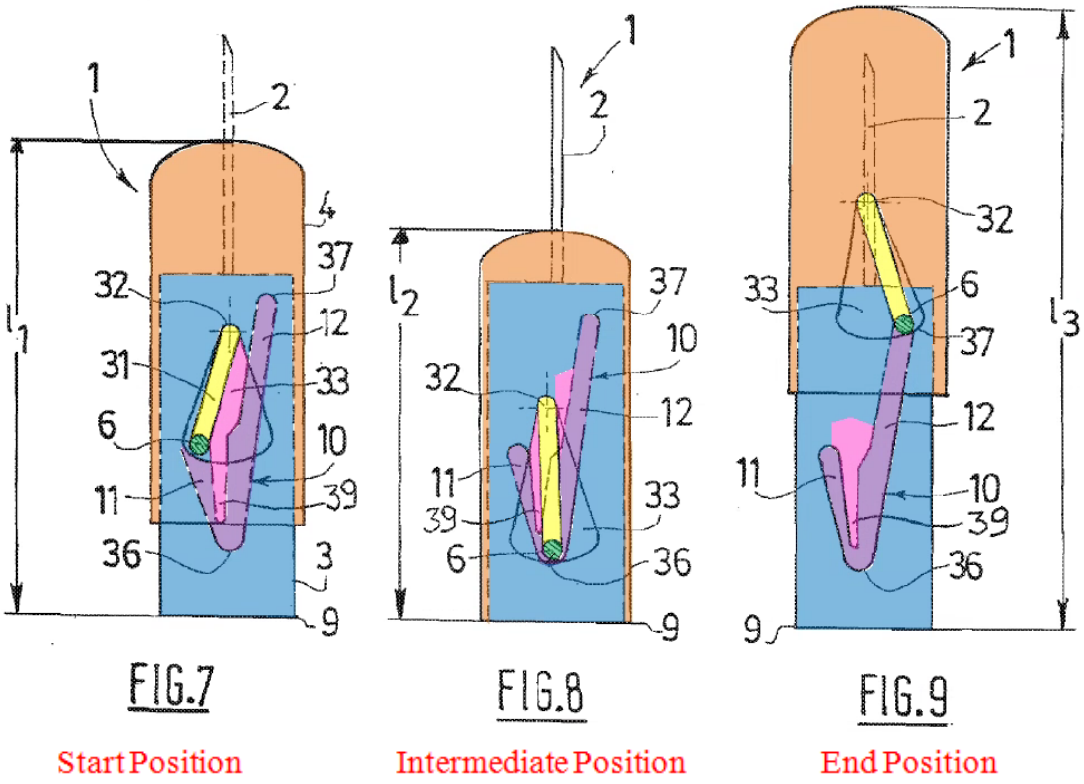


Id., FIGS. 7-9 (annotated). Based on the foregoing, a POSA would have understood that the combination of Carrel and David-Hegerich teaches this limitation. Ex. 1003, ¶136.

3) [7.3]: "wherein… the needle shield is arranged to be substantially received in the support body in the retracted position and to protrude from the distal end of the support body in the advanced position."

As described in the preceding two sections and illustrated in the embodiment of Figures 8 and 9, Carrel's needle shield (sleeve 4) is arranged to be substantially received in the support body (support 3) in the retracted position (injection position) and to protrude from the distal end of the support body in the advanced position (protection position). *Id*., ¶¶137- 140.

Once again, the configurations of this embodiment in Carrel are set forth in Figures 7-9.



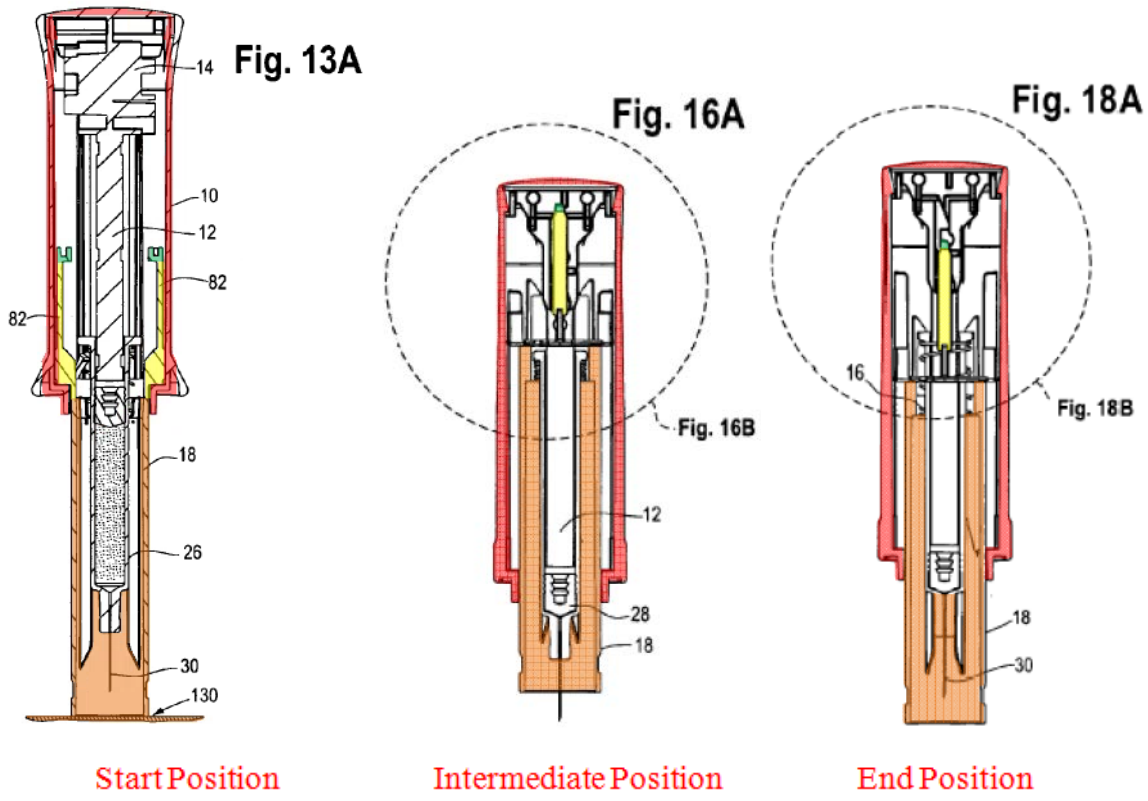
Ex. 1005, FIGS. 7-9 (annotated). Based on the foregoing, a POSA would have understood that the combination of Carrel and David-Hegerich teaches this limitation. Ex. 1003, ¶139. Thus, the combination of Carrel and David-Hegerich teach claim 7. *Id.*, ¶140.

I. Claim 8: "The safety device according to claim 7, wherein the guide pin in a start position, in the end position, and in the intermediate position is non-biased in a lateral direction perpendicular to the central axis."

In the embodiment described above with respect to dependent claim 7, Carrel's deflectable, flexible arm appears to be non-biased only in the intermediate,

injection position. Dependent claim 8 of the ’011 Patent, however, requires that the deflectable, flexible arm and guide pin are non-biased in all three of the start position, end position, and intermediate position. Carrel does not describe such an embodiment. *Id*., ¶142. But devising an alternate guide track so that the deflectable, flexible arm and guide pin meets these requirements would nonetheless have been obvious to a POSA. *Id*. Indeed, David-Hegerich discloses just such an alternative configuration for its deflectable, flexible arm and guide pin.

Specifically, David-Hegerich discloses a “track follower 82 of the needle guard 18 [that] is an elongate flexible finger-like feature that extends axially and embodies a hooked end at an approximate 90° angle.” Ex. 1006, [0067]. The mechanical properties of David-Hegerich’s track follower 82 “allow a flexible, cantilevered deflection in multiple planes.” *Id*.



Id., FIGS. 13A, 16A, and 18A (annotated).

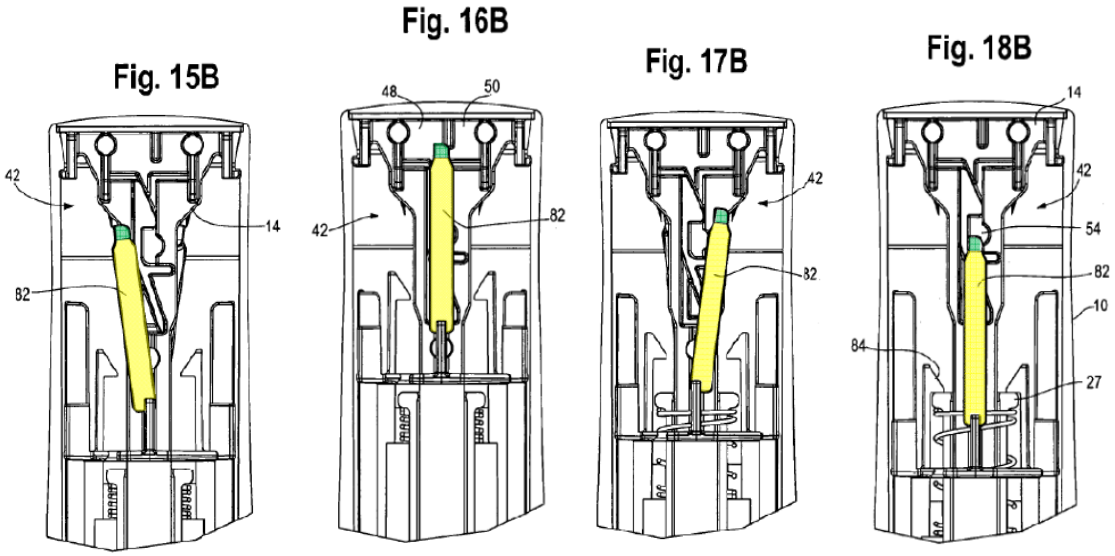
The David-Hegerich track followers 82 follow tracks 42, which are "any physical structure, whether characterized by walls, grooves, slots, or combination thereof, which serves a function to guide the travel of another part, the 'track follower.'" *Id*., [0065]. David-Hegerich provides additional details regarding the movement of the track followers:

> As the injection process proceeds, the track follower 82 will engage with the ramp 44 and be deflected to the left. After engagement, as the needle guard 18 and handle 10 continue relative coaxial motion, the hook of the track follower 82 traverses the track 42 along a path to the left of the wall 46 which guides it along a mostly axial path but with a

> slight deflection to the left... At the bottom of the injection stroke, the side walls of the track 42 are configured to allow the track follower 82 to enter the open region 48 (FIG.5C) ***and move back into the original relaxed position***… Following injection, when the user lifts the device from the injection site... the track follower 82 will now follow along the track 42 down the ramp 52. At the point where the needle guard is again extended over the tip needle, the track features a corner 56 which terminates the bottom of the ramp 52. The flexible characteristics of the track follower ***cause the hook of the track follower to slide past the end of the corner 56 and to move into a lock pocket 54*** (FIG. 5C).

Id., [0068].

Track follower 82 thus has an "original relaxed position" that is non-biased in a lateral direction perpendicular to the central axis. Ex. 1003, ¶145. As is further set forth in FIG. 16B, below, the intermediate position at the bottom of the injection stroke, track follower 82 is again in the "original relaxed position" that is non-biased in a lateral direction perpendicular to the central axis. *Id*. Following injection, the track follower is locked into a lock pocket while in a non-biased in a lateral direction perpendicular to the central axis, as set forth in Figure 18B, below. *Id*.



Ex. 1006, FIGS. 15B, 16B, 17B and 18B (annotated).

David-Hegerich thus teaches an alternate configuration for a deflectable, flexible arm, where the start, intermediate, and end positions are non-biased in a lateral direction perpendicular to the central axis. A POSA would have recognized the benefits of having the deflectable, flexible arm be in a biased or stressed position for as little time as necessary—i.e., just during the actual injection and retraction strokes. Ex. 1003, ¶¶141-146. For example, reducing stress time on the deflectable, flexible arm would reduce opportunities for failure. *Id*. So a POSA would have been motivated by David-Hegerich's teachings to further alter either the guide track, or the location of the deflectable, flexible arm in Carrel's modified device to achieve the configuration set forth in dependent claim 8 and described in David-Hegerich. *Id*.

Thus, a POSA would have modified Carrel, in view of David-Hegerich, to construct a device having this limitation. *Id*., ¶147.

J. Claim 9: "The safety device according to claim 1, wherein the flexible arm is deflectable to bias the guide pin in the lateral direction when the guide pin moves along the guide track from the intermediate position towards the end position."

Carrel's flexible tab 5 is deflectable to bias peg 6 in the lateral direction when peg 6 moves along the running passageway 10 from the intermediate position (injection position) towards the end position (protection position):

> At the end of injection, the user releases the pressure be was [sic] exerting on the support 3 via the syringe and proceeds to withdraw the needle 2 from the injection site, thus releasing the spring 14 which returns to its relaxed position carrying with it the support 3 which completely covers the needle 2. The flexible tab 5 and its radial peg 6 then take the path marked out by the intermediate section 13 and the second longitudinal section 12 of the running passageway 10, as shown in FIG. 4.

Ex. 1005, [0065].

In Carrel's protection position, as illustrated in Figure 4, "the flexible tab 5 is in a stressed deflected position and the peg 6 is kept bearing against the proximal end 22 of the second longitudinal section 13 by the action of the spring 14 which is then in the at least partially relaxed position." *Id*., [0069]. These features are set forth in Figures 3-4, included below.

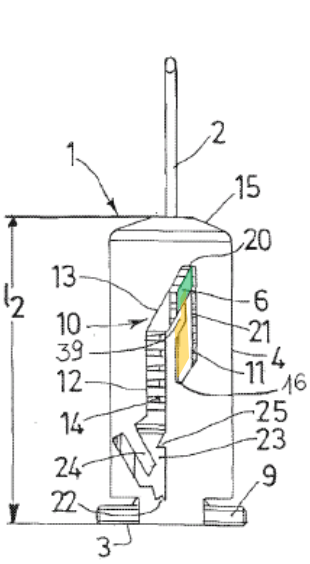


FIG.3

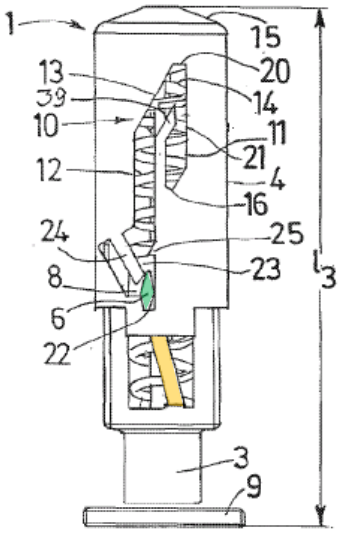


FIG.4

Ex. 1005, FIGS. 3-4. As illustrated in Figure 3, a flexible tab (shaded in yellow) is non-biased in the intermediate position, but in Figure 4, when peg 6 (shaded in green) moves along passageway 10 from an intermediate position toward an end position, the flexible tab is deflected to bias peg 6 in a lateral direction. This feature is thus obvious in view of at least Carrel. Ex. 1003, ¶¶148-151.

As set forth immediately above with respect to dependent claim 8, David-Hegerich also teaches a similar configuration for its deflectable, flexible arm. Ex. 1003, ¶¶152-153. As Figures 16B, 18B and 18B illustrate, David-Hegerich's track follower (i.e., its deflectable, flexible arm) also "bias[es] the guide pin in the lateral direction when the guide pin moves along the guide track from the intermediate position towards the end position," as claimed. *Id.* David-Hegerich thus also teaches this limitation.

K. Claim 10: "The safety device according claim 1, wherein the needle shield is retainable in an initial position by a flexing gate element configured to retain the guide pin in a start position between a distal end and a proximal end of the guide track."

Carrel's Figures 2-4 each illustrate that its "first longitudinal section 11 comprises, situated proximally at its distal end 20, a narrowing 21 defined by a flexible tongue 39 which allows the peg 6 to pass in the distal direction and prevents the said peg 6 from returning in the proximal direction." Ex. 1005, [0066]. Carrel further discloses that the flexible tongue 39 is "elastically deformable" and is configured to prevent "peg 6 from returning from the said second section 12 to the said first section 11." *Id*. During an injection sequence, between the storage position and the injection position, Carrel's "peg 6 is displaced along the first longitudinal section 11 where it presses against the flexible tongue 39 and bends it to reach the vertex 36 of the U." Ex. 1005, [0077].

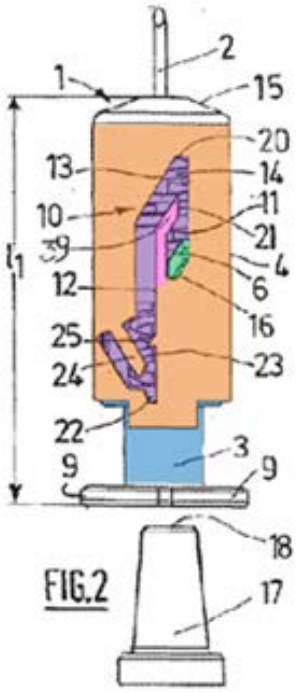


FIG.2

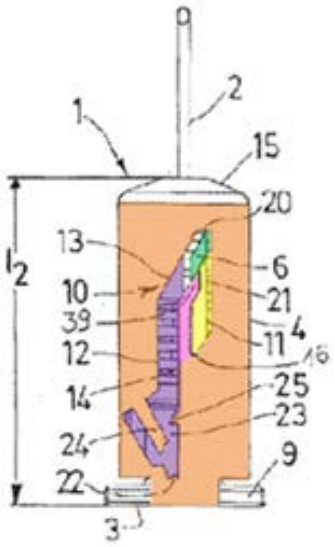


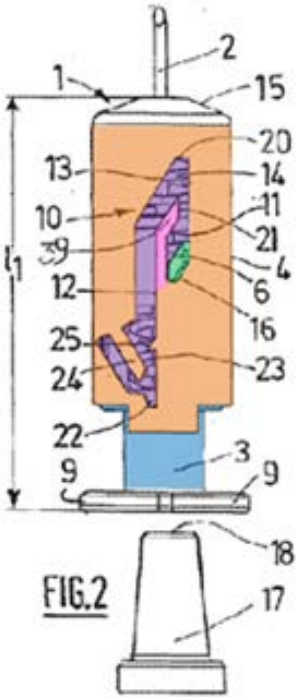
FIG.3

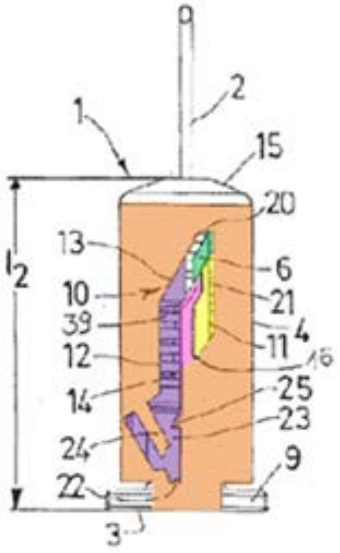
Id., FIGS. 2-3.

Based on the shape and physical characteristics of flexible tongue 39, namely, that flexible tongue 39 is angled to define a narrowing 21 for peg 6 to pass through and that flexible tongue 39 is elastically deformable, a POSA would have understood that flexible tongue 39 would retain the needle shield (sleeve 4) in an initial position and retain the guide pin (peg 6) in a start position between a distal end and a proximal end of the guide track (passageway 10). *Id*., FIGS. 2-4, [0066]; Ex. 1003, ¶156. Thus, the combination of Carrel and David-Hegerich teaches this claim. Ex. 1003, ¶¶154-157.

L. Claim 11: "The safety device according to claim 10, wherein the flexing gate element is configured to guide the movement of the guide pin within the guide track."

Carrel's Figures 2-4 each illustrate that its "first longitudinal section 11 comprises, situated proximally at its distal end 20, a narrowing 21 defined by a flexible tongue 39 which allows the peg 6 to pass in the distal direction and *prevents the said peg 6 from returning in the proximal direction*." Ex. 1005, [0066]. Carrel further discloses that "flexible tongue 39 forms at least in part the first safety means, elastically deformable, *preventing the peg 6 from returning from the said second section 12 to the said first section 11*." *Id*.





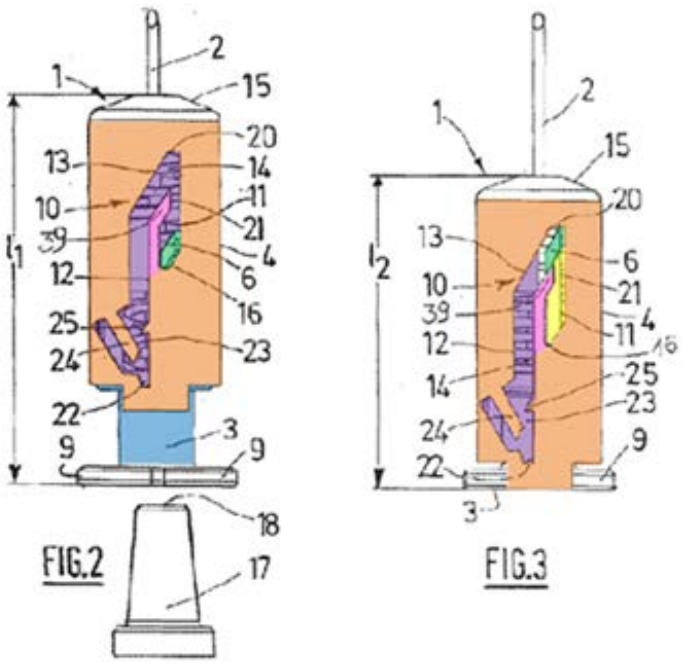
Id., FIGS. 2-3.

By preventing guide pin (peg 6) from returning from second section 12 to first section 11, flexing tab 39 guides the movement of the guide pin within the guide track (passageway 10). Ex. 1003, ¶160. Thus, the combination of Carrel and David-Hegerich teaches this claim. *Id*., ¶¶158-161.

M. Claim 12: "The safety device according to claim 10, wherein the flexing gate element is deflectable in a lateral direction as to allow the guide pin to move from the start position towards the intermediate position."

As provided in Sections VII.K-L above, Carrel's Figures 2-4 illustrate a "flexible tongue 39 which allows the peg 6 to pass in the distal direction and prevents the said peg 6 from returning in the proximal direction." Ex. 1005, [0066].

Carrel further discloses that the flexible tongue 39 is "elastically deformable" and is configured to prevent "peg 6 from returning from the said second section 12 to the said first section 11." *Id*. During Carrel's injection sequence, "*[b]etween the storage position and the injection position*, the peg 6 is displaced along the first longitudinal section 11 where it presses against the flexible tongue 39 and bends it to reach the vertex 36 of the U." *Id*., [0077]. These elements are set forth in Figures 2-3, included below.



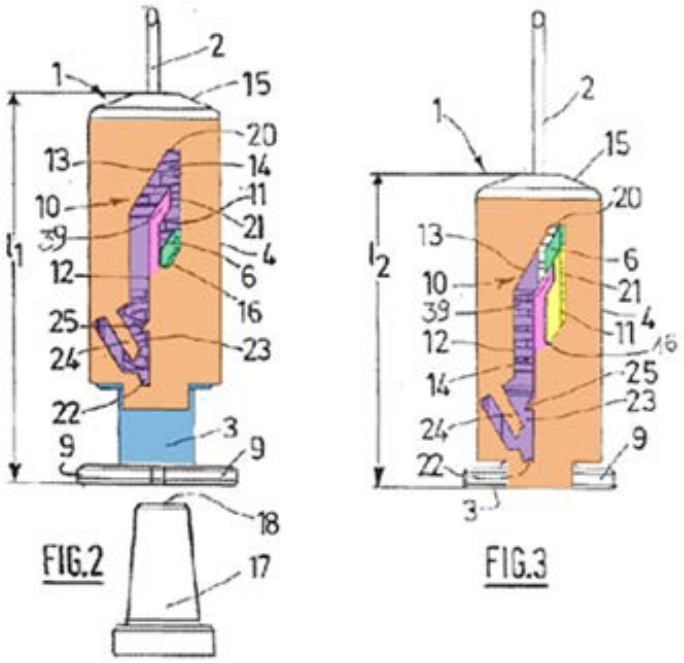
Id., FIGS. 2-3.

As described and illustrated, Carrel's flexing gate element (flexing tab 39) is deflectable in a lateral direction as to allow the guide pin (peg 6) to move from the start position (storage position) towards the intermediate position (injection position). Ex. 1003, ¶¶162-165. Thus, the combination of Carrel and David-Hegerich teaches this claim. *Id*.

N. Claim 13: "The safety device according to claim 10, wherein a sloped section of the flexing gate element is configured to guide the movement of the guide pin along a section of the guide track and inhibit the guide pin from re-entering the start position."

As provided in Sections VII.K-M above, Carrel's Figures 2-4 depict a "flexible tongue 39 which allows the peg 6 to pass in the distal direction and prevents the said peg 6 from returning in the proximal direction." Ex. 1005, [0066].

Carrel further discloses that "flexible tongue 39 forms at least in part the first safety means, elastically deformable, *preventing the peg 6 from returning from the said second section 12 to the said first section 11*." *Id*. These features are set forth in Figures 2-3, included below.

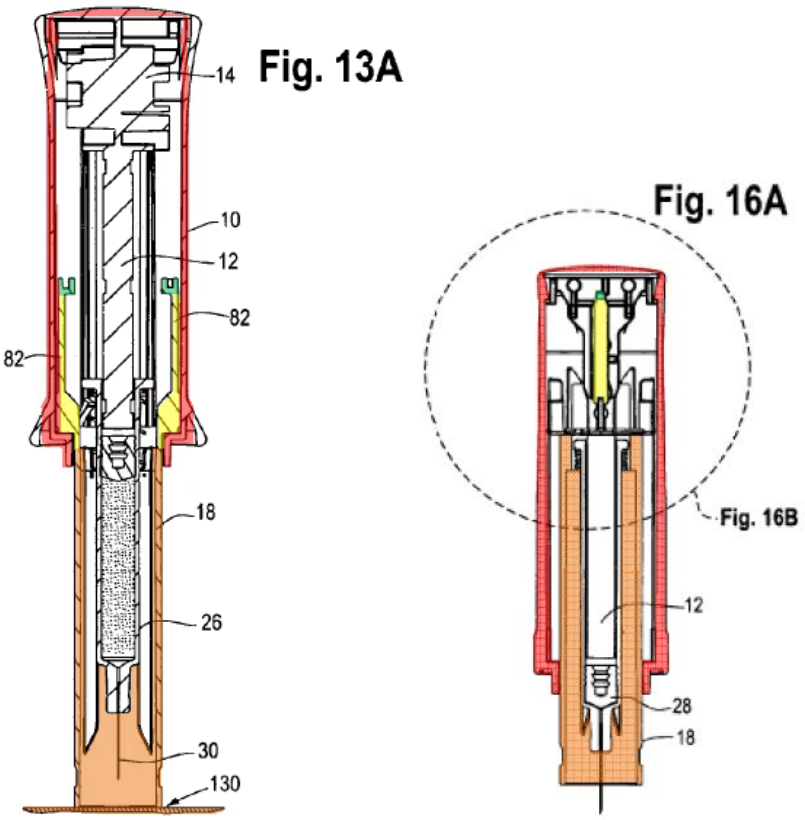


Id., FIGS. 2-3. As illustrated, flexing tab 39 comprises a sloped section that defines narrowing 21. A POSA would have understood that the sloped section of the flexing gate element (flexing tab 39) is configured to guide the movement of the guide pin along a section of the guide track and inhibit the guide pin from re-entering the start position. Ex. 1003, ¶¶166-168. Thus, the combination of Carrel and David-Hegerich teaches this claim. *Id*.

O. Claim 18: "The safety device of claim 1, wherein the outer body is configured to advance a piston rod of a pre-filled syringe in a distal direction when the outer body is translated in the distal direction relative to the support body."

Carrel is directed to "an injection device comprising at least one injection needle and a reservoir of product that is to be injected." Ex. 1005, [0040]. Carrel further teaches that "syringe body 17, partially depicted in FIG. 2, [is] prefilled with the medicinal product to be injected into the injection site." *Id*., [0061]. Carrel does not teach or suggest an outer body, however, this limitation is taught by David-Hegerich. Ex. 1003, ¶170.

As explained above, David-Hegerich's handle 10 is an outer body. *See supra* Section VII.B.2. As further explained in Section VII.B.3, the combination of Carrel and David-Hegerich teaches the outer body is capable of receiving a hollow support body that is slidably arranged relative to the outer body to perform an injection stroke. This feature is set forth in Figures 13A and 16A, included below.



Ex. 1006, FIGS. 13A and 16A (annotated). David-Hegerich further teaches that its "plunger 12 includes a top portion 14 which is attached to the open proximal end of the generally cylindrically-shaped handle 10." *Id*., [0049]. David-Hegerich provides additional details about its plunger:

> *As the handle 10 is moved towards the injection site* during an injection (as will be explained more fully below in conjunction with FIGS. 14-16), *the handle moves the plunger 12 tip 15 through the interior of the pre-filled syringe 26 to expel medicament* from the pre-filled syringe through the needle 30. At the completion of the injection and as the device is removed from the injection site, the needle guard 18 is moved distally by a spring 16 and locked into a position to cover

> the tip of the syringe needle 30 to prevent an accidental needle stick (FIG. 18).

Id. David-Hegerich's plunger 12 is a piston rod, as claimed. Ex. 1003, ¶172. Based on the foregoing, a POSA would have understood that David-Hegerich's handle 10 is configured to advance plunger 12 or a pre-filled syringe in a distal direction when handle 10 is translated in the distal direction relative to support 3. *Id*. Thus, Carrel's device, when modified in view of David-Hegerich, teaches this claim. *Id*.

Carrel would benefit from the larger easy-to-use handle that is slidable, as taught in David-Hegerich. Ex. 1003, ¶173; *see* Ex. 1006, [0050]. Thus, a POSA would have been motivated to enhance Carrel with David-Hegerich's handle. *See supra* Section VII.A; Ex. 1003, ¶173.

P. Independent Claim 20

There is no material difference between claim elements [20.P]-[20.8] and elements [1.P]-[1.7] of claim 1. For at least the reasons described in Sections VII.B.1 through VII.B.8 above, Carrel or Carrel as modified in view of David-Hegerich, teaches each this limitations. Ex. 1003, ¶¶81-112. Independent claim 20, however, has an additional limitation [20.9] directed to the positioning of the hypodermic needle. Carrel or Carrel as modified in view of David-Hegerich teaches this limitation also. *Id*., ¶¶183-188.

1) [20.1]: "a pre-filled syringe"

This claim element is substantially similar to element labeled [1.P] herein. For at least the reasons described in Section VII.B.2 above, Carrel teaches this limitation. *Id*., ¶¶81-82, 175.

2) [20.2]: "a safety device comprising an outer body"

This claim element is substantially similar to elements labeled [1.P]-[1.1] herein. For at least the reasons described in Sections VII.B.1 and VII.B.2 above, the combination of Carrel and David-Hegerich teaches this limitation. *Id*., ¶¶83-84, 176.

3) [20.3]: "a hollow support body to retain the pre-filled syringe therein, wherein the hollow support body is received in the outer body and slidably arranged relative to the outer body to perform an injection stroke"

This claim element is substantially similar to element labeled [1.2] herein. For at least the reasons described in Section VII.B.3 above, the combination of Carrel and David-Hegerich teaches this limitation. *Id*., ¶¶85-93, 177.

4) [20.4]: "a hollow needle shield slidable relative to the support body"

This claim element is substantially similar to element labeled [1.3] herein. For at least the reasons described in Section VII.B.4 above, Carrel teaches this limitation. *Id*., ¶¶94-96, 178.

5) [20.5]: "a guiding mechanism to guide the movement of the needle shield relative to the support body, the guiding mechanism comprising a deflectable flexible arm with a guide pin radially extending therefrom, the flexible arm extending essentially parallel to a central axis of the safety device"

This claim element is substantially similar to element labeled [1.4] herein. For at least the reasons described in Section VII.B.5 above, Carrel teaches this limitation. *Id*., ¶¶97-100, 179.

6) [20.6]: "a guide track configured to guide the guide pin within and along the guide track so that the guide pin follows the guide track when the needle shield is slid relative to the support body"

This claim element is substantially similar to element labeled [1.5] herein. For at least the reasons described in Section VII.B.6 above, Carrel teaches this limitation. *Id*., ¶¶101-106, 180.

7) [20.7]: "wherein the flexible arm is configured to be deflected laterally as the guide pin follows the guide track"

This claim element is substantially similar to element labeled [1.6] herein. For at least the reasons described in Section VII.B.7 above, Carrel teaches this limitation. *Id*., ¶¶107-110, 181.

8) [20.8]: "wherein the flexible arm is connected to or is integrally formed to the needle shield *or* the support body, and the guide track is formed into *the other of* the needle shield or the support body"

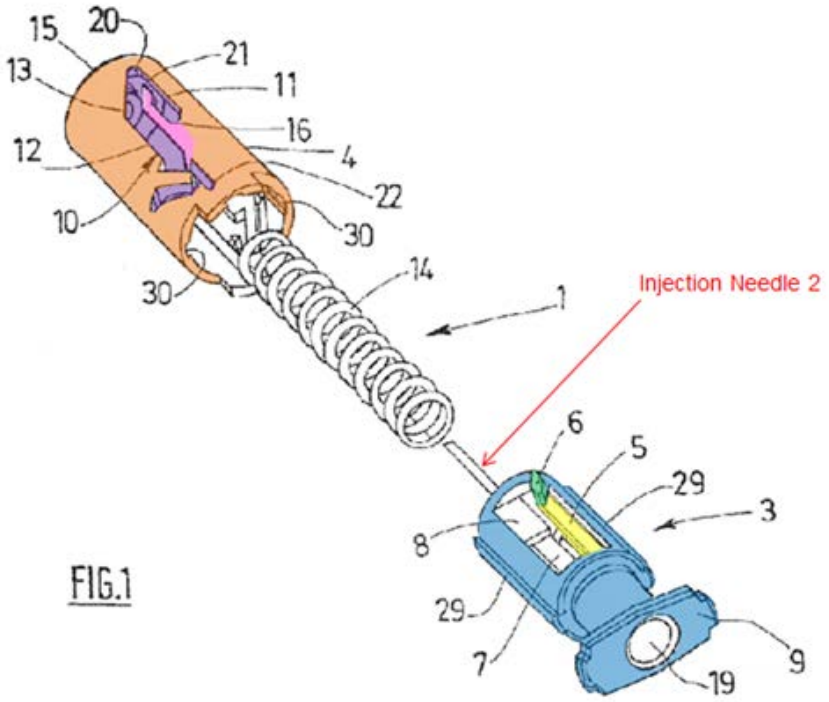
This claim element is substantially similar to element labeled [1.7] herein. For at least the reasons described in Section VII.B.8 above, Carrel teaches this limitation. *Id*., ¶¶111-112, 182.

9) [20.9]: "wherein the pre-filled syringe is retained within the support body of the safety device, so that the hypodermic needle[2] protrudes the distal end of the support body, whereas the hypodermic needle is surrounded by the needle shield in the initial position *and/or* in the advanced position and the hypodermic needle is exposed when the needle shield is in the retracted position."

As described in Section VII.B.3 above, Carrel teaches wherein the pre-filled syringe is retained within the support body of the safety device. *Id*., ¶¶85-94, 183. Carrel also teaches a hypodermic needle that protrudes the distal end of the support

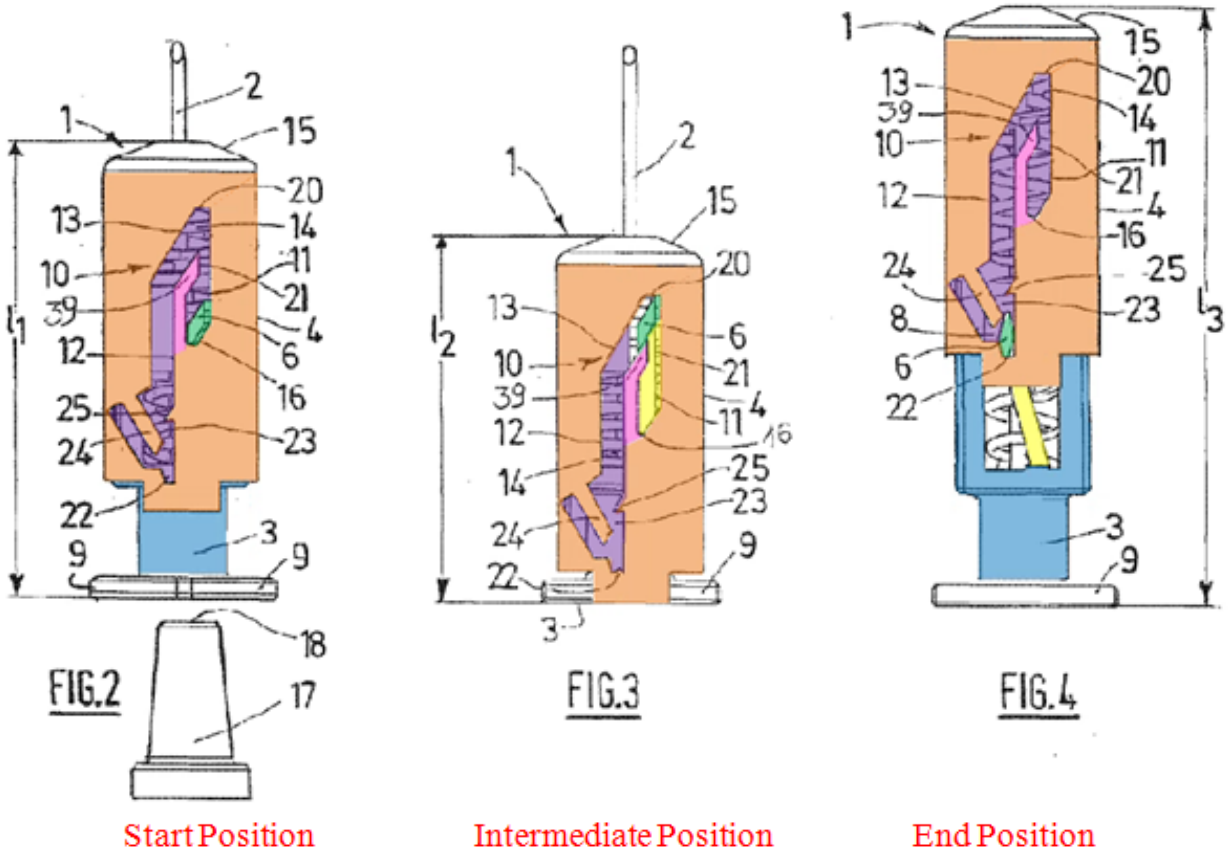
[2] Claim element [20.9] recites "***the*** hypodermic needle," however claim 20 fails to recite "***a*** hypodermic needle." This lack of antecedent basis renders claim 20 indefinite under 35 U.S.C. §112. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 n.6 (2014); *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006). However, in the event the Board finds that claim 20 is not indefinite, Petitioner interprets the first instance of the term "***the*** hypodermic needle" to be "***a*** hypodermic needle."

body. For example, Carrel's Figure 1 illustrates "a protection device 1 for protecting an injection needle 2." Ex. 1005, [0051].



Id., FIG. 1 (annotated).

As illustrated, Carrel's injection needle 2 protrudes the distal end of the support body (support 3, shaded in orange). Ex. 1003, ¶184. A POSA would have understood that Carrel's injection needle 2 is a hypodermic needle, as claimed. *Id*. Carrel also teaches a configuration where the hypodermic needle is surrounded by the needle shield in the advanced position (protection position) and the hypodermic needle is exposed when the needle shield is in the retracted position (injection position). *See supra* Section VII.H; Ex. 1003, ¶185.

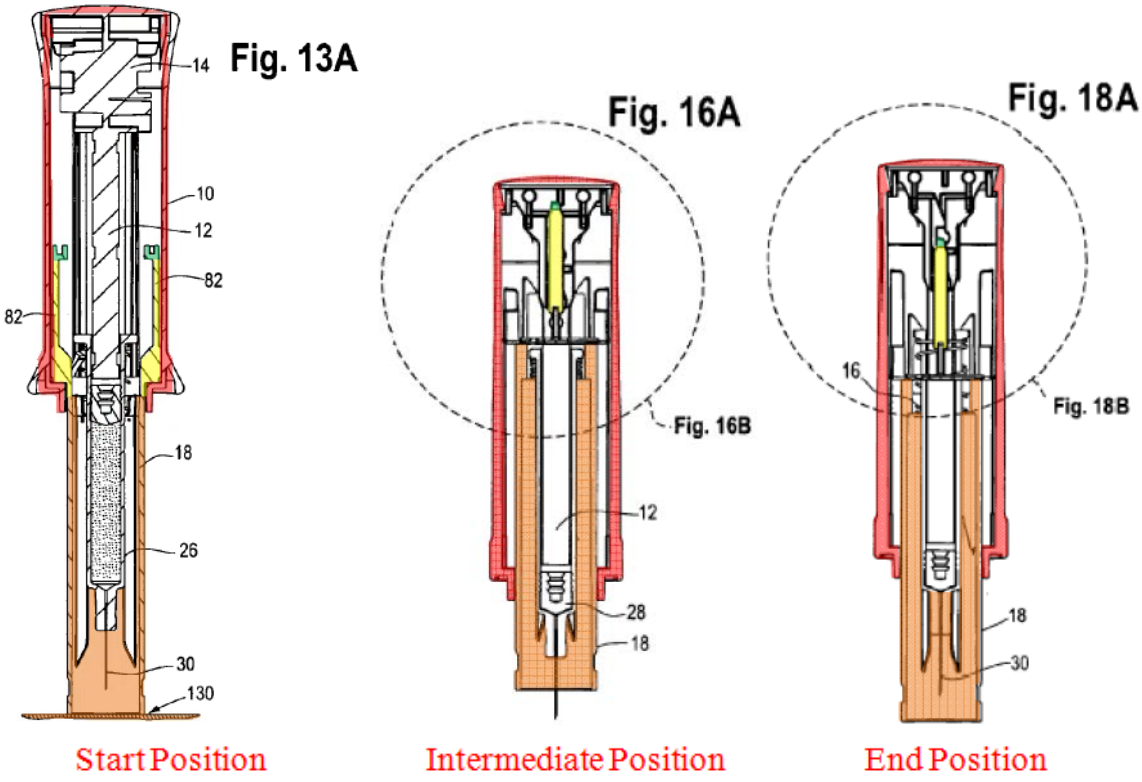


Ex. 1005, FIGS. 2-4 (annotated).

As illustrated, Figure 4 shows that Carrel's needle is surrounded by the needle shield in the advanced position (protection position), as claimed. Ex. 1003, ¶186. Figure 3 illustrates that Carrel's needle is exposed when the needle shield is in the retracted position (injection position), as claimed. *Id*. Because the claim uses "and/or," Carrel teaches this limitation in the "or" embodiment. Thus, Carrel teaches this limitation. *Id*.

David-Hegerich also discloses this feature in the "and" embodiment. More specifically, David-Hegerich teaches that the needle is protected prior to administration of the injection (Ex. 1006, [0100]); FIG. 13A); that the needle is

exposed to complete the expelling of medicament from the syringe and needle (*id*., [0106]; FIG. 16A); and that the needle guard is extended to protect the needle and is locked from re-use (*id*., [0110]; FIG. 18A).



Id., FIGS. 13A, 16A, and 18A (annotated). Thus, Carrel's device, when modified in view of David-Hegerich, also teaches the "and" embodiment of this claim. Ex. 1003, ¶¶187-188.

VIII. West Pharmaceutical Services, Inc. is Unaware of Any Secondary Considerations That Would Render the Challenged Claims Non-Obviousness

While it is the patent owner's burden to produce evidence of objective indicia showing that the challenged claims are not obvious, West is not aware of

any indicia of non-obviousness at this time. If Patent Owner Sanofi makes such a competent showing, then Petitioner West reserves its right to respond to any such information, and to then meet its burden to persuade the Board that the claims are nonetheless obvious.

IX. Standing (37 C.F.R. § 42.104(a))

West Pharma certifies that the ’011 Patent is available for *inter partes* review, and that West Pharma is not barred or estopped from requesting an *inter partes* review of the ’011 Patent.

X. Mandatory Notices (37 C.F.R. § 42.8)

A. Real Party In Interest

The real party-in-interest of this Petition is West Pharmaceutical Services, Inc.

B. Related Matters

West Pharmaceutical Services, Inc. is not aware of the ’011 Patent being the subject of any civil action or a proceeding before the United States Patent and Trademark Office.

C. Lead and Back-up Counsel

Pursuant to 37 C.F.R. § 42.8(b)(3) and 42.10(a), Petitioner West Pharmaceutical Services, Inc. appoints the following counsel:

Jon E. Wright (Reg. No. 50,720, jwright-PTAB@sternekessler.com) as its lead counsel; and **Kyle E. Conklin** (Reg. No. 59,425, kconklin-PTAB@sternekessler.com), and **Trent W. Merrell** (Reg. No. 73,771, tmerrell-PTAB@sternekessler.com), as its back-up counsel, all at the address: STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C., 1100 New York Avenue, N.W., Washington, D.C., 20005, phone number (202) 371-2600, and facsimile (202) 371-2540.

D. Service Information

Petitioner consents to electronic service by email at: **jwright-PTAB@ sternekessler.com**, **kconklin-PTAB@sternekessler.com, tmerrell-PTAB@sternekessler.com,** and **PTAB@sternekessler.com.**

Respectfully submitted,
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Jon E. Wright/

Jon E. Wright, Reg. No. 50,720
Attorney for Petitioner

Date: June 1, 2018

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that on June 1, 2018, true and correct copies of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,586,011**, Petitioner's Power of Attorney, and all associated exhibits were served in their entireties on the following parties via Express Mail:

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P.O. BOX 1022
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/Jon E. Wright/

Jon E. Wright, Reg. No. 50,720
Attorney for Petitioner

Date: June 1, 2018

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This Petition complies with the type-volume limitation of 14,000 words, comprising 12,059 words, excluding the parts exempted by 37 C.F.R. § 42.24(a).

2. This Petition complies with the general format requirements of 37 C.F.R. § 42.6(a) and has been prepared using Microsoft® Word 2010 in 14 point Times New Roman.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Date: June 1, 2018

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