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. 9,352,099

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I. Introduction

Petitioner West Pharmaceutical Services, Inc. ("Petitioner" or "West") requests *inter partes* review of claims 1-14 and 16-19 of U.S. Patent No. 9,352,099 (Ex.1001 or the "'099 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 (claims 1-14 and 16) and an injection device (claims 17-19) including a pre-filled syringe having a hypodermic needle. To protect the needle and avoid needle-stick injury during use, Sanofi's claimed device comprises three basic parts: (1) a "*hollow support body*" for mounting a pre-filled syringe therein, (2) a "*hollow needle shield*," and (3) a "*guiding mechanism to guide the movement of the needle shield relative to the support body*." The Office should never have granted Sanofi's patent because at the time the application was filed in mid-2010, the claims would have been obvious over prior-art needle safety devices for pre-filled syringes by 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 '099 Patent.

Specifically, by at least 2005, BD had designed a safety device which at least partially covered the needle to protect patients and users from needle-stick injury. BD's device has every feature claimed in Sanofi's '099 Patent, except the

entirely functional limitation that in its initial, pre-injection position (i.e., its start position), a small portion of the distal end of the needle may extend from the needle shield. At the time, avoiding needle sticks was a major concern throughout the injectable drug delivery industry. And by at least 2007, BMS (like many others at the time) recognized the need to shield an exposed portion of the needle before injection. In view of that need, BMS designed a needle safety to protect the needle at the start position as well. That device that was very similar to the device later claimed by Sanofi in the ’099 patent. Like BD’s device, BMS’s device also has almost every feature claimed in Sanofi’s ’099 Patent, *and* it shields a hypodermic needle at both the start and the end positions, i.e., before and after, delivery of an injectable medicine.

BD’s device is disclosed in U.S. Patent Pub. No. 2009/0024093 to Carrel et al. (Ex.1005 or “Carrel”). BMS’s device is set forth in U.S. Patent Publication No. 2008/0228147 to David-Hegerich et al. (Ex.1006 or “David-Hegerich”). Given the pervasive need in the industry at the time to avoid needle-sticks, a person of ordinary skill in the art (a “POSA”) would have been motivated to find a solution to shield the needle at all times, both before and after drug delivery, and to modify Carrel to include David-Hegerich’s needle safety device for a pre-filled syringe comprising a hypodermic needle attached to the distal end of the syringe and needle shield that protects the needle in both the start position and the end position.

Indeed, there are no structural differences between the disclosed device in Carrel and the challenged claims, but even so, David-Hegerich expressly discloses protecting a needle before and after an injection, and the benefits of doing so.

Petitioner West will thus prove in detail below that independent claims 1 and 17 of the ’099 Patent are unpatentable over Carrel in view of David-Hegerich. The same is true for all of the challenged dependent claims as well because they merely recite other well-known aspects of safety and injection devices for pre-filled syringes. The challenged claims should thus be canceled.

II. Statement of Unpatentability Grounds for Claims 1-14 and 16-19 of the ’099 Patent

Petitioner requests *inter partes* review of claims 1-14 and 16-19 of the ’099 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 ’099 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 on the face of the ’099 Patent is July 2, 2010. The prior art references cited for the ground above thus both qualify as prior art to the ’099 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 in the art 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-safety and injectable drug delivery devices. 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 '099 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 ’099 Patent is clear and straightforward. At this early stage of the IPR proceeding, Petitioner does not believe that any term of the ’099 Patent requires an express 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 challenged ’099 Patent claims be accorded their ordinary and customary meaning, in view of the ’099 Patent specification, and as understood by a POSA.

V. The ’099 Patent

The needle-safety and injector devices claimed in the ’099 Patent use a simple mechanical approach to prevent accidental needle pricks. Ex.1001, ’099 Patent, 1:46-49.

A. Overview of the ’099 Patent

The needle safety device of the ’099 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 claimed device comprises three main components, including a “*hollow support body*” for mounting the pre-filled syringe with a needle, a “*hollow needle shield*,” and a “*guiding mechanism to guide the movement of the needle shield relative to the support body*.” These basic features are illustrated in Figure 1, set forth below:

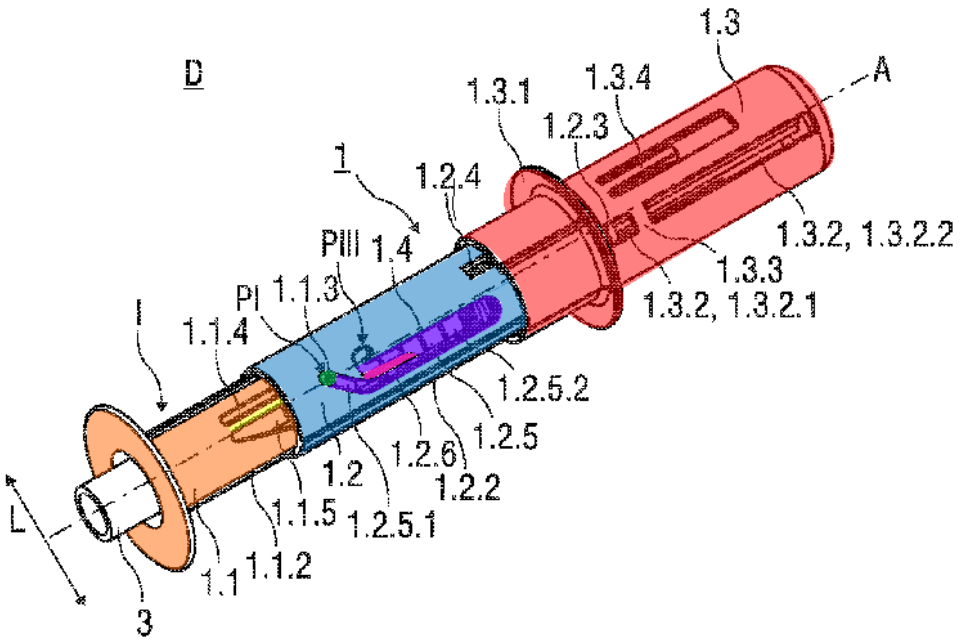


FIG 1

Id., FIG. 1 (annotated with color).

The hollow support body that holds the needle is element 1.2 (shaded in blue). The hollow needle shield is element 1.1 (shaded in orange). With respect to the guiding mechanism, the claimed guide track is element 1.2.2 (shaded in purple), and disposed on the hollow support body. The device further comprises an outer body or handle, element 1.3 (shaded in red).

The guide track 1.2.5 works in conjunction with a deflectable "flexible arm" 1.1.4 (shaded in yellow) with a guide pin 1.1.3 (shaded in green) extending therefrom. *Id.*, 2:3-5. The guide track is formed as an aperture in the hollow support body, as shown in Figure 1, above. *Id.* 3:31-33 and 7:10-13. Alternatively, the guide track may form a recess within the hollow needle shield or the hollow support body and is "inaccessible from the outside." *Id.* 7:13. The flexible arm is

disposed on the hollow needle shield. The guide pin on the deflectable flexible arm follows the guide track and around separating wall 1.2.6 (shaded in pink) as the needle shield 1.1 moves relative to the support body 1.2. The separating wall extends parallel to the central axis.

The claimed invention transitions between three stages shown below. Initially, in a starting or storage position, the needle shield is extended over the needle, as illustrated in Figure 2. At an intermediate position, the device is pressed against an object (i.e., a patient's skin), the needle shield 1.1 is retracted. At the advanced position, the needle shield 1.1 is again extended over needle 2.1, as depicted in Figure 5.

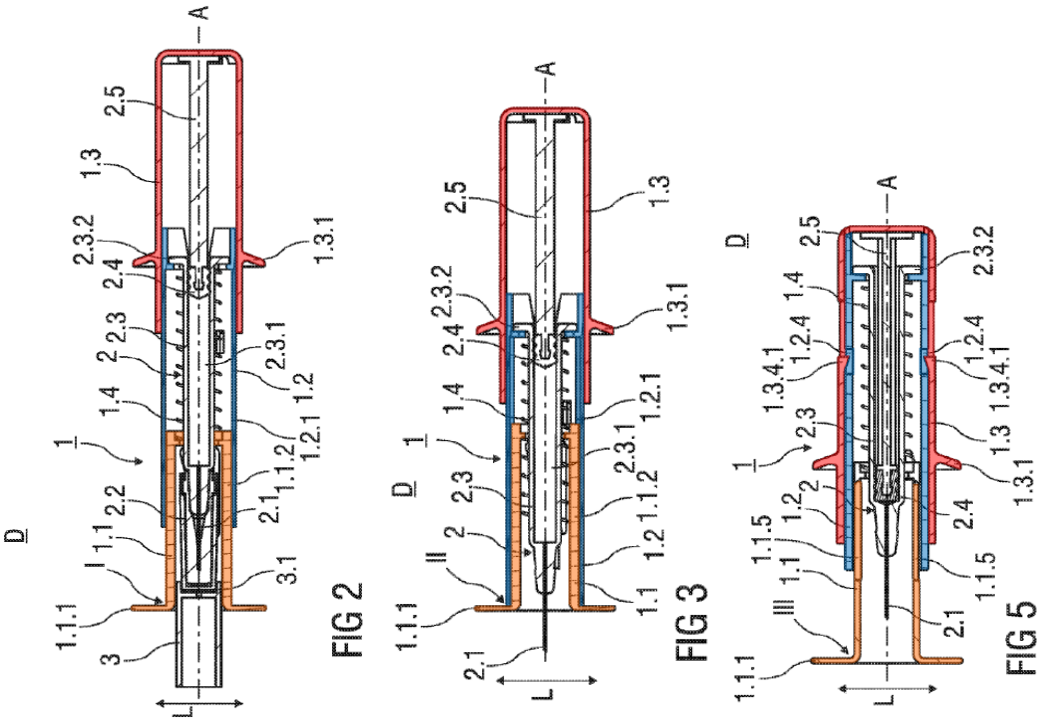
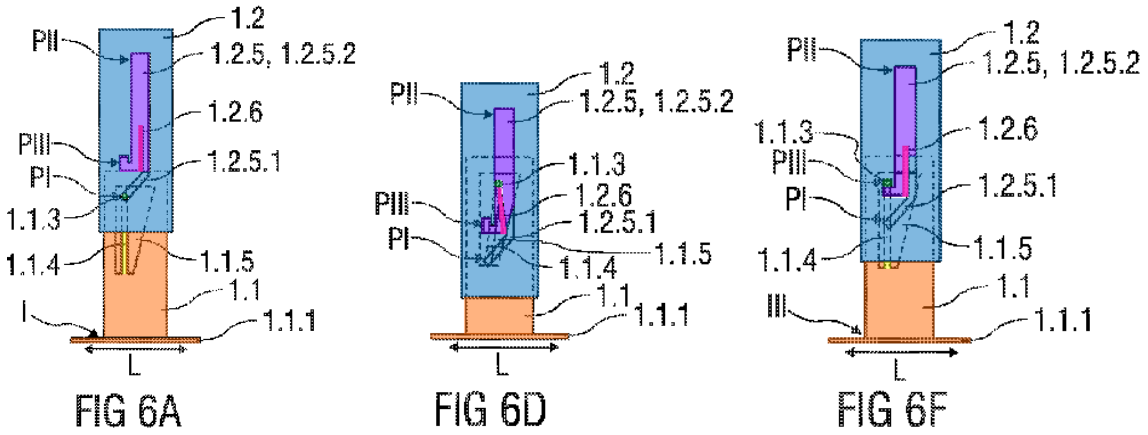


FIG 2 FIG 3 FIG 5

Id., FIGS. 2, 3, and 5 (annotated). The transition between the three stages correlates with the movement of the guide pin through the track.

The guide pin movement is illustrated by Figures 6A-6F. Figures 6A, 6D, and 6F are shown below.



Id., FIGS. 6A, 6D, and 6F (annotated). The guide pin's starting position PI illustrated in Figure 6A corresponds to state of the injection device in its starting position (Figure 2), before the injection stroke. *See id*., 7:29-32. As the injection stroke begins, the guide pin 1.1.3 slides up towards intermediate position PII above separating wall 1.2.6 (shaded in pink) as the needle is inserted into the skin (or other object), as illustrated in Figure 6D. Then, as the injection stroke completes and the needle is extracted, the guide pin travels back down the guide track where it is deflected by flexible arm 1.2.3 away from the starting position PI, and towards the end position PIII, as illustrated in Figure 6F. The particular shape of the guide

track is not claimed yet the length of the track dictates whether the needle shield partially or completely covers the tip of the needle.

The safety device described in the challenged ’099 Patent claims thus relies on simple mechanical techniques, utilizes three main components— (1) a hollow support body, (2) a hollow needle shield and (3) a guiding mechanism (shown in claim 1 below in bold)—to protect the needle and prevent accidental needle sticks. Ex.1001, 1:46-49.

Claim 1 of the ’099 Patent is illustrative:

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

[1.1] a **hollow support body** for mounting the pre-filled syringe therein, the pre-filled syringe comprising a hypodermic needle attached to a distal end of the pre-filled syringe,

[1.2] **a hollow needle shield** that is slidable relative to the support body, the needle shield and the support body being configured such that relative rotation of the support body and the needle shield is inhibited, and

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

[1.3.A] a flexible arm,

[1.3.B] a guide pin extending from the flexible arm in a radial direction,

[1.3.C] a guide track, wherein the guide pin protrudes

into the guide track, and

[1.3.D] a separating wall that extends into the guide track in a direction parallel to a central axis of the safety device,

[1.4] wherein, the guide pin is configured to move along the guide track to deflect the flexible arm in a lateral direction perpendicular to the central axis when the needle shield is slid relative to the support body,

[1.5] wherein the guide pin is movable within the guide track from a start position through an intermediate position to an end position such that a distal end of the needle of the pre-filled syringe is surrounded by the needle shield when the guide pin is in the start position and the end position, and

[1.6] wherein the flexible arm interacts with the separating wall to guide movement of the guide pin along the guide track.

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

B. The Prosecution History

During prosecution, the examiner rejected the original claims, except for dependent claim 5, as being anticipated by Carrel (Ex.1005). Ex.1002, '099 File

History, 37. For dependent claim 5, which recites the feature of "audible feedback" during the injection stroke, the Examiner relied on David-Hegerich (Ex.1006). *Id*.

To address the rejections, the applicant filed an amendment and reply in an attempt to avoid Carrel. Specifically, the applicant amended originally-filed claim 1 to (A) specify that the "pre-filled syringe" comprises "a hypodermic needle attached to a distal end of the pre-filled syringe;" and (B) specify that "a distal end of the needle of the pre-filled syringe is surrounded by the needle shield when the guide pin is in the start position and the end position." *Id*., 26. The applicant then argued that the amendment (B) avoids Carrel because Carrel "fails to describe" a start position where the pre-filled syringe is surrounded by the needle shield. *See id*., p. 31-33. The applicant did not address dependent claim 5 or the David-Hegerich reference, except for a single sentence concluding (wrongly) that David-Hegerich "fails to cure the deficiencies of Carrel with respect to amended claim 1." *Id*., p. 33.

Upon receiving the applicant's amendment and reply, the examiner conducted an additional search and then issued a notice of allowance. In a puzzling statement on the reasons for allowance, the examiner explained why a new piece of art—U.S. Patent Pub. No. 2006/0189933 to Alheidt *et al.*—does not disclose or render obvious independent originally-filed claims 1 and 18 (which issued as claims 1 and 17, respectively). In distinguishing the newly cited Alheidt, the

examiner focused not on the amended features or on the applicant's arguments, but rather on the movement of the guide pin on the flexible arm through the guide track—an issue the applicant did not raise in its reply. *Id*.at 14. The examiner did not again discuss, let alone critically analyze, Carrel, David-Hegerich, the applicant's amendment, or the applicant's argument. The reason for allowance was thus a complete non-sequitur to the amendment and reply.

Applicant proceeded to pay the issue fee and the '099 patent issued.

C. Section 325(d) does not apply to the proposed ground of unpatentability.

The Director "may take into account whether, and reject the petition because, the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d); *see also Becton Dickinson & Co. v. B. Melsungen A.G.*, IPR2017-01586, Paper 8 (PTAB 2017) (designated informative March 21, 2018). In determining whether to exercise its discretion under § 315(d), the Director will consider several, non-exclusive factors. *See Becton Dickinson*, Paper 8 at 17-18.

The factors most relevant here are (1) "the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;" (2) "the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;" (3) "whether Petitioner has pointed out

sufficiently how the Examiner erred in its evaluation of the asserted prior art;" and (4) "the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments." *Id.*

Here, these factors weigh in favor of the Petitioner. Even though the examiner cited both Carrel and David-Hegerich, § 325(d) does not apply because the examination was deficient. At the outset, the examiner did not apply the proposed ground of unpatentability to any claim, except for dependent claim 5, which the applicant ignored during prosecution. Moreover, the examiner erred because he did not appreciate the full scope of David-Hegerich, which teaches far more than claim 5's "audible feedback," for which it was used.

Specifically, the applicant amended independent claim 1 to add two features—(A) specifying that the "pre-filled syringe" includes "a hypodermic needle attached to a distal end of the pre-filled syringe;" and (B) specifying that "a distal end of the needle of the pre-filled syringe is surrounded by the needle shield when the guide pin is in the start position and the end position." Ex.1002, p. 26. First, both Carrel and David-Hegerich disclose using the needle safety devices disclosed in them with a pre-filled syringe. So the first amendment should not have alleviated the prior art rejection. Second, adding that the tip of the syringe is surrounded by the needle shield in the start and end positions is a functional limitation and does not affirmatively claim structure in the device which permits or

allows this to occur. This amendment, too, should not have been allowed as overcoming even Carrel, much less David-Hegerich.

Moreover, as Petitioner explains in detail below, David-Hegerich unambiguously teaches not only a pre-filled syringe in a needle safety device but also that the needle shield of the needle safety device covers the tip of the needle both before and after use. *See infra* Sections VII.A.1-2, VI.B, and VII.B.4.c. David-Hegerich also expressly explains why a POSA would have modified a device like Carrel to protect the needle in the start position. *See infra* Sections VII.A.1-2 and VII.B.4.c. Petitioner has thus fully refuted the applicant's conclusory and unsupported statement that David-Hegerich "fails to cure" Carrel's alleged deficiencies.

Importantly with respect to Section 325(d), there is no evidence in the prosecution history that the examiner critically examined the applicant's amendment and reply in view of David-Hegerich's needle shield. In allowing the claims, the examiner did not address the applicant's amendments or arguments, nor did the examiner revisit the scope of either the Carrel or the David-Hegerich references. Rather, in allowing the claims the examiner argued against his own newly discovered art (Alheidt), finding that it did not disclose pre-amendment features. Ex.1002, 14. The examination was, thus, deficient.

Finally, at no time did the examiner ever apply the combination of Carrel and David-Hegerich proposed below to any claim, except for dependent claim 5, directed to the "audible feedback" feature. Given that the structural features of the needle safety device were not changed by the amendment (only functional language was added), the Examiner should have considered whether the claims were still anticipated in view of Carrel or obvious over Carrel alone, or in combination with David-Hegerich. Again, the Examiner never asserted that the claims were obvious, instead focusing almost exclusively on a cursory anticipation rejection based on Carrel, and the applicant never disputed the anticipation rejection in view of Carrel or obviousness of any kind.

* * *

In sum, there is no record evidence that the examiner below critically considered the full scope of David-Hegerich. The Examiner never evaluated during examination the combination set forth in detail below where David-Hegerich is used in combination with Carrel to invalidate the independent claims. Carrel alone as a basis for obviousness was also not raised or evaluated by either the Examiner or the applicant. There is, thus, no overlap between the arguments the applicant made during examination and the manner in which Petitioner relies on the prior art. Further, Petitioner has pointed out clear error in the Examiner's failure to recognize that David-Hegerich unambiguously discloses every feature the

applicant added in its first amendment and reply. More significantly, the Examiner below simply did not examine elements of the device affirmatively claimed. Finally, Petitioner presents here additional evidence in the form of expert testimony that also warrants reconsideration of the prior art and arguments presented to the Office below. There is thus no compelling reason why Section 325(d) would prevent institution on the ground of unpatentability presented in the Petition here.

VI. Overview of the Prior Art

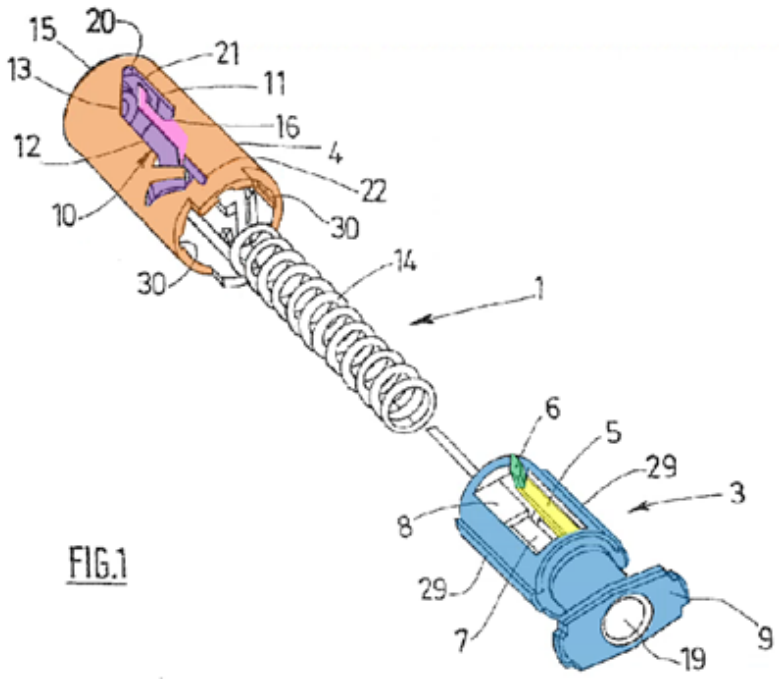
The sole ground of unpatentability under 35 U.S.C. § 103 relies on Carrel (Ex.1005) in view of David-Hegerich (Ex.1006). Carrel is the base reference that discloses and teaches every feature of the challenged claims, except a "*pre-filled syringe comprising a hypodermic needle attached to a distal end of the pre-filled syringe*" and "*a guide pin [that] is movable within the guide track from a start position through an intermediate position to an end position such that a distal end of the needle of the pre-filled syringe is surrounded by the needle shield when the guide pin is in the start position and the end position*." For those features, which were added by amendment during prosecution, Petitioner relies on David-Hegerich and proves below that a POSA would have found it obvious to incorporate David-Hegerich's device into Carrel's device to arrive at the purported invention set forth in the challenged claims. Indeed, David-Hegerich discloses the very feature that

the applicant added to the claims during prosecution to obtain the ’099 Patent, and moreover expressly teaches why the proposed modification would have been both useful and beneficial on a device like Carrel’s.

A. Carrel

Carrel is directed to a “protection device (1) intended to at least partially cover the needle (2) of an injection device.” Ex.1005, Carrel, Abstract. More specifically, like the ’099 Patent, Carrel is adapted to protect patients and users “from any risk of needlestick injury.” *Id*., [0003].

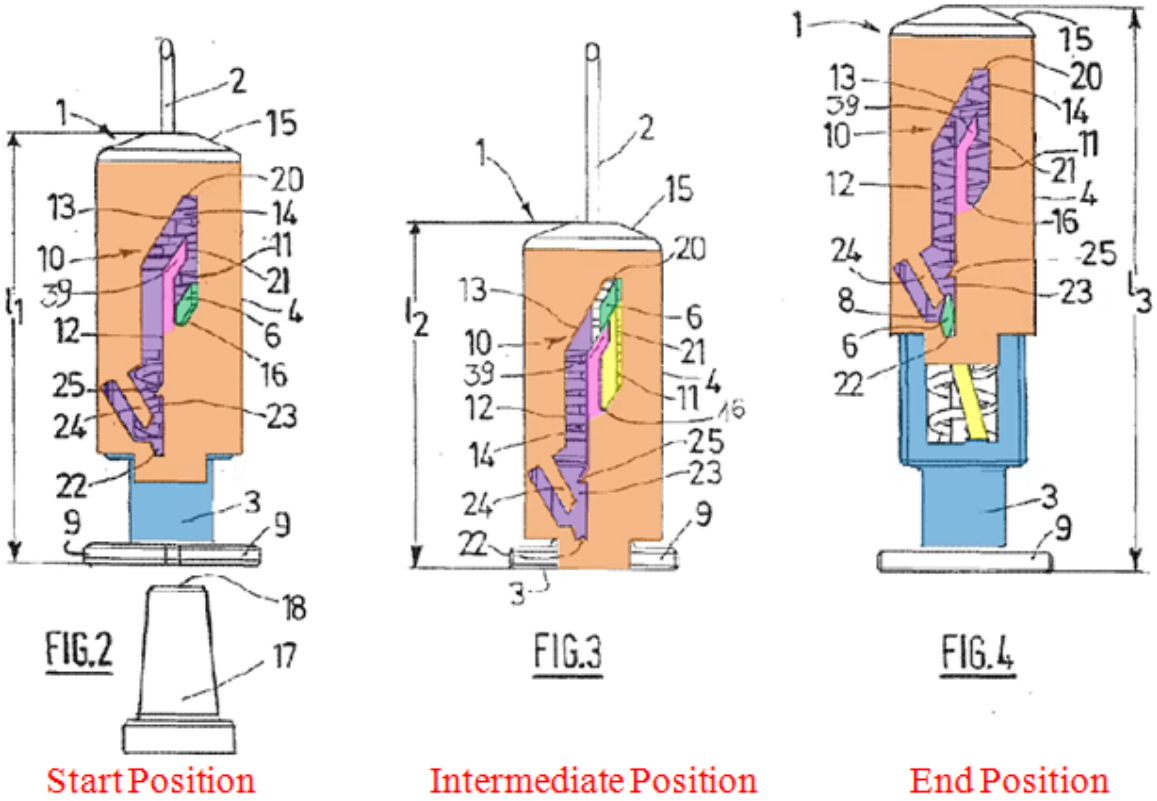
Carrel achieves this using three basic parts, including a *hollow support body* (support 3) that retains the prefilled syringe with a needle, a *hollow needle shield* (sleeve 4) to protect the needle, and a *guiding mechanism to guide the movement of the needle shield relative to the support body* (passageway 10). These basic features are illustrated in Figure 1, set forth below:



Id., FIG. 1 (annotated in color).

The hollow needle shield is sleeve 4 (shaded in orange). The hollow support body that holds the syringe and needle is support 3 (shaded in blue). The guiding mechanism is described as including the guide track, passageway 10 (shaded in purple), and disposed on the hollow support body, working 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 to cover the needle before (at least partially) and after injection. *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*. Figure 1 is again illustrative.

As illustrated above, Carrel's passageway 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* 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 in color). Carrel's starting position corresponds to state of the device in its storage position, before an injection stroke. As the injection

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

begins, the guide pin (peg 6, shaded in green) moves past flexible arm (flexing gate element 39, shaded in pink) as the guide pin slides up to the intermediate position (as the needle is inserted into the skin (or other object). Then, as the injection stroke completes and the needle is extracted, 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, David-Hegerich, 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*. David-Hegerich is thus solving the same problem of preventing accidental needle sticks using a safety device that works axially with a pre-filled syringe while it is being injected, like Carrel.

The David-Hegerich device comprises three basic parts, also like Carrel: a *handle*, a *hollow needle shield* (hollow tubular needle guard 18), and a *guiding mechanism to guide the movement of the needle shield relative to the outer body* (tracks 42 and track followers 82). These basic features are illustrated in Figure 13A (annotated in color).

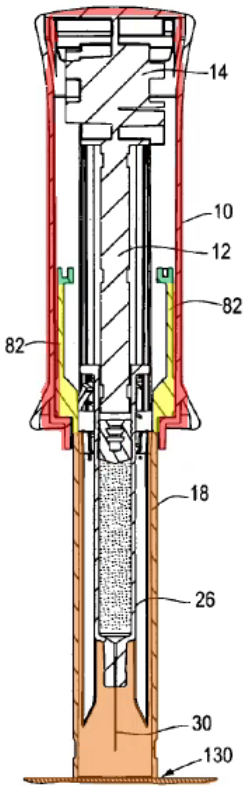


Fig. 13A

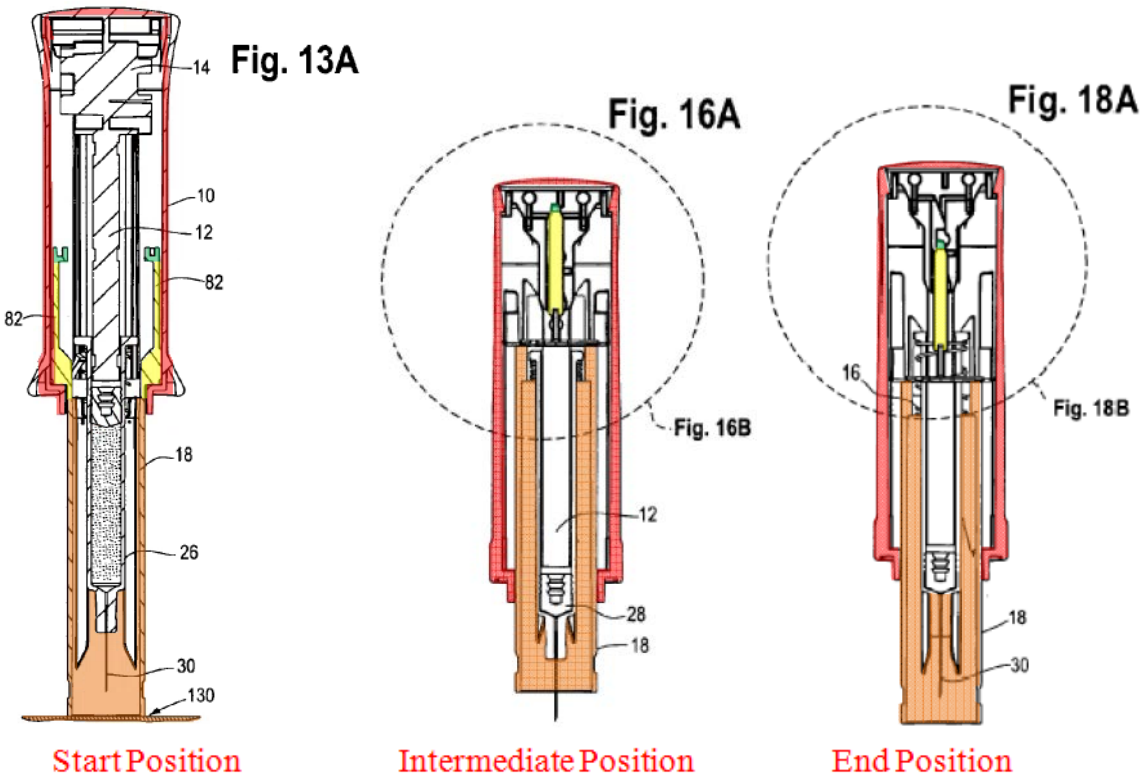
The hollow needle shield is hollow tubular needle guard 18 (shaded in orange). The outer body or handle is handle 10 (shaded in red). With respect to the guiding mechanism, a portion of the mechanism is illustrated as track followers 82 (shaded in yellow and green) follows the channels of track features 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 … *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*. (emphasis added). As the device is removed from the skin, 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 further provides that the purpose of its "needle guard 18 is to function as a protective guard for the syringe needle 30 both before and after an injection," which prevents the "possibility of [an] inadvertent needle stick," *Id*., [0053] and [0079]. David-Hegerich thus discloses a syringe comprising a hypodermic needle attached to the distal end of the syringe and a needle shield that protects the needle in both the start position and the end position, which the applicant argued during prosecution was missing from Carrel. The following Figures are illustrative:



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

Finally, David-Hegerich also expressly explains the advantages of employing a slidable handle in a safety device for a pre-filled syringe with a hypodermic needle, including facilitating use for persons having low dexterity. *See id*., [0050] and [0020].

The David-Hegerich safety device, thus, discloses the same basic three components, as Carrel, and simple mechanical techniques to advance the needle shield "beyond the tip of the needle to prevent against an accidental needle stick," (*id*., [0037]) like the device in the '099 patent. This needle shield technique is directly applicable to Carrel's needle shield.

VII. Ground 1: The Combination of Carrel and David-Hegerich Renders Obvious Claims 1-14 and 16-19 of the '099 Patent

A. Motivation to combine

At the outset, Carrel and David-Hegerich each use a guide mechanism and needle shield to solve the age-old problem of preventing accidental needle sticks, as does the challenged '099 Patent. Ex.1003, ¶¶70-71. Both are directed to a needle safety device for a pre-filled syringe with a hypodermic needle. And both are similarly concerned with needle protection, safety, and ease of use, as described in Sections VI.A and B above. *Id*.

A POSA would have been motivated to make the minor modification required to Carrel's needle safety device to include David-Hegerich's handle and to surround the needle with a needle shield when the guide pin is both in the start position and the end position. *Id*., ¶72. The resulting combination is little more than use of a known mechanical configuration or technique to improve the device safety—e.g., an safety device that surrounds a needle before and after an injection event to minimize when a needle is exposed. *Id*. A POSA thus would have improved injection devices, like Carrel's, in the same way that David-Hegerich suggests—namely, improving needle safety, injection safety, and providing tamper resistance. *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).

1. Reasons a POSA would have combined Carrel and David-Hegerich

To be more specific, a POSA would have modified and enhanced Carrel's device with David-Hegerich's handle and pre-filled syringe for at least four reasons. *First,* a POSA would have recognized the advantages of David-Hegerich's teachings with respect to surrounding a needle before and after an injection event. *See* Ex.1006, [0079]; Ex.1003, ¶73. David-Hegerich teaches that the purpose of its "needle guard 18 is to function as a protective guard for the syringe needle 30 both before and after an injection." Ex.1006, [0079]. Thus, extending Carrel's needle guard so that it protects the needle in the starting position would have been an obvious modification to also guard the needle at the starting position. Ex.1003, ¶73.

Second, a POSA would have recognized the advantages of David-Hegerich's "handle" for improving handling for low dexterity users. Ex.1006, [0050]; Ex.1003, ¶74. 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*. David-Hegerich's handle supports a prefilled syringe with an attached hypodermic needle.

Third, a POSA would have recognized the advantages of advancing David-Hegerich's handle down (and over) Carrel's 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 id*., [0061]; Ex.1003, ¶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. Ex.1003, ¶75. Thus, a POSA would have recognized the advantages of applying the injection force closer to the injection site, as taught by David-Hegerich. *Id*.

As provided in Sections V, VI.A and VI.B above, the '099 Patent, Carrel, and David-Hegerich are concerned with needle protection and safety. David-Hegerich expressly teaches that the "possibility of inadvertent needle stick prior to initiation of the injection is limited [by the David-Hegerich device] because the injector includes a needle guard feature (needle guard 18) which covers the needle 30 prior to the injection." Ex.1006, [0053]. For example, David-Hegerich teaches that the "purpose of the needle guard 18 is to function as a protective guard for the syringe needle 30 both before and after an injection." *Id*., [0079]. Protecting a needle tip prior to initiation of the injection may also prevent the needle from

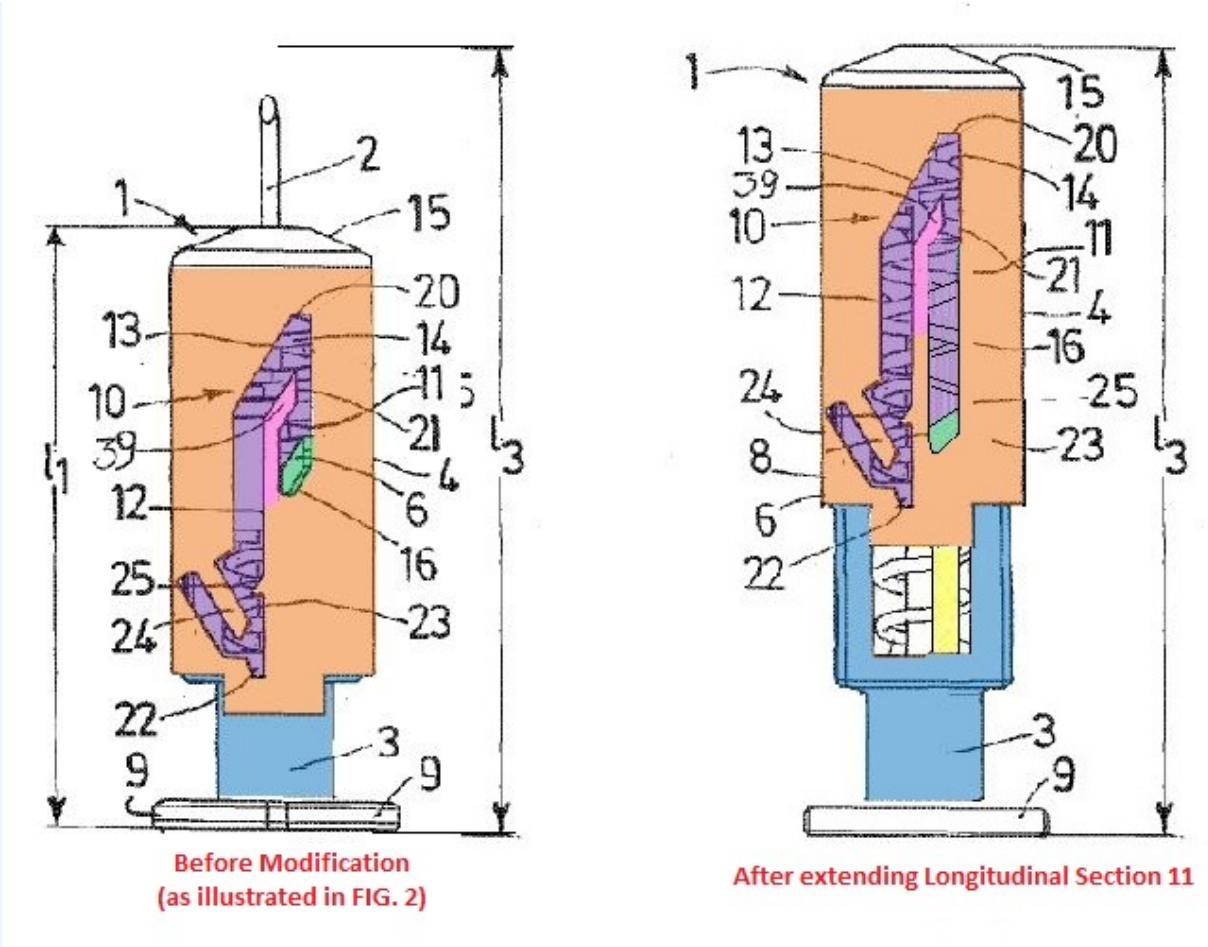
coming into contact with surfaces, thereby reducing the risk of contamination due to contact with non-sterile surfaces. *Id*., [0055] Protecting the needle further reduces the possibility of damage or dulling of the needle tip, thereby reducing the likelihood of a painful injection due to a dull needle tip. *Id*. A POSA would have understood the advantages of covering a needle to reduce inadvertent needle sticks, contamination, and/or the dulling of the needle tip, as taught by David-Hegerich. *Id*.; Ex.1003, ¶76-77.

David-Hegerich thus expressly teaches numerous benefits of employing a handle on a needle safety device for a pre-filled syringe. The benefits of employing a handle like in David-Hegerich on a needle safety device as in Carrel would have thus been predictable to a POSA. *KSR*, 550 U.S. at 417; Ex.1003, ¶¶73-77.

2. How a POSA would have combined Carrel and David-Hegerich

As provided above, Carrel's device would have benefited David-Hegerich's mechanism for surrounding a needle before and after an injection event. Ex.1003, ¶78. Because Carrel's needle shield (sleeve 4) is large enough to extend and surround a needle after an injection, it is also large enough to accommodate a needle shield extension before an injection. *Id.* A POSA would have understood that the shape and length of a guide track, as described in each of the '099 Patent, Carrel, and David-Hegerich, determines the relative movement of the needle guard. *Id.* Thus, to achieve David-Hegerich's movement, it would have been obvious to

extend Carrel's track downward, as shown in the annotated drawing below, using routine engineering practices. *Id*.



Ex.1005, FIGS. 2 and 4 (annotated). As illustrated, Carrel's first longitudinal section 11 may be extended further toward the proximal end of sleeve 4. *Id*. By extending the first longitudinal section 11, peg 6 would allow sleeve 4 to extend over the tip of the needle at the starting position. *Id*.

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 applying the injection force closer to the injection site, as taught by

David-Hegerich. Ex.1003, ¶79. More specifically, 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 difficulty of the injection. *Id.*, ¶80. Accordingly, the force required to perform the injection stroke using the David-Hegerich handle and pre-filled syringe occurs closer to the injection site than is described in Carrel. *Id.* Therefore, a POSA would have been motivated to modify Carrel's device to include a David-Hegerich-style outer handle. *See* Ex.1006, [0061]; Ex.1003, ¶80.

Finally, a POSA would have had a reasonable expectation of success in mounting David-Hegerich's slidable outer handle onto Carrel's needle-safety system. As Mr. Clemens explains, such a modification would have been a routine matter for a POSA. Ex.1003, ¶81.

* * *

For at least the foregoing reasons, a POSA would have found it obvious to modify Carrel's device to include a David-Hegerich-style slidable outer handle to arrive at the safety device for a pre-filled syringe, as recited in the challenged claims of the '099 Patent. *Id.*, ¶¶69-87.

B. Independent Claim 1

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

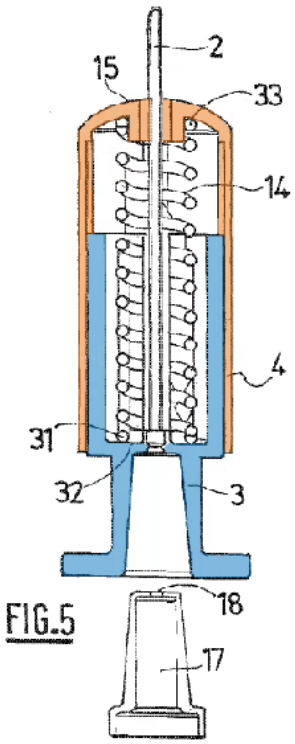
Carrel is directed to a safety device (protection device 1) to at least partially cover the needle of an injection device. Ex.1005, Abstract. Carrel teaches that its "protection device 1" is configured to accept and retain "the syringe body 17, partially depicted in FIG. 2, *prefilled with the medicinal product* to be injected into the injection site." Ex.1005, [0061]. Thus, Carrel teaches a safety device for a pre-filled syringe. Ex 1003, ¶90.

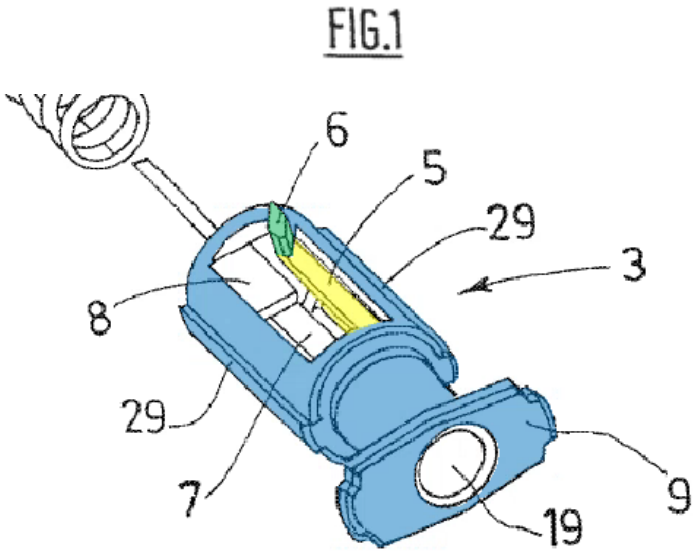
Although Carrel is the primary reference, David-Hegerich is also directed to a safety device for a syringe such as a pre-filled syringe. *See* Ex.1006, Abstract.

2. [1.1]: "a hollow support body for mounting the pre-filled syringe therein, the pre-filled syringe comprising a hypodermic needle attached to a distal end of the pre-filled syringe"

Carrel teaches a hollow support body (support 3) for mounting the pre-filled syringe (syringe body prefilled with the medicinal product) therein. Ex.1005, [0061]; Ex.1003, ¶92.

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





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

A POSA would have understood that, upon attaching the syringe tip to Carrel's support 3, Carrel's syringe would then comprise a hypodermic needle attached to a distal end of the pre-filled syringe. Ex.1003, ¶¶92-95. Therefore, when the Carrel device is fully assembled and ready for use, Carrel teaches or suggests "a hollow support body for mounting the pre-filled syringe therein, the pre-filled syringe comprising a hypodermic needle attached to a distal end of the pre-filled syringe," as claimed. *Id*.

To the extent Patent Owner argues that Carrel does not teach or suggest a hypodermic needle attached to a distal end of the pre-filled syringe, David-Hegerich discloses this feature. Ex.1003, ¶96. David-Hegerich teaches "a hollow tubular needle guard 18 which surrounds *the needle 30 of the pre-filled syringe 26*." Ex.1006, [0048]. The structure of David-Hegerich's syringe 26 and needle 30 are set forth in Figure 13A. David-Hegerich thus teaches a hypodermic needle attached to a distal end of the pre-filled syringe. Ex.1003, ¶96.

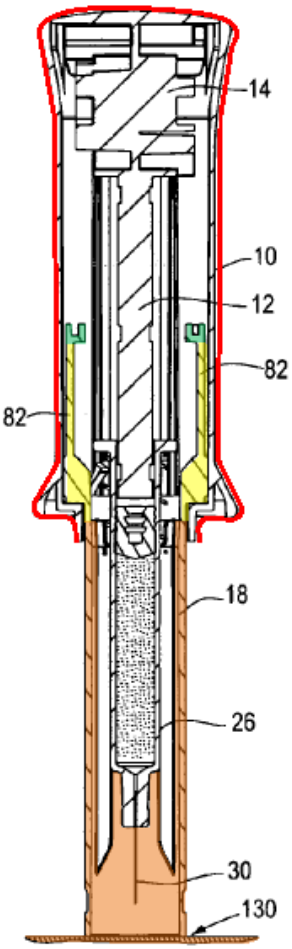


Fig. 13A

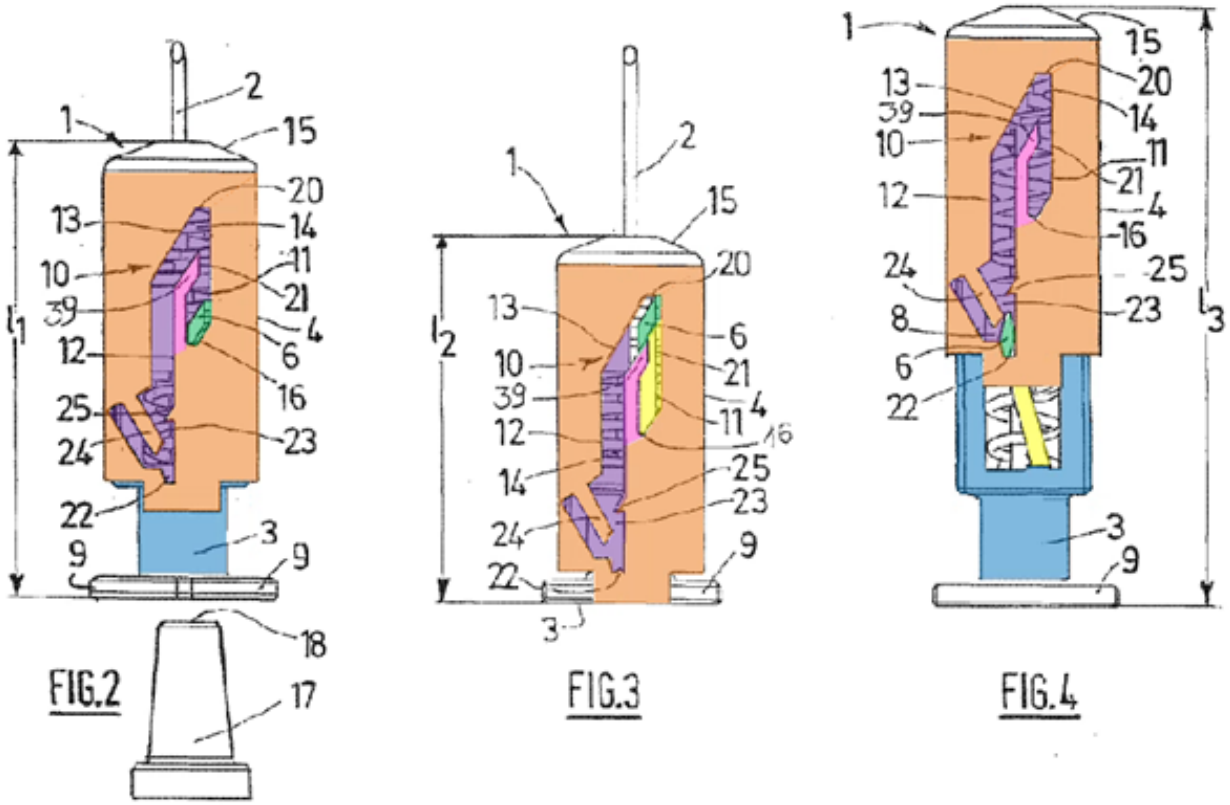
As provided above, it is important to prevent tampering with the injection device and to take additional measures to reduce the possibilities of introducing any contamination to the syringe. *See supra*, Section VII.A; Ex.1003, ¶97. Because the Carrel device requires a user to attach the pre-filled syringe to support 3, there is an increased chance of introducing a contaminant into the injection device—thereby causing undesirable results. *See supra*, Section VII.A; Ex.1003, ¶97. A POSA would thus appreciate that Carrel would benefit from the addition of a hypodermic needle that is already attached to

a distal end of the pre-filled syringe, as taught in David-Hegerich. Ex.1006, [0048]; Ex.1003, ¶98. For this reason, and the reasons set forth above in Section VII.A, a POSA would have been motivated to enhance Carrel's injection device with the addition of a David-Hegerich-like handle 10 and prefilled syringe 26 comprising needle 30. Ex.1003, ¶99.

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*., ¶¶70-87, 100-101.

3. [1.2]: "a hollow needle shield that is slidable relative to the support body, the needle shield and the support body being configured such that relative rotation of the support body and the needle shield is inhibited"

Carrel teaches a hollow needle shield (sleeve 4) that is slidable relative to the support body (moved in translation with respect to the support 3), Ex.1003, ¶¶102-106, 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, ¶103. Thus, Carrel teaches this limitation. *Id*.

Carrel also teaches that its needle shield and the support body are configured such that relative rotation of the support body and the needle shield is inhibited:

> 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.

Id., [0052]. This feature is illustrated in Figure 1 below.

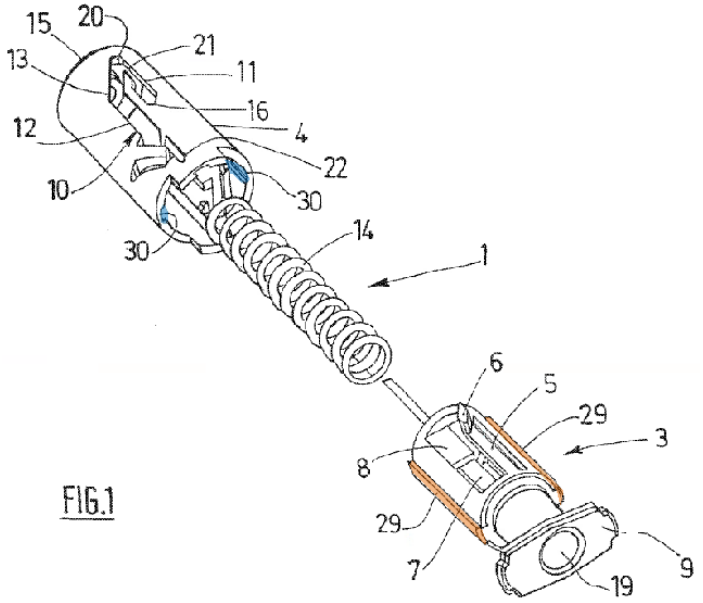


FIG.1

Id., FIG. 1 (annotated).

As illustrated, Carrel's longitudinal bulges 29 (shaded in orange) are longitudinal tongues, and Carrel's slideways 30 (shaded in blue) are longitudinal grooves. Ex.1003, ¶104. 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. Ex.1005, Abstract; Ex.1003, ¶¶104-105. Thus Carrel teaches this limitation. *Id*.

Although Carrel is the base reference, David-Hegerich also discloses a very similar 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].

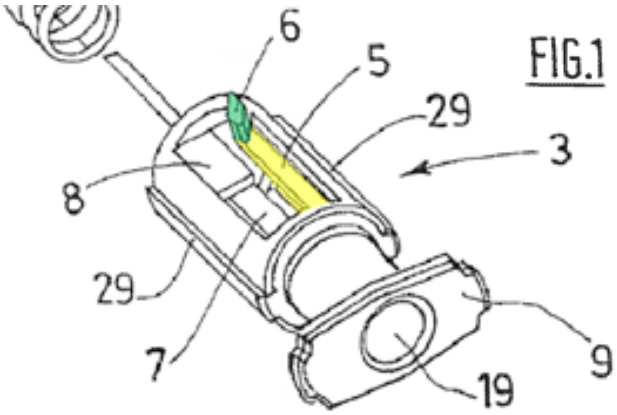
4. [1.3]: "a guiding mechanism to guide the movement of the needle shield relative to the support body, the guiding mechanism comprising:"

Carrel teaches a guiding mechanism to guide the movement of the needle shield (sleeve 4) relative to the support body (support 3). Specifically, Carrel teaches a guiding mechanism including a deflectable flexible arm (flexible tab 5), a guide pin (peg 6) extending from the flexible arm in a radial direction, a guide track (running passageway 10), wherein the guide pin protrudes into the guide track, and a separating wall (gate element 39) that extends into the guide track in a

direction parallel to a central axis of the safety device. Ex.1003, ¶107. Each of these guiding mechanism elements are discussed further below.

a. [1.3.A-B] "the guiding mechanism comprising…a deflectable flexible arm and a guide pin extending from the flexible arm in a radial direction"

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 structure of Carrel's flexible tab 5 and peg 6 are set forth in Figure 1 below.



Id., FIG. 1 (annotated).

Like the challenged '099 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.

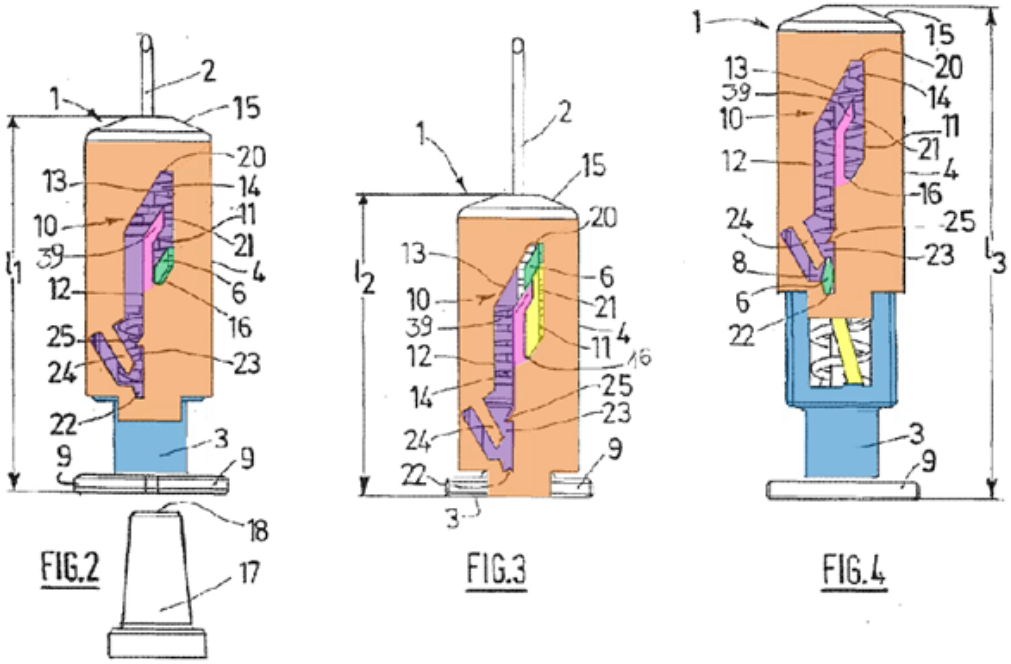
Id., [0067]. In view of the foregoing, a POSA would have understood that Carrel's flexible tab 5 and peg 6 together teach the guiding mechanism comprising "a deflectable flexible arm and a guide pin extending from the flexible arm in a radial direction," as claimed. Ex.1003, ¶108-111. Thus, Carrel teaches this limitation. *Id*.

Although Carrel is the base reference, David-Hegerich also discloses a deflectable flexible arm (track followers 82) and a guide pin extending from the flexible arm in a radial direction. *See* Ex.1006, FIGS. 15-18, [0065]-[0068].

b. [1.3.C] "the guiding mechanism comprising…a guide track, wherein the guide pin protrudes into the guide track"

Carrel teaches a guide track (running passageway 10) configured to guide the guide pin (peg 6), which is protruding into the guide track (within and along), the guide track so that the guide pin follows the guide track. Ex.1003, ¶112.

Carrel's passageway 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." Ex.1005, [0025], FIGS. 1-4. Carrel further teaches that "sleeve 4 comprises a *running passageway 10* forming a U, 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].



Id., FIGS. 2-4 (annotated). In view of the foregoing, a POSA would have understood that Carrel teaches a guide track (passageway 10) and a guide pin (peg 6) that protrudes into the guide track. Ex.1003, ¶113. Thus, Carrel teaches this limitation. *Id*., ¶114.

Although Carrel is the base reference, David-Hegerich also discloses a similar guide track (tracks 42) and guide pin (track followers 82). *See* Ex.1006, FIGS. 15-18, [0065]-[0068].

c. [1.3.D] "the guiding mechanism comprising…a separating wall that extends into the guide track in a direction parallel to a central axis of the safety device"

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].

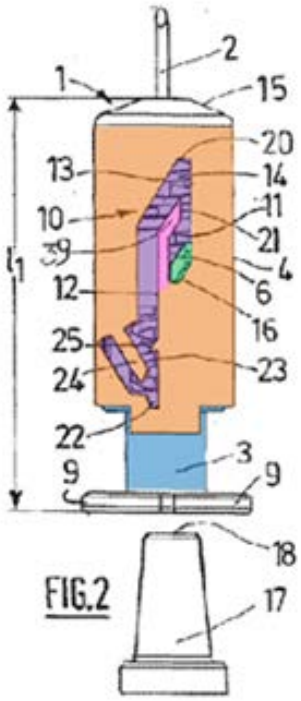


FIG.2

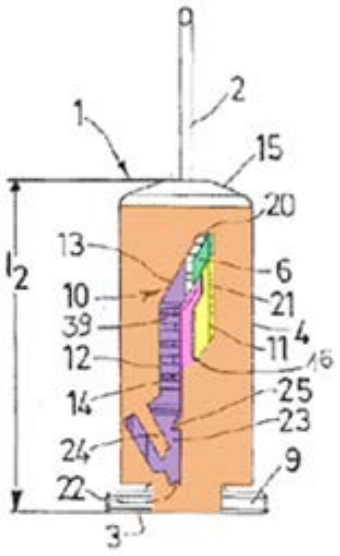


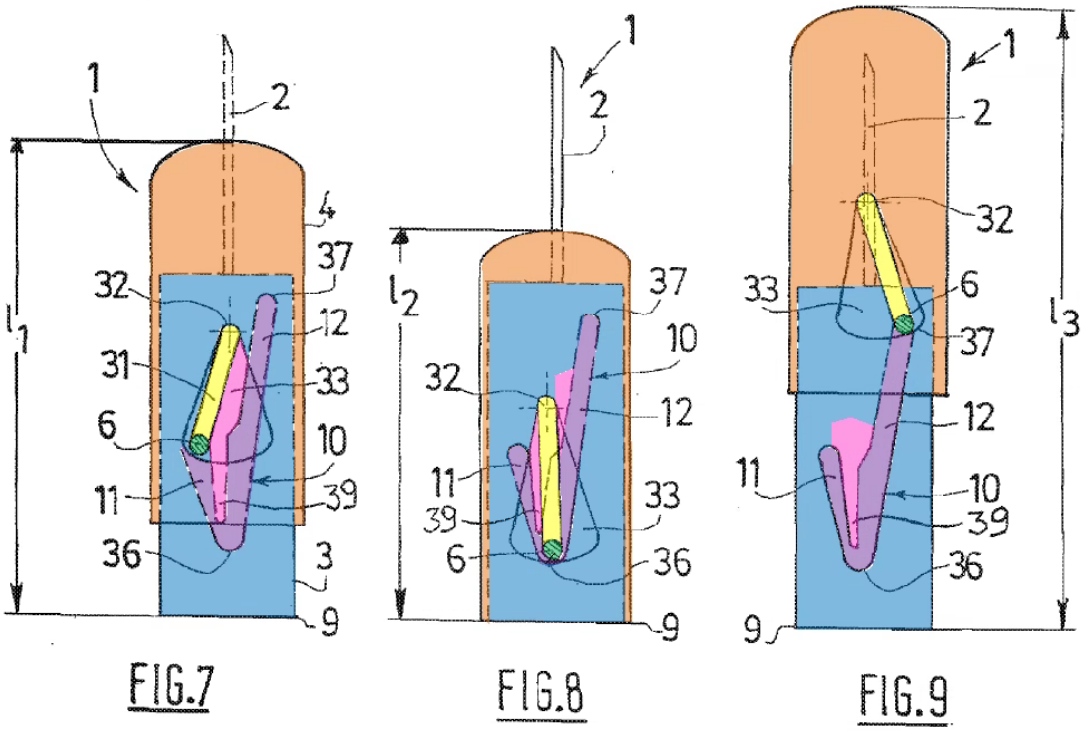
FIG.3

Id., FIGS. 2-3. As illustrated, flexing tab 39 extends into the guide track in a direction parallel to the central axis of the safety device. Ex.1003, ¶116. Thus, Carrel's flexing tab teaches the separating wall, as recited in this limitation. *Id*.

To the extent Patent Owner argues that the flexing tab 39, as depicted in Figures 2-3, does not extend into the guide track in a direction parallel to the central axis of the safety device,[2] Carrel offers additional embodiments of flexing

[2] During prosecution of the '099 Patent's European counterpart, EP Application No. 2,588,168, the European examining corps rejected such an argument from the applicant. *See* Ex.1011, EP Application No. 2,588,168

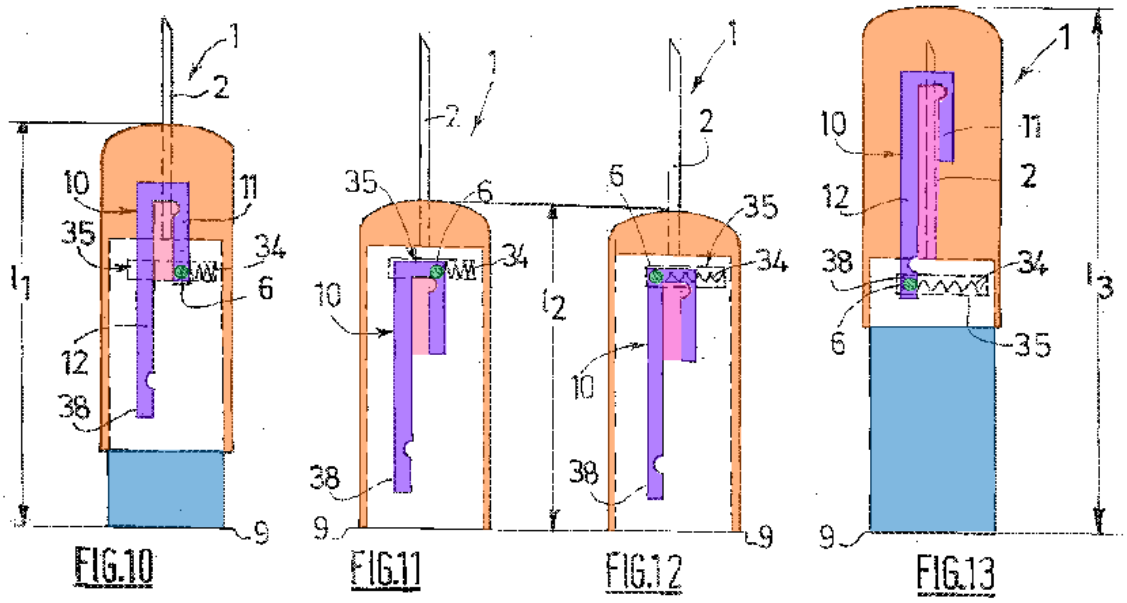
tab 39 that also teach or suggest this limitation. Ex.1003, ¶117. For example, Carrel's Figures 7-9 depict "protection device 1" that " is similar to the device of FIGS. 1 to 6." As set forth in Figures 7-9 below, Carrel's running passageway 10 is "U-shaped…The branches of the U are separated by a flexible tongue 39." *Id.*



Ex.1005, FIGS. 7-9 (annotated). In this embodiment, Carrel again depicts flexing tab 39 extending into the guide track in a direction parallel to the central axis of the safety device. Ex.1003, ¶117.

Prosecution File History, pp. 0203-0204 (Reply of the Patent Proprietor), p. 1140 (Grounds for Decision Rejecting Opposition).

Carrel provides yet an additional embodiment depicting a separating wall that extends into the guide track in a direction parallel to a central axis of the safety device in Figures 10-13.



Ex.1005, FIGS. 10-13.

A POSA would have understood that there were no advantages for using the flexible tongue illustrated in Figures 2-4 over that depicted in Figures 7-9 and/or Figures 10-13 and that implementing one disclosed flexible tongue embodiment or another disclosed embodiment would have been merely a design choice. Ex.1003, ¶119. In view of the foregoing, a POSA would have understood that Carrel's flexing tab teaches the separating wall, as recited in this limitation. *Id.*, ¶119. Thus, Carrel teaches this limitation. *Id.*, ¶¶116-120.

5. [1.4]: "wherein, the guide pin is configured to move along the guide track to deflect the flexible arm in a lateral direction perpendicular to the central axis when the needle shield is slid relative to the support body"

Carrel teaches that its flexible tab 5 is configured to be laterally deflected as peg 6 follows running passageway 10 when sleeve 4 is slid relative to the support 3. *See supra* Section VII.B.4; Ex.1003, ¶121. 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*.

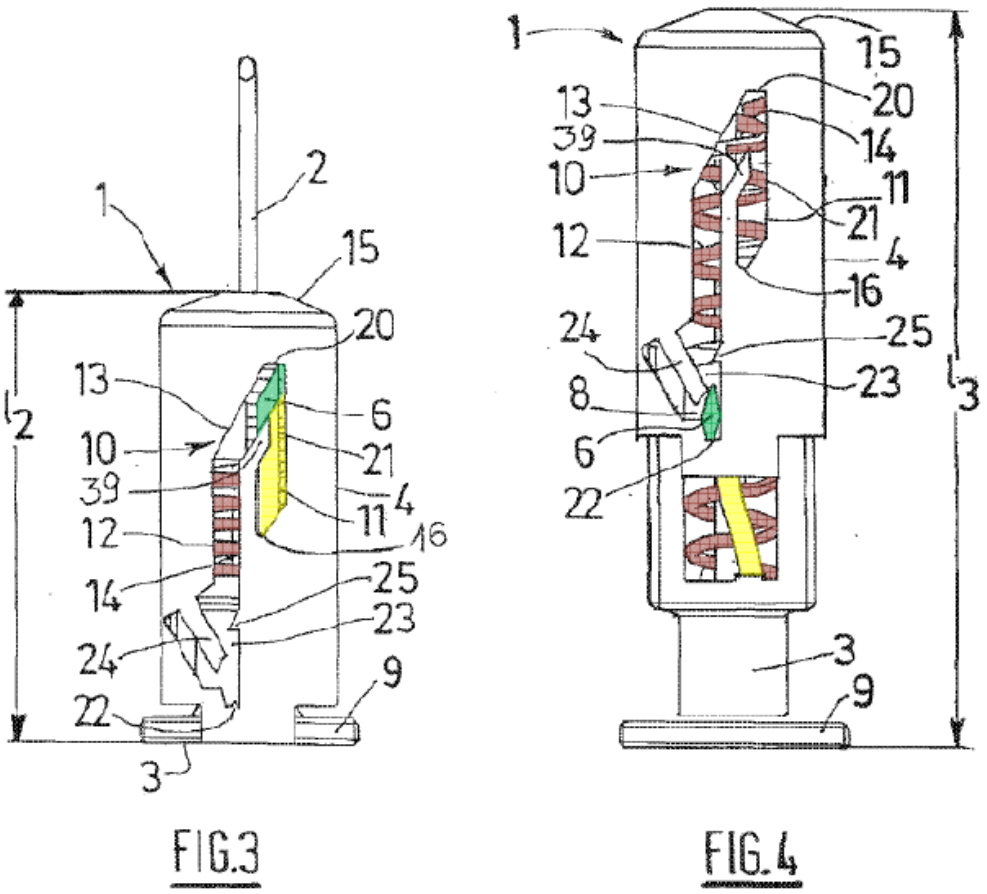


FIG.3 FIG.4

Id., FIGS. 3-4 (annotated). As illustrated in 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 Figure 4). *See* Ex.1005, FIGS. 2-4; Ex.1003, ¶122. Based on the foregoing, a POSA would have understood that Carrel's flexible tab is deflected in a direction perpendicular to the central axis when the needle shield (sleeve 4) is slid relative to the support body (support 3). Ex.1003, ¶122.

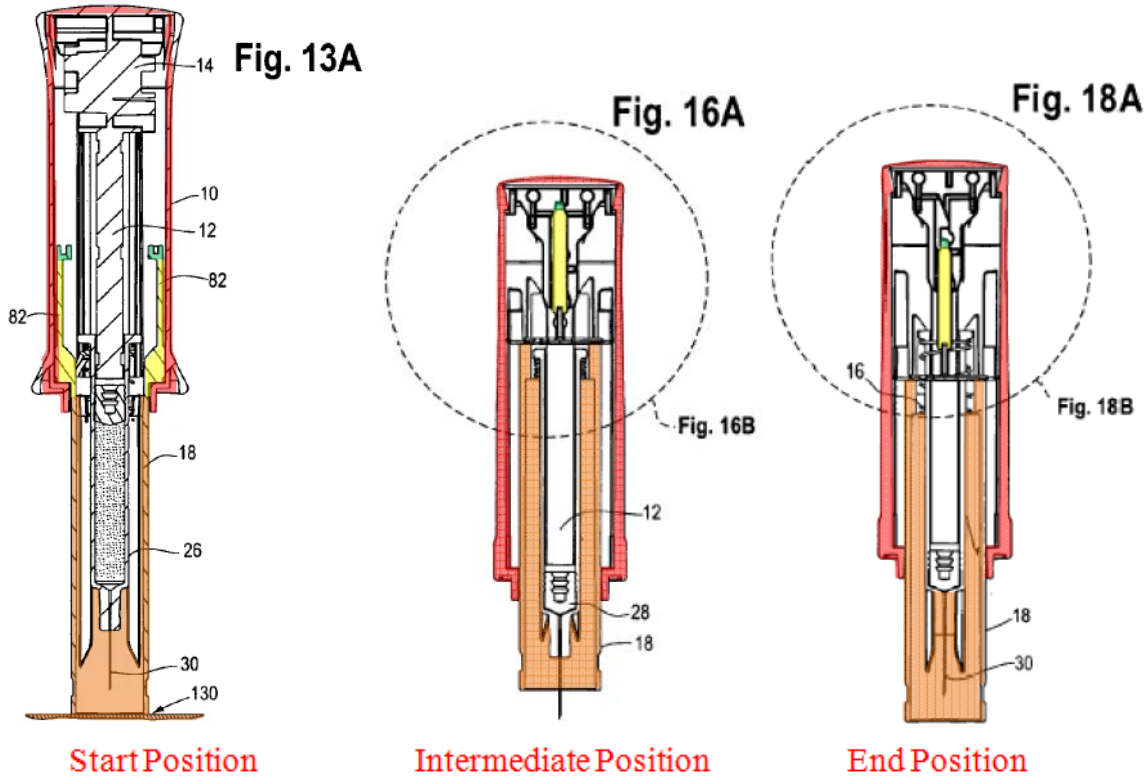
Further, in Figure 1, Carrel's flexible tab 5 is "depicted in its normal position," but tab 5 "is able to move from its normal position to its stressed deflected position within a window 7 cut into the wall of the support 3." Ex.1005, [0053]. Thus, Carrel teaches this limitation. Ex.1003, ¶123.

Although Carrel is the base reference, 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].

6. [1.5]: "wherein the guide pin is movable within the guide track from a start position through an intermediate position to an end position such that a distal end of the needle of the pre-filled syringe is surrounded by the needle shield when the guide pin is in the start position and the end position"

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*. The 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 also teaches that the needle is protected prior to administration of the injection (*id*., [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). Ex.1003, ¶125-126.



Ex.1006, FIGS. 13A, 16A, and 18A (annotated). As illustrated, David-Hegerich wherein the guide pin (hooked end of track follower 82) is movable within the guide track (tracks 42) from a start position through an intermediate position to an end position such that a distal end of the needle of the pre-filled syringe is

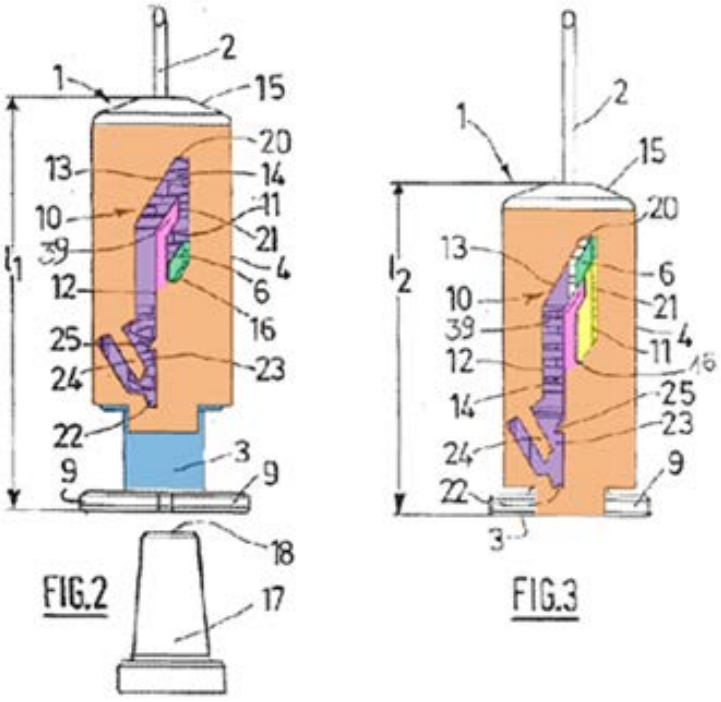
surrounded by the needle shield when the guide pin is in the start position and the end position. Ex.1003, ¶126.

As provided above, it is important to cover and protect a needle before and after an injection event. *See supra*, Section VII.A.; Ex.1003, ¶127. Carrel would benefit from covering and protecting the needle prior to an injection, as taught in David-Hegerich. Ex.1006, [0079]; Ex.1003, ¶127. For this reason, and the reasons set forth above in Section VII.A, a POSA would have been motivated to enhance Carrel's injection device by covering and protecting the needle with sleeve 4 prior to an injection. *Id*. Such a modification may be as simple as extending Carrel's first longitudinal section 11 further toward the proximal end of sleeve 4. *Id*. By extending the first longitudinal section 11, peg 6 would allow sleeve 4 to extend over the tip of the needle. *Id*.

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. Ex.1003, ¶128-130. Thus, Carrel's device, when modified in view of David-Hegerich, teaches this limitation. *Id*.

7. [1.6]: "wherein the flexible arm interacts with the separating wall to guide movement of the guide pin along the guide track"

As provided in Section VII.B.4 above, 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*.

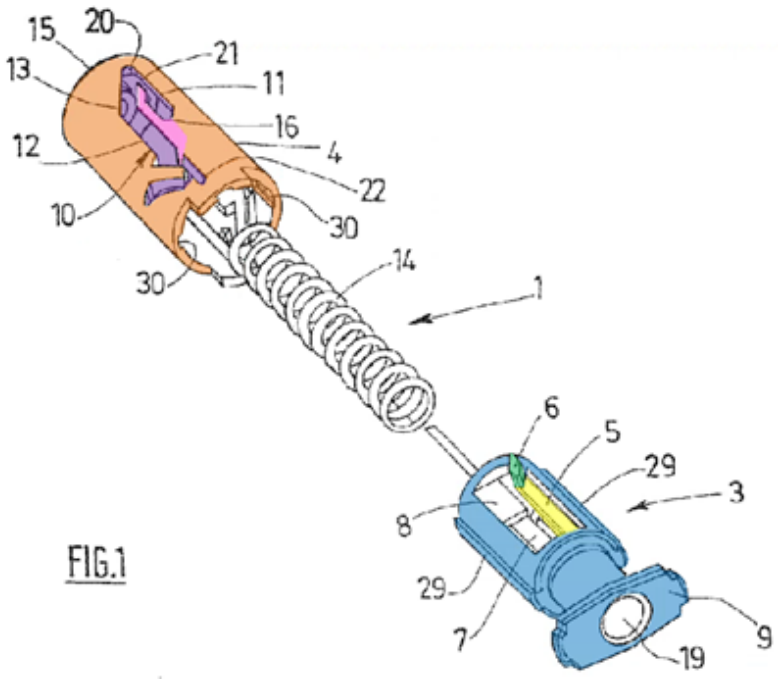


Id., FIGS. 2-3 (annotated in color). By preventing guide pin (peg 6) from returning from second section 12 to first section 11, flexing tab 39 guides the movement of

the guide pin within the guide track (passageway 10). Ex.1003, ¶131. Thus, Carrel teaches this limitation. *Id*., ¶132.

C. Claim 2: "The safety device according to claim 1, wherein the flexible arm is connected to one of the needle shield and the support body, and the guide track is formed into the other of the needle shield and the support body."

This claim recites two alternative embodiments. One of the recited embodiments describes Carrel's preferred embodiment. Ex.1003, ¶¶133-134. As explained throughout Sections VII.B.2-7 above and illustrated in Figure 1, Carrel's flexible arm is connected to the support body and the guide track is formed into the needle shield. *Id*.



Ex.1005, FIG. 1 (annotated in color).

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." *Id*., FIG. 1, [0053]. 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 this claim. Ex.1003, ¶135.

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, ¶136.

Thus, the combination of Carrel and David-Hegerich teaches this claim. *Id*., ¶¶133-137.

D. Claim 3: "The safety device according to claim 1, wherein the separating wall extends into a widened section of the guide track that extends parallel to the central axis of the safety device."

Carrel's flexing tab 39 extends into the guide track in a direction parallel to the central axis of the safety device. *See supra* Section VII.B.4. As illustrated in Figures 1-2, Carrel's separating wall also extends into a widened section of the guide track (longitudinal section 12) that extends parallel to the central axis of the safety device. Separating wall extends into the guide track at a section that is wider than, for example, "narrowing" 23 of the track. Ex.1003, ¶139.

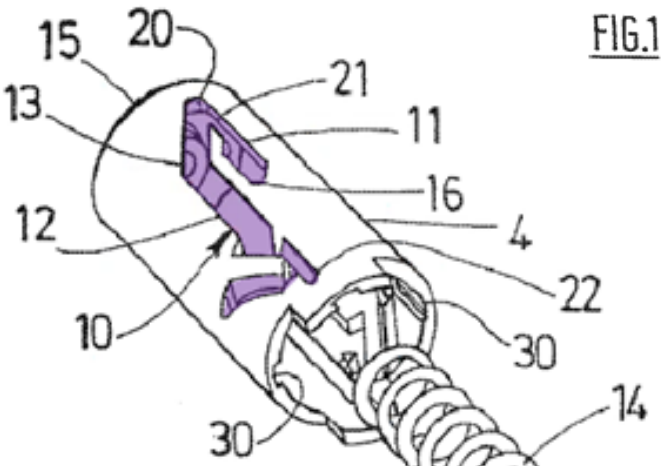


FIG.1

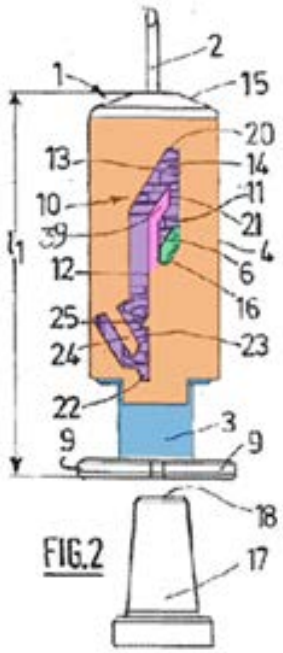
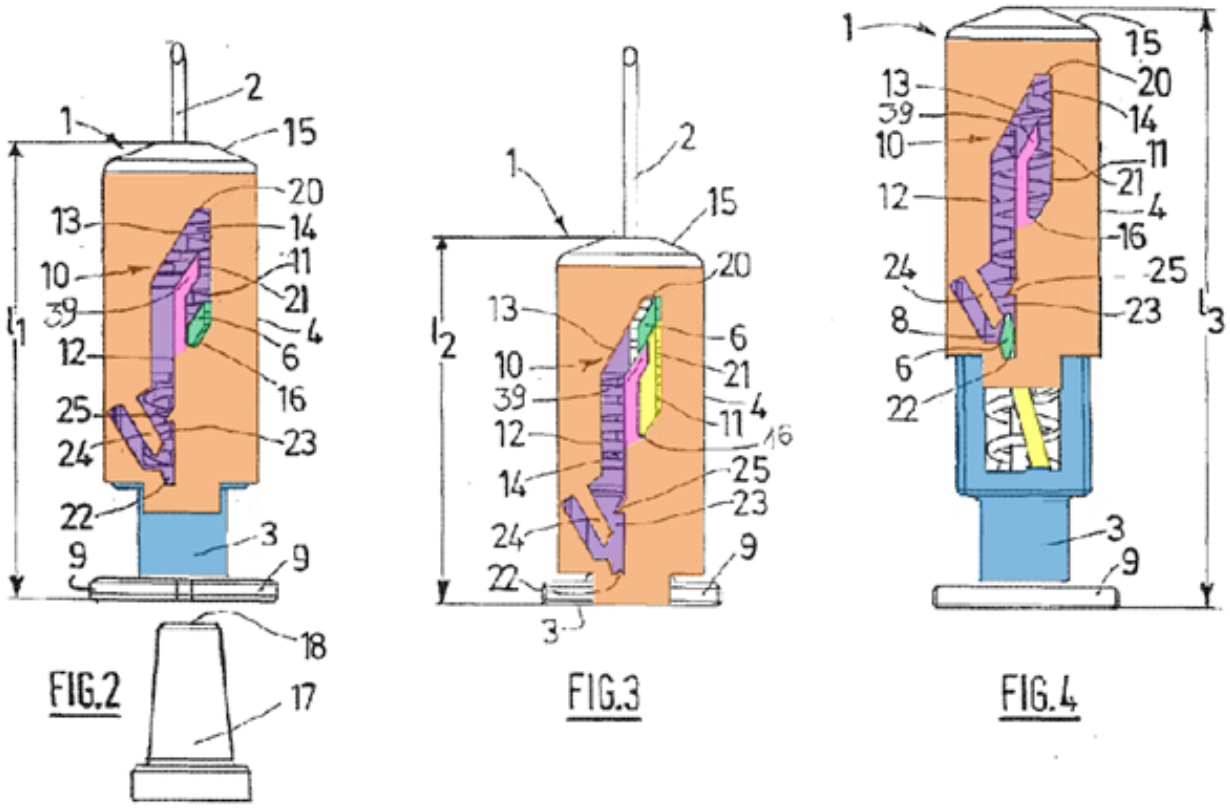


FIG.2

Ex.1005, FIGS. 1-2 (annotated). As illustrated, Carrel's "longitudinal section 12" extends parallel to the central axis of the safety device. Ex.1003, ¶139. Thus, the combination of Carrel and David-Hegerich teaches this claim. *Id*., ¶¶138-139.

E. Claim 4: "The safety device according to claim 1, wherein the separating wall has an axial dimension extending parallel to the central axis that defines substantially a minimal axial distance that the needle shield has to be moved with respect to the support body until the safety device is prevented from re-usage."

Carrel teaches a separating wall (flexing tab 39) that has an axial dimension extending parallel to the central axis that defines substantially a minimal axial distance that the needle shield has to be moved (longitudinal section 11) with respect to the support body (support 3) until the safety device is prevented from re-usage. *Id*., ¶¶141-142. These features are set forth in Figures 2-4 below.

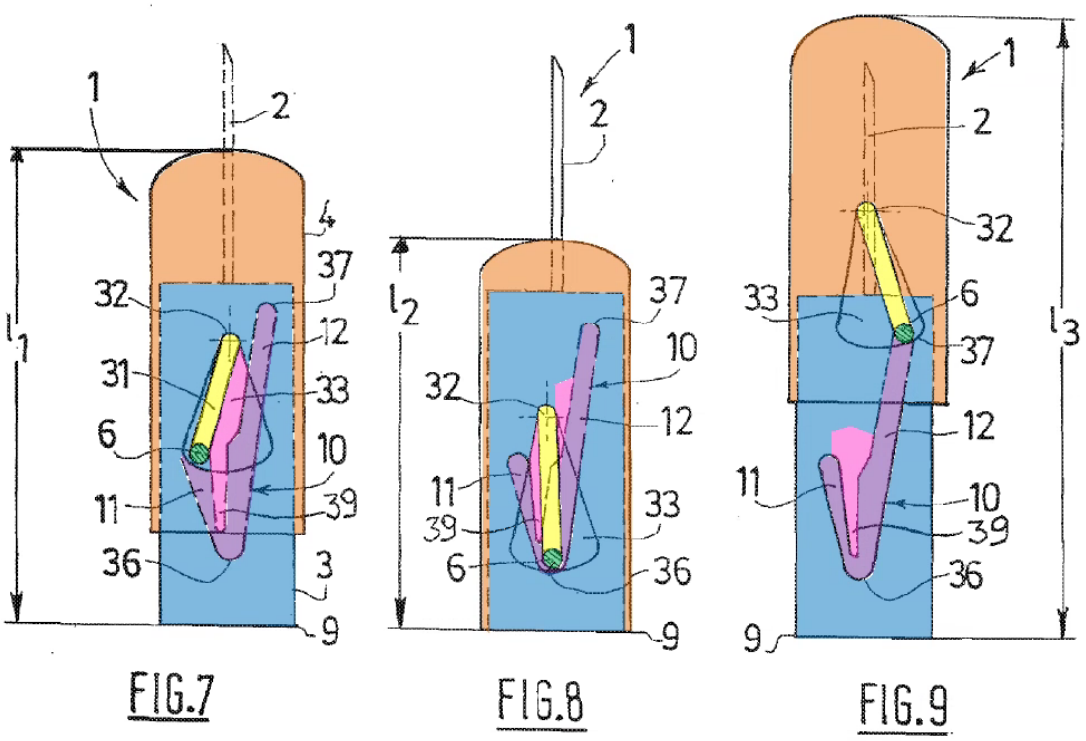


Ex.1005, FIGS. 2-4 (annotated). As illustrated above, "first and second sections have different lengths arranged in such a way as to delimit the said storage and

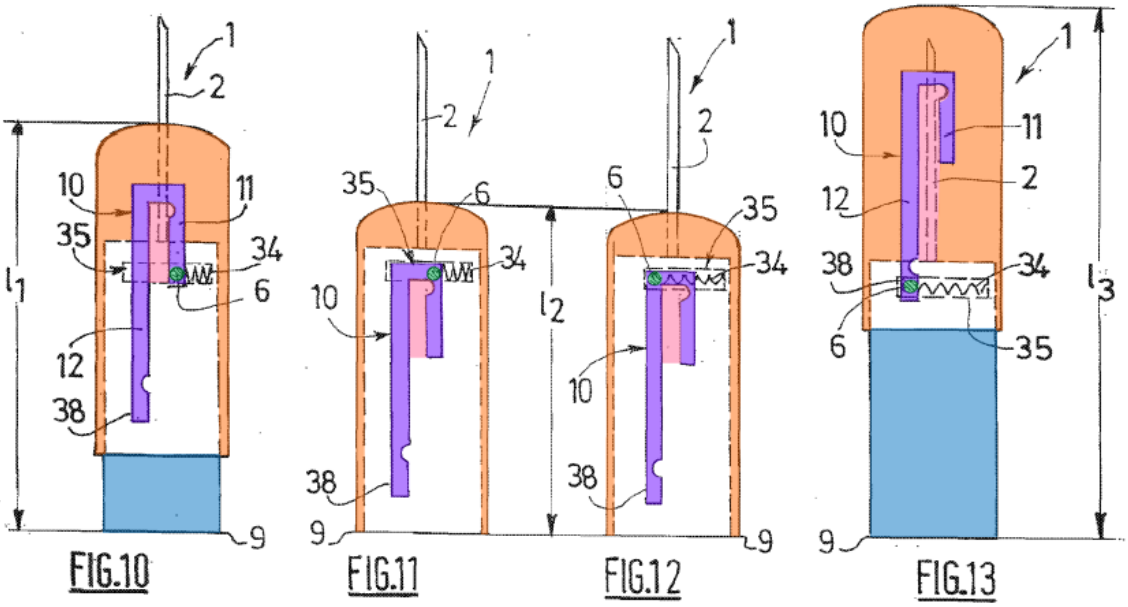
protection positions such that the said distance 13 is greater than the said distance 11." *Id*., [0030].

As can be further seen, "the 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." *Id*., [0066]. This disclosure substantially tracks claim 4's inclusion of a "*separating wall*" that "*has an axial dimension extending parallel to the central axis that defines substantially a minimal axial distance that the needle shield has to be moved with respect to the support body until the safety device is prevented from re-usage*." In the protection position, as depicted in Figure 4, "peg 6 faces the stop wall 8 formed in the window 7 of the support 3. This stop wall 8 prevents the flexible tab 5 from deflecting radially towards the inside of the support: thus, it is not possible to separate the sleeve 4 from the support 3 and to re-expose the needle 2." Ex.1005, [0071].

This feature is also illustrated and taught by the embodiments of Figures 7-13. Ex.1003, ¶143.



Ex.1005, FIGS. 7-9 (annotated).



Ex.1005, FIGS. 10-13 (annotated).

Based on the foregoing, a POSA would have understood that the combination of Carrel and David-Hegerich teaches this claim. Ex.1003, ¶¶140-144.

F. Claim 5: "The safety device according to claim 1, wherein an audible feedback is generated when the needle shield is retracted with respect to the support body by a distance that matches or exceeds a minimal axial distance."

David-Hegerich teaches a track feature that produces an audible noise when contacted by the track follower:

> [T]rack includes a feature, e.g., rib, wall or other feature, wherein the track follower contacts the feature when the medicament is substantially completely expelled from the syringe during the injection…The construction of the track, the feature and the track follower is such that the contact with the track follower with the feature produces an audible sound indicating to the user of the device that the injection of the medicament from the syringe is substantially completed.

Ex.1006, [0013].

A POSA would have understood that if the injection of the medicament from the syringe is substantially completed, the needle shield is retracted with respect to the support body by a distance that matches or exceeds a minimal axial distance. Ex.1003, ¶147. Therefore, the audible sound produced by David-Hegerich's track follower and feature teaches the audible feedback, as claimed. *Id*.

As explained in Section VII.A, Carrel and David-Hegerich are similarly concerned with needle protection. *Id*. ¶148. Carrel would benefit from including

audible feedback to make the user aware that the injection is substantially complete, as taught in David-Hegerich. *Id.* A POSA would have understood that David-Hegerich's audible click informs a user that the needle shield will extend over the needle upon completion of the injection. *Id.* For at least this reason, a POSA would have been motivated to enhance Carrel's injection device by configuring the device to generate audible feedback and doing so would have been a routine engineering exercise to a POSA. *Id*. Thus, the combination of Carrel and David-Hegerich teaches this claim. Ex.1003, ¶¶147-149.

G. Claim 6: "The safety device according to claim 5, wherein the separating wall prevents the guide pin from accessing an end position within the guide track from one of a distal direction and a proximal direction, whereas guide pin is allowed to enter the end position from the other of the distal direction and the proximal direction."

As provided in Section VII.B.4 above, Carrel's Figures 2-3 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].

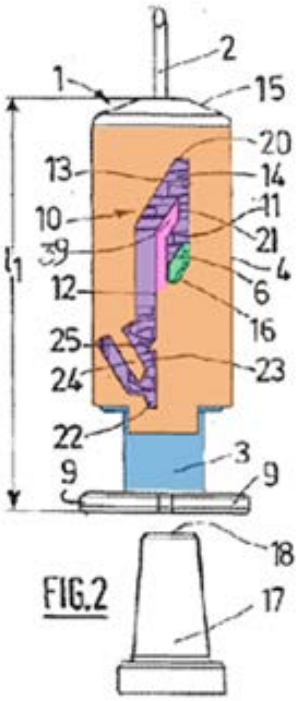


FIG.2

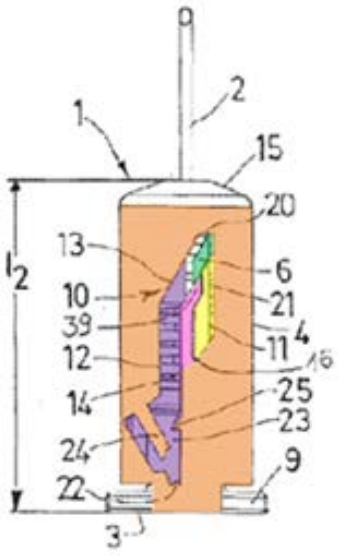


FIG.3

Id., FIGS. 2-3. From the storage position depicted in Figure 2, separating wall (flexible tongue 39) prevents the guide pin (peg 6) from accessing an end position within the guide track from a proximal direction. *See* Ex.1005, [0066]; Ex.1003, ¶152. However, Carrel's guide pin (peg 6) is allowed to enter the end position from the distal direction, relative to the initial position of the guide pin, as set forth in Figure 2 above. *See id*.

Thus, the combination of Carrel and David-Hegerich teach this claim. Ex.1003, ¶¶150-153.

H. Claim 7: "The safety device according to claim 1 wherein the guide track is formed into a surface of the support body or into a surface of the needle shield as a recess."

The '099 Patent's guide track forms a recess when the guide track is inaccessible from the outside of the support body or needle shield. *See supra* V.A; Ex.1003, ¶155.

As explained in Sections VII.B-C above and illustrated in Figures 2-4, Carrel's guide track (passageway 10) forms an aperture in the needle shield. *Id*., ¶156. Carrel also teaches an alternate embodiment with the opposite configuration. Specifically, Carrel teaches that "the running passageway 10 is formed within the wall of the support 3." Ex.1005, [0073]. Thus, Carrel's guide track may be formed into a surface of the support body or into a surface of the needle shield. Ex.1003, ¶156.

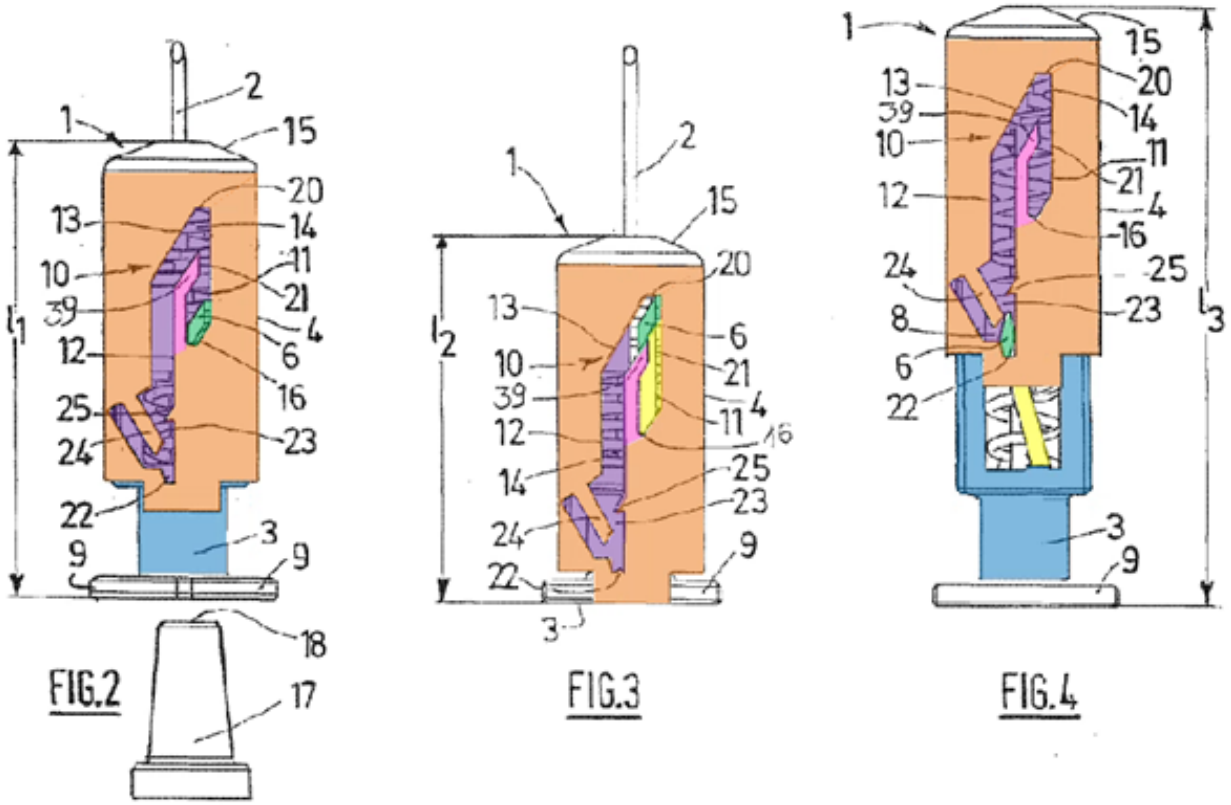
To the extent Patent Owner argues that Carrel's guide track is not a "recess," this limitation was known in the art, as taught by David- Hegerich. *Id*., ¶157. For example, as provided in Section VII.B.6 above with respect to element [1.5], David-Hegerich teaches a "track follower 82 of the needle guard 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 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]. Accordingly, a POSA would have understood that David-Hegerich's walls or grooves teach a "recess" as claimed. Ex.1003, ¶158.

At least for the reasons set forth in Section VII.A above, a POSA would have been motivated to enhance Carrel's injection device with the David-Hegerich's teachings. *Id*., ¶159. Thus, Carrel's device, when modified in view of David-Hegerich, teaches this claim. *Id*.

I. Claim 8: "The safety device according to claim 1, wherein the guide track forms an aperture in one of the needle shield or the support body."

As illustrated in the '099 Patent's Figure 1, the guide track forms an aperture when a portion of the needle shield or support body is cut out. *See supra* V.A; Ex.1003, ¶161. As explained in Sections VII.B-C above and illustrated in Figures 2-4, Carrel's guide track (passageway 10) forms an aperture in the needle shield. *Id*., ¶162.

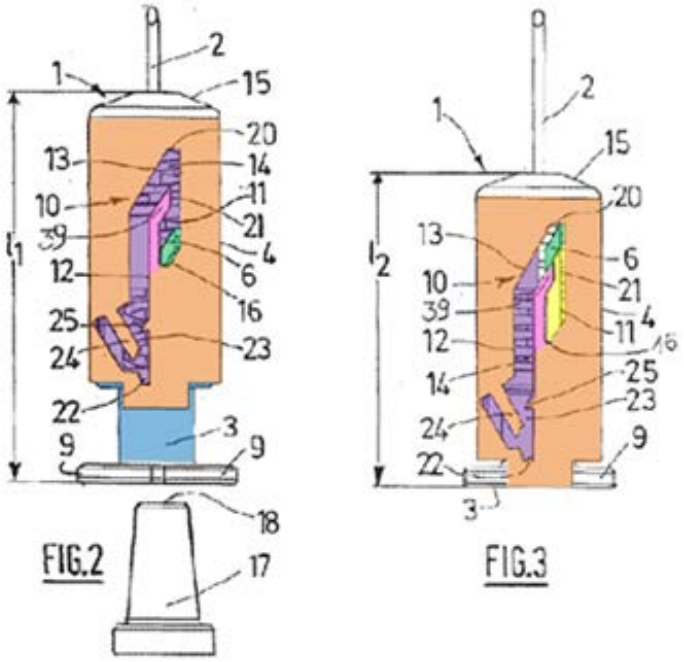


Ex.1005, FIGS. 2-4 (annotated). As illustrated, Figures 2-4 depicts a guide track that forms an aperture in needle shield (sleeve 4). Ex.1003, ¶162. Thus, the combination of Carrel and David-Hegerich teaches this claim. Ex.1003, ¶¶161-163.

J. Claim 9: "The safety device according to claim 8, wherein the separating wall is flexible and the guide pin moves along the guide track to deflect the separating wall, whereby the deflection of the flexible separating wall depends on the deflection of the flexible arm."

As provided in Sections VII.B.4 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]; Ex.1003, ¶165.

Carrel further discloses that the flexible tongue 39 is "elastically deformable" (i.e., flexible) and is configured to prevent "peg 6 from returning from the said second section 12 to the said first section 11." Ex.1005, [0066]. 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]. Flexible tongue deflects when it is bent by peg 6. Ex.1003, ¶166 These elements are set forth in Figures 2-3, included below.



Ex.1005, FIGS. 2-3.

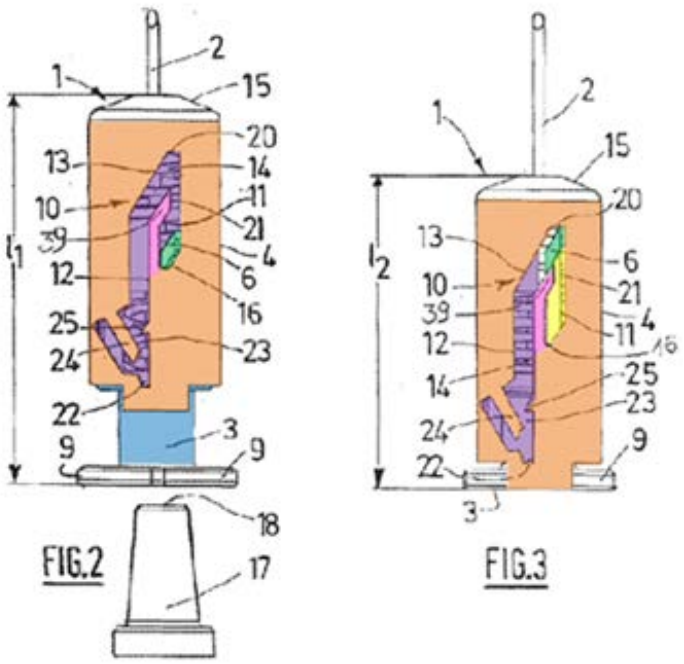
As described and illustrated above, Carrel's separating wall (flexing tab 39) is flexible and the guide pin (peg 6) moves along the guide track (passageway 10) to deflect the separating wall, whereby the deflection of the flexible separating wall

depends on the deflection of the flexible arm (flexible tab 5) because the separating wall would remain stationary but for the force applied by the deflecting flexible arm. *See id*., [0077]; Ex.1003, ¶167. Thus, the combination of Carrel and David-Hegerich teaches this claim. *Id*., ¶¶164-167.

K. Claim 10: "The safety device according claim 8, wherein an elasticity of the separating wall is adapted to an elasticity of the flexible arm, so that the separating wall is deflectable by the deflected flexible arm."

As provided in Sections VII.B.4 and VII.J 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.

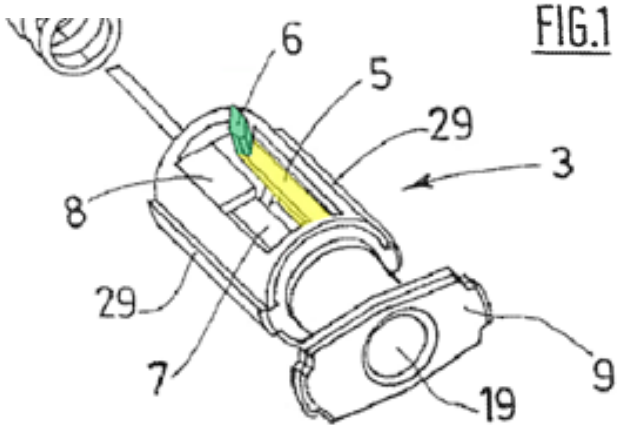


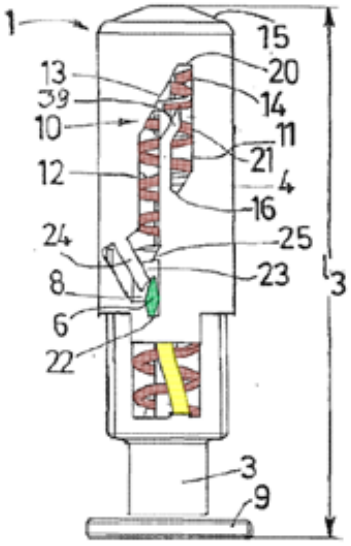
Id., FIGS. 2-3. To operate as described, the elasticity of the separating wall (flexible tongue 39) must be adapted, or proportional, to the elasticity of the flexible arm. Ex.1003, ¶¶170. For example, if the separating wall were significantly more rigid than the flexible arm, it is possible that the guide pin would not be able to cause the separating wall to deflect, as described. *Id*. Thus, a POSA would have understood that the combination of Carrel and David-Hegerich teaches this claim. Ex.1003, ¶¶168-171.

L. Claim 11: "The safety device according to claim 1 wherein the guide pin is biased in the lateral direction by the deflected flexible arm."

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 structure of Carrel's flexible tab 5 and peg 6 are set forth in Figures 1 and 4 below.





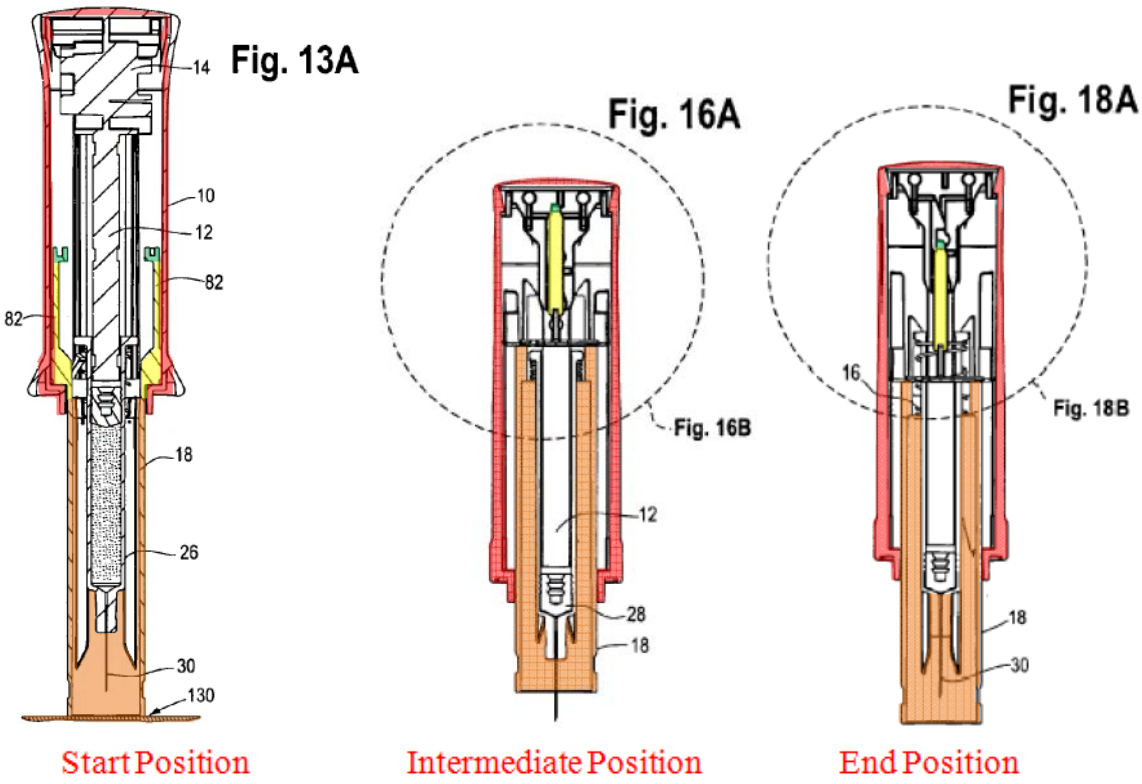
Id., FIGS. 1 and 4 (annotated).

As illustrated, Figure 4 shows the guide pin (peg 6) is biased in the lateral direction (to the left) by the deflected flexible arm (flexible tab 5). *See id*., [0069]; Ex.1003, ¶173. Thus, the combination of Carrel and David-Hegerich teaches this claim. Ex.1003, ¶¶172-174.

M. Claim 12: "The safety device according to claim 1, wherein the flexible arm in a rest position extends essentially parallel to the central axis, the flexible arm being in the rest position when the guide pin is in the start position and the end position"

In the embodiment described in Section VII.B.4.c above with respect, Carrel's Figures 3 and 7-9, Carrel's flexible arm appears to extend essentially parallel to the central axis in either the starting position or the intermediate, injection position. Ex.1003, ¶176. Dependent claim 12 of the '099 Patent, however, requires that the flexible arm be at a rest position, extending essentially parallel to the central axis, at the end position. Carrel does not describe such an embodiment. *Id*. But devising an alternate guide track so that the flexible arm meets these requirements would nonetheless have been obvious to a POSA. *Id*. Indeed, David-Hegerich discloses just such an alternative configuration for its flexible arm.

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).

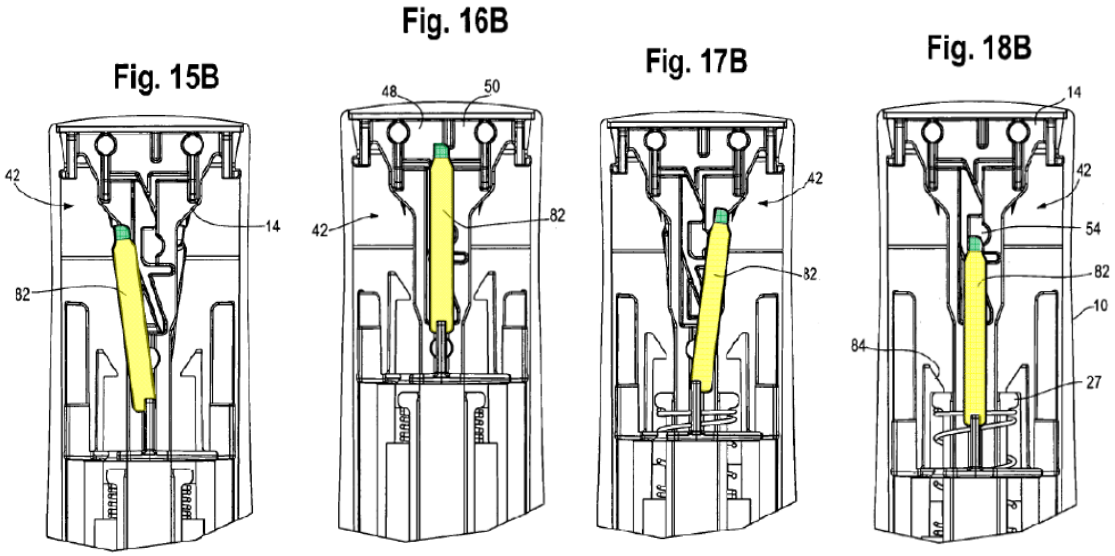
The David-Hegerich track followers 82 follow tracks 42, which are "any physical structure, whether characterized by walls, grooves, slots, or combination thereof, which serves a function to guide the travel of another part, the 'track follower.'" *Id*., [0065]. David-Hegerich provides additional details 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, ¶179. 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*.



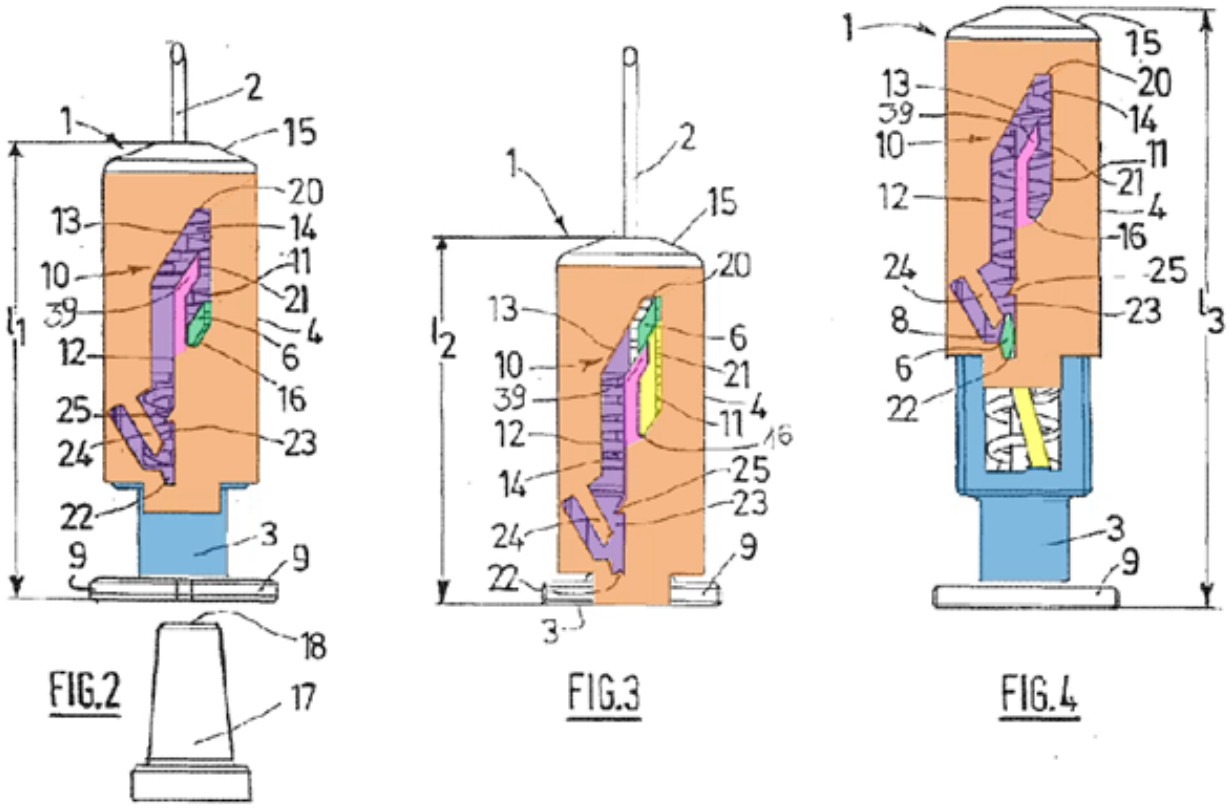
Ex.1006, FIGS. 15B, 16B, 17B, and 18B (annotated).

David-Hegerich thus teaches an alternate configuration for a deflectable, flexible arm extends essentially parallel to the central axis, the flexible arm being in the rest position when the guide pin is in the start position and the end position. 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, ¶180. 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 flexible arm in Carrel's modified device to achieve the configuration set forth in dependent claim 12 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. Ex.1003, ¶¶175-181.

N. Claim 13: "The safety device according to claim 1, wherein the guide track comprises an inclined section oriented at an angle with respect to the central axis."

As illustrated in Figures 2-4, the "first longitudinal section 11 comprises, situated proximally at its distal end 20, a narrowing 21 defined by a flexible tongue 39." Ex.1005, [0066]. Carrel's inclined section (narrowing feature 21) is illustrated in Figures 2-4 below.



Id., FIGS 2-4 (annotated). Based on the foregoing, Carrel's guide track (passageway 10) comprises an inclined section (narrowing 21 of tongue 39)

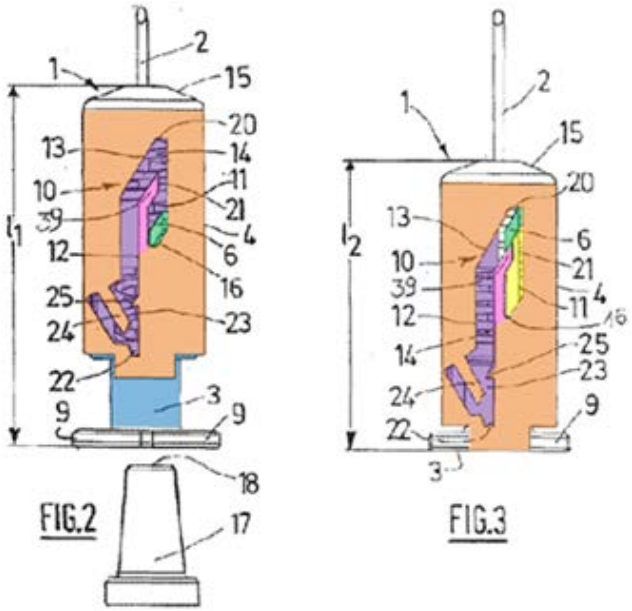
oriented at an angle with respect to the central axis. *See* Ex.1005, [0066]; Ex.1003, ¶184.

Thus, the combination of Carrel and David-Hegerich teaches this claim. Ex.1003, ¶¶182-184.

O. Claim 14: "The safety device of claim 13, wherein the needle shield is retained in an initial position by the guide pin being retained in the start position within the inclined section of the guide track, the needle shield in the initial position protruding the support body in a distal direction, the needle shield is movable from the initial position to a retracted position and further to an advanced position, the needle shield protruding the support body in the initial position and in the advanced position."

Carrel teaches wherein the needle shield is retained in an initial position by the guide pin (peg 6) being retained in the start position within the inclined section (narrowing feature 21) of the guide track (passageway 10). *Id*., ¶186.

Carrel's Figures 2-4 each illustrate that its flexible tongue 39 is "elastically deformable." Ex.1005, [0066]. 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." *Id*., [0077].



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 retains 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, ¶188. In other words, absent a sufficient applied force, the tongue 39 interferes with the movement peg 6, retaining the needle shield in an initial position. *Id. Only* after a sufficient applied force is applied will the peg 6 pass tongue 39 as the needle shield moves away from the initial position. *Id.*

As provided in Section VII.B.6, Carrel does not teach (and David-Hegerich does teach) the needle shield in the initial position protruding the support body in a distal direction, the needle shield is movable from the initial position to a retracted position and further to an advanced position, the needle shield protruding the support body in the initial position and in the advanced position.

As provided above, a POSA would have appreciated the importance of covering and protecting a needle before and after an injection event. *See supra*, Section VII.A; Ex.1003, ¶¶189-190. Carrel, specifically, would benefit from covering and protecting the needle prior to an injection, as taught in David-Hegerich, to protect the needle from damage and to protect against an accidental needle stick. Ex.1006, [0079]; Ex.1003, ¶¶190-194. For this reason, and the reasons set forth above in Section VII.A, a POSA would have been motivated to enhance Carrel's injection device by covering and protecting the needle with sleeve 4 prior to an injection. Ex.1003, ¶194. Such a modification may be as simple as extending Carrel's first longitudinal section 11 further toward the proximal end of sleeve 4. *Id*. By extending the first longitudinal section 11, peg 6 would allow sleeve 4 to extend over the tip of the needle. *Id*.

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.*, ¶195.

Thus, Carrel's device, when modified in view of David-Hegerich, teaches this claim. *Id*., ¶¶185-195.

P. Claim 16: "The safety device of claim 1, further comprising a first longitudinal groove and a first longitudinal tongue to inhibit relative rotation of the needle shield and the support body."

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].

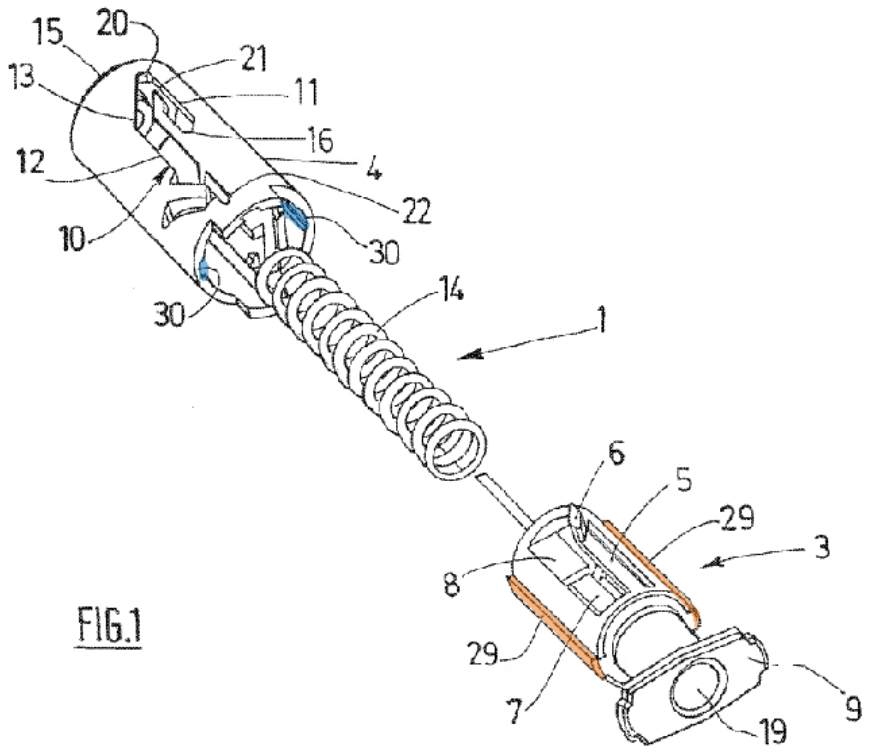


FIG.1

Id., FIG. 1 (annotated). As illustrated, one of Carrel's slideways 30 (shaded in blue) is the claimed longitudinal groove, and one of Carrel's longitudinal bulges 29 (shaded in orange) is the claimed longitudinal tongue. Ex.1003, ¶197.

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 a way 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, [0084] ; Ex.1003, ¶198.

Thus, the combination of Carrel and David-Hegerich teaches this claim. Ex.1003, ¶196-199.

Q. Independent Claim 17

There is no material difference between claim elements [17.P]-[17.7] and elements [1.P]-[1.6] of claim 1. For at least the reasons described in Sections VII.B.1-7 above, Carrel as modified in view of David-Hegerich, renders independent claim 17 obvious. *Id*., ¶¶90-132, 200-211.

1. [17.P]: "[a]n injection device"

This claim element is substantially similar to element labeled [1.P] herein. For at least the reasons described in Section VII.B.1 above, Carrel teaches this limitation. *Id*., ¶¶90-91, 201.

2. [17.1]: "a pre-filled syringe with a hypodermic needle attached to a distal end of the pre-filled syringe;

This claim element is substantially similar to element labeled [1.P] and [1.1] herein. For at least the reasons described in Sections VII.B.1-2 above, Carrel teaches this limitation. *Id*., ¶¶90-101, 202.

3. [17.2]: "a safety device comprising: a hollow support body for mounting the pre-filled syringe therein such that the hypodermic needle protrudes past a distal end of the support body"

This claim element is substantially similar to elements labeled [1.1] herein. For at least the reasons described in Section VII.B.2 above, the combination of Carrel and David-Hegerich teaches this limitation. *Id*., ¶¶92-101, 203.

4. [17.3]: "a hollow needle shield that is slidable relative to the support body, the needle shield and the support body being configured such that relative rotation of the support body and the needle shield is inhibited"

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*., ¶¶102-106, 204.

5. [17.4]: "a guiding mechanism to guide movement of the needle shield relative to the support body, the guiding mechanism comprising:"

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*., ¶¶107, 205.

a. [17.4.A-B]: "a flexible arm, a guide pin extending from the flexible arm in a radial direction"

These claim elements are substantially similar to elements labeled [1.3.A] and [1.3.B] herein. For at least the reasons described in Section VII.B.4.a above, Carrel teaches this limitation. *Id*., ¶¶108-111, 206.

b. [17.4.C]: "a guide track, wherein the guide pin protrudes into the guide track"

This claim element is substantially similar to element labeled [1.3.C] herein. For at least the reasons described in Section VII.B.4.b above, Carrel teaches this limitation. *Id*., ¶¶112-115, 207.

c. [17.4.D]: "a separating wall that extends into the guide track in a direction parallel to a central axis of the safety device"

This claim element is substantially similar to element labeled [1.3.D] herein. For at least the reasons described in Section VII.B.4.c above, Carrel teaches this limitation. *Id*., ¶¶116-120, 208.

6. [17.5]: "wherein the guide pin is configured to move along the guide track to deflect the flexible arm in a lateral direction perpendicular to the central axis when the needle shield is slid relative to the support body"

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*., ¶¶121-124, 209.

7. [17.6]: "wherein the guide pin is movable within the guide track from a start position through an intermediate position to an end position such that a distal end of the needle of the pre-filled syringe is surrounded by the needle shield when the guide pin is in the start position and the end position"

This claim element is substantially similar to element labeled [1.5] herein. For at least the reasons described in Section VII.B.6 above, David-Hegerich teaches this limitation. *Id*., ¶¶125-130, 210.

8. [17.7]: "wherein the flexible arm interacts with the separating wall to guide movement of the guide pin along 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*., ¶¶131-132, 211.

R. Claim 18: "The safety device of claim 17, wherein the needle shield is movable from an initial position to a retracted position and further to an advanced position, the needle being surrounded by the needle shield in the initial position and in the advanced position and exposed in the retracted position."

This claim is substantially similar to claim 14 herein. For at least the reasons described in Section VII.O above, the combination of Carrel and David-Hegerich teaches this claim. *Id*., ¶¶185-195, 212-213.

S. Claim 19: "The safety device of claim 17, wherein the flexible arm in a rest position extends essentially parallel to the central axis, the flexible arm being in the rest position when the guide pin is in the start position and the end position."

This claim is substantially similar to claim 12 herein. For at least the reasons described in Section VII.M above, the combination of Carrel and David-Hegerich teaches this limitation. *Id*., ¶¶175-181, 214-215.

VIII. West Pharmaceutical Services, Inc. is Unaware of Any Secondary Considerations of 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 '099 Patent is available for *inter partes* review, and that West Pharma is not barred or estopped from requesting an *inter partes* review of the '099 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 ’099 Patent being the subject of any civil action or 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 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/

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. 9,586,099**, Petitioner's Power of Attorney, and all associated exhibits were served in their entireties on the following party via Express Mail:

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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 13,939 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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Jon E. Wright, Reg. No. 50,720
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Date: June 1, 2018

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