

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

DECLARATION OF CHARLES E. CLEMENS

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Ex. 1003
West Pharma v. Sanofi
U.S. Patent No. 9,586,011

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I. Introduction

I, Charles E. Clemens, resident at 1621 Hill Top Lane, Encinitas, CA 92024, hereby declare as follows:

1. I have been retained as an expert witness by Sterne, Kessler, Goldstein & Fox PLLC to provide testimony on behalf of West Pharmaceutical Services, Inc. (“West” or “Petitioner”) for the above-captioned *inter partes* review proceeding. This Declaration concerns technical subject matter relevant to the *inter partes* review petition (the “Petition”) concerning U.S. Patent No. 9,586,011 (“the ’011 Patent”) titled “Safety device for a pre-filled syringe and injection device” by Gareth Roberts *et al.* It is my understanding that ’011 Patent is currently assigned Sanofi-Aventis Deutschland GMBH (“Sanofi” or “Patent Owner”).

2. I am over 18 years of age. I have personal knowledge of the facts stated in this Declaration and could testify competently to them if asked to do so. I am being compensated for my time at the rate of \$495 per hour. My compensation is not contingent upon the content of my testimony nor on the outcome of this *inter partes* review.

3. I have reviewed and am familiar with the specification and claims of the ’011 Patent. I will cite to the specification using the following format: Ex. 1001, 1:1-10. This example citation points to Exhibit 1001, the ’011 Patent, specification at column 1, lines 1-10.

4. I have reviewed and am familiar with the following documents and materials:

Exhibit	Description
1001	U.S. Patent No. 9,586,011 to Roberts <i>et al.</i>
1005	U.S. Patent Application Publication No. 2009/0024093 to Carrel <i>et al.</i> (“Carrel”)
1006	U.S. Patent Application Publication No. 2008/0228147 to David-Hegerich <i>et al.</i> (“David-Hegerich”)
1007	WHO guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health care settings, World Health Organization (2016) (“WHO Guideline”)
1008	Smetana, EpiPen inventor helped millions and died in obscurity, Tampa Bay Times (accessed on May 7, 2018 at: http://web.archive.org/web/20130201055705/http://www.tampabay.com/news/humaninterest/epipen-inventor-helped-millions-and-died-in-obscurity/1038756) (“Smetana”)
1009	Rex, J., A Review of 20 Years’ Experience With the Novapen Family of Insulin Injection Devices, Clinical Drug Investigation (August 10, 2006) (“Rex”)
1010	Popken, B., Mylan’s Upgraded EpiPen Torn Apart By Experts, NBC News (accessed on May 8, 2018 at: https://www.nbcnews.com/business/consumer/mylan-says-it-upgraded-epipen-2009-so-experts-looked-inside-n652651) (“Popken”)

I understand that Carrel and David-Hegerich are both prior art to the ’011 Patent. I have also considered all other materials cited herein.

5. To the best of my knowledge, Exhibits listed in the above table, and that I reviewed, are true and accurate copies of what they purport to be. As publications from the U.S. Patent and Trademark Office, an expert in the field would reasonably rely on them to formulate opinions such as those set forth in this declaration.

6. The '011 Patent describes a “[s]afety device for a pre-filled syringe and injection device.” Ex. 1001, '011 Patent, Title. I am familiar with the technology described in the '011 Patent as of its July 2, 2010 priority date.

7. I have been asked to provide my technical review, analysis, insights, and opinions regarding the '011 Patent and the references that form the basis for the grounds of rejection set forth in the Petition for *Inter Partes* Review of the '011 Patent.

II. Qualifications and Expertise

8. I received a Bachelor's Degree in Mechanical Engineering from San Diego State University in 1979. From 1979 to 1981, I worked as a Program Manager at Carbomedics Inc., a manufacturer of pyrolytic carbon coated bioimplants, such as heart valves.

9. Between 1981 and 1995, I held various positions at IVAC Corp., (later Alaris Medical Systems, now Carefusion, Inc.), the largest manufacturer of drug delivery and vital signs devices in the United States. From 1981 to 1983, I

was the Department Manager of the Instrument Sustaining Engineering Department (1981-1983) at IVAC. From 1984-1995, worked in the Product Development Engineering Department at IVAC, initially as the Mechanical Engineering Department Manager (1984-1990), and later as the Technical Leader (1991-1995) for the highest featured and most technically advanced automated drug delivery system in the company's history.

10. In 1995, I founded a consulting company (Clemens Consulting Co.), specializing in technical and management consulting for medical device and in-vitro diagnostic product development.

11. My specific areas of expertise include intravenous drug delivery systems, drug injector pens, insulin delivery systems, intravenous disposable sets and components, and blood handling equipment and disposable circuits such as those used for dialysis and blood collection systems. I thus have extensive experience related to the technology at issue in this proceeding.

12. Since the early 1990's, I have been aware of and involved in needle-stick safety awareness. Much of my design development experience has involved devices, methods, and systems that deal either directly, or indirectly, with needle use. For example, I developed and sustained in manufacturing numerous single use disposable needle assemblies and components for IVAC Corp. In 2006, I redesigned and optimized a single use auto-injector design for epinephrine

featuring dual dose capability with needle shield called TwinJect®, manufactured then by Verus Pharmaceutical (now marketed as Adrenaclick® by Amedra Pharmaceuticals). I have researched and analyzed the auto-injector device design of Mylan's EpiPen® with and without automatic safety needle shield, and I investigated patented precision low flow measurement technology for application to drug delivery and blood handling systems.

13. I co-invented a system and method for conducting hemodialysis and hemofiltration that requires needle use (see U.S. Patent No. 8,114,288), and I am a named inventor on many other patents and published patent applications in the medical device field, which are listed in my attached resume.

14. Whether working directly or indirectly with needles, persons skilled in the art understand that special considerations must be taken to ensure needle safety and integrity, and to prevent accidental needle sticks.

15. My Curriculum Vitae is provided as Exhibit 1004, which contains further details on my education, experience, and other qualifications to render an expert opinion.

III. Legal Understanding

A. My Understanding of Claim Construction

16. I understand that claim terms are given their ordinary and customary meaning as would be understood by a person of ordinary skill in the relevant art in

the context of the entire disclosure. A claim term, however, will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the claim term in the specification. In such a case, the claim term will receive the definition set forth in the patent.

B. Level of Ordinary Skill in the Art

17. I have been informed that in considering the validity of a patent, the analysis is always through the lens of a hypothetical “person of ordinary skill in the art,” or a “POSA.” Here, the “art” is needle-based, self-injection, drug delivery devices having prefilled syringes, and the always-present usability and safety concerns that accompany such devices.

18. In ascertaining the appropriate level of ordinary skill in the art, I am informed that 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 active 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.

19. Based on the disclosure of the '011 Patent, it is my opinion that one of ordinary skill in the art would be a person with an undergraduate degree in

mechanical engineering, and 3-5 years of work in designing needle-based drug delivery systems beyond the completion of their degree.

20. I am well qualified to determine the level of ordinary skill in the art. At the outset, I was personally very familiar with the technology of the '011 Patent in the July 2010 timeframe.

21. Moreover, by 2010, I had completed my formal education and had been working in the relevant field for more than 27 years. I have supervised, recruited, advised, and taught individuals at all levels of training in the relevant field. And as a technical consultant, I have worked with individuals in industry at all levels of training in the relevant field.

22. I thus understand the knowledge and expertise one of ordinary skill in the art of needle-based drug delivery systems would possess.

C. My Understanding of Obviousness

23. I am not a lawyer and will strive not to provide any legal opinions. Although I am not a lawyer, I have been advised that certain legal standards are to be applied by technical experts in forming opinions regarding meaning and validity of patent claims.

24. I understand that a patent claim is invalid if the claimed invention would have been obvious to a person of ordinary skill in the field at the time the application was filed. This means that even if all of the requirements of the claim

cannot be found in a single prior art reference, the claim can still be invalid if it would have been obvious to the ordinarily skilled artisan over a combination of prior-art references.

25. As part of this inquiry, I have been asked to consider the validity of the challenged '011 Patent claims from the perspective of a POSA (*see* ¶19 above), at the time the claimed invention was made.

26. To obtain a patent, a claimed invention must have, as of the priority date, been nonobvious in view of the prior art in the field. I understand that an invention is obvious when the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

27. I understand that to prove that prior art, or a combination of prior art, renders a patent obvious, it is necessary to: (1) identify the particular references that singly, or in combination, make the patent obvious; (2) specifically identify which elements of the patent claim appear in each of the asserted references; and (3) explain how the ordinarily skilled artisan would have combined or modified the prior art references to create the inventions claimed in the challenged claims.

28. I also understand that prior art references can be combined under several different circumstances. For example, it is my understanding that one such

circumstance is when a proposed combination or modification of prior art references results in a system that represents a predictable variation, which is achieved using prior art elements according to their established functions.

29. I understand that certain objective indicia (secondary indicia) can be important evidence in avoiding hindsight when determining whether a claim is obvious or nonobvious. I have been informed that such indicia include: commercial success of products covered by the patent claims; a long-felt need for the invention; failed attempts by others to make the invention; copying of the invention by others in the field; unexpected results achieved by the invention as compared to the closest prior art; praise of the invention by the infringer or others in the field; the taking of licenses under the patent by others; expressions of surprise by experts and those skilled in the art at the making of the invention; and the patentee proceeded contrary to the accepted wisdom of the prior art.

30. I further understand that such evidence must have a nexus, or causal relationship to the elements of a claim, in order to be relevant to the obviousness or non-obviousness of the claim.

31. At this point, I am not aware of any secondary indicia of non-obviousness that have any nexus to the challenged claims, or that would have any bearing on my determination below that the challenged claims would have been obvious to a POSA at the time of the purported invention. I nonetheless reserve the

right to supplement or amend my opinions to the extent that any such secondary indicia are brought to my attention.

32. Moreover, I do not recall hearing about any innovation in the field of safety devices that provide needle safety for pre-filled syringes by Patent Owner. I am not aware of any products in the field of safety devices for pre-filled syringes, particularly in safety devices that provide needle safety for pre-filled syringes by Patent Owner, any customers of Patent Owner, or anything suggesting commercial success of any such products developed by Patent Owner.

33. I am also unaware of any long-felt need at the time of the alleged invention for an invention utilizing the elements recited in the challenged claims of the '011 Patent. Safety devices that provide needle safety for pre-filled syringes were well-known to one having ordinary skill in the art, including but not limited to the injection devices described in Carrel and David-Hegerich, both of which pre-date the July 2, 2010, which I have been informed is the earliest priority date of the '011 Patent.

34. I am also not aware of any failure of others to design or implement an invention similar to the ones recited in the challenged claims of the '011 Patent. In fact, I believe there are numerous similar safety devices that provide needle safety for pre-filled syringes, including but not limited to the ones described in Carrel and

David-Hegerich, both of which pre-date the July 2, 2010 priority date of the '011 Patent.

35. I am not aware of any copying of designs or products of Patent Owner.

36. Moreover, for the reasons I set out below, in my opinion, the prior art references demonstrate a strong case of obviousness against the '011 Patent.

37. My analysis below is always from the perspective of a POSA unless otherwise noted, even if that is not explicitly stated.

IV. Background of the Technologies Disclosed in the '011 Patent

A. Needle Safety Generally

38. Needle safety and safety syringes have been well established since at least 1990 as “official performance requirements and definitions have been added and developed over time, beginning with AD [Auto-disposable] syringes for immunization” Ex. 1007, WHO Guidline, p. 9. Since the 1990’s, a large number and wide variety of safety devices have been developed and commercialized to provide safety for the large number and variety of injection applications in practice. *See id.*, pp. 14-23. These devices range from simple mechanical plastic needle shields and one-handed mechanical needle covers applied after injection, to more complicated auto retractable needles, automatic needle covers, syringe re-use prevention via plunger locks or breakage, and other active or passive safety

features. *See id.* The type of mechanical safety approach described in the '011 patent is one of the automatic needle covers after injection.

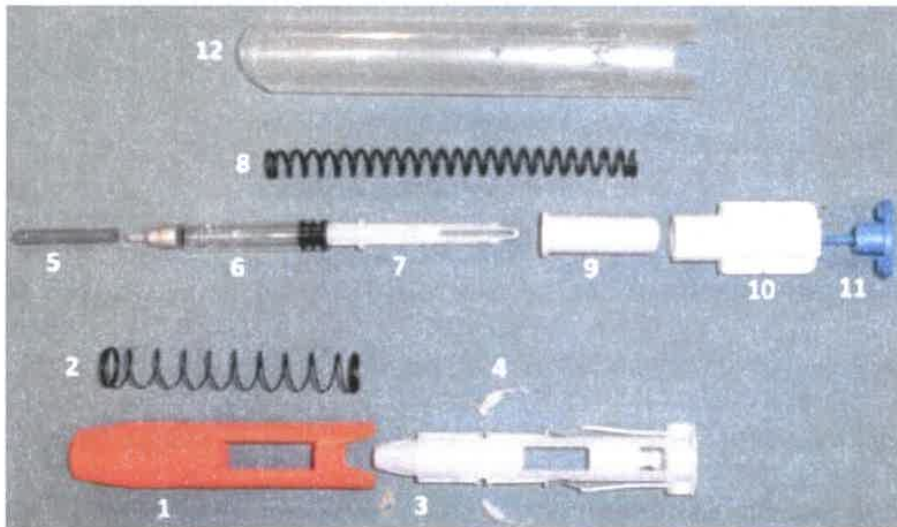
B. Auto- or Self-Injection Systems Before 2010

39. Auto- or Self-Injection devices were first invented in the mid 1970's by Sheldon Kaplan for military applications to deliver nerve gas antidotes. *See* Ex. 1008, Smetana, p. 2. This early device design has evolved over time (first approved for marketing by the FDA in 1987) to become the modern day and well known EpiPen® marketed by Mylan Pharmaceutical; a single dose, hand gripped epinephrine auto-injector. Also, in 1985 the first (Self-Injection) insulin pen injector was introduced as the NovoPen®. Ex. 1009, Rex, p. 1. Since these early introductions of hand held auto-injectors, numerous competing designs and brands have been developed and commercialized prior to 2010 and continues with robust activity in 2018. One of the key attributes of all these auto-injectors is the “gripping style” ease of use to self-inject critical medication with a single hand particularly if the patient has any aversion to needle injections. Thus medical injector designs incorporating a “hand gripping” type of use for injection have been utilized for about 40 years. *See generally* Ex. 1009; *see also* Ex. 1010, Popken.

40. In 2009, Mylan started marketing a new style of EpiPen® which featured a “slidable/guidable” needle shield that automatically and safely shielded the needle after use. Included below are images of Mylan’s new style of EpiPen®.



Rev 2 EpiPen® Complete Device



Rev 2 EpiPen® Part Breakdown

- | | |
|--------------------------|-------------------|
| 1. Shroud | 7. Plunger |
| 2. Control Spring | 8. Drive spring |
| 3. Carrier | 9. Release collar |
| 4. Control Clips | 10. Rear case |
| 5. Needle cover | 11. Safety Cap |
| 6. Cartridge and Stopper | 12. Housing |

Ex. 1010, p.4. As shown in the images, the concepts disclosed in the '011 Patent were already known to a POSA.

V. Overview of the '011 Patent

41. The '011 Patent is directed to “safety devices for pre-filled syringes.” Ex.1001, 1:17-19. More specifically, the '011 Patent is “adapted to avoid accidental needle pricks and needle injuries before, during and after an injection of a medication or drug contained in the pre-filled syringe.” *Id.*, 1:19-22.

42. The primary way the device claimed by Sanofi achieves this is using three main components: (1) a “*hollow support body*” to retain the pre-filled syringe, (2) a “*hollow needle shield*” to cover the needle before and after injection and (3) a “*guiding mechanism to guide the movement of the needle shield relative to the support body*” before and after injection. A handle is added to the proximal end to presumably make the needle safety device easier to grasp and use, but the claims do not otherwise require that the handle cooperate with the hollow support body, needle shield or guiding mechanism to aid in protecting the needle to avoid accidental needle sticks in the challenged claims. These basic features are illustrated in Figure 1, set forth below:

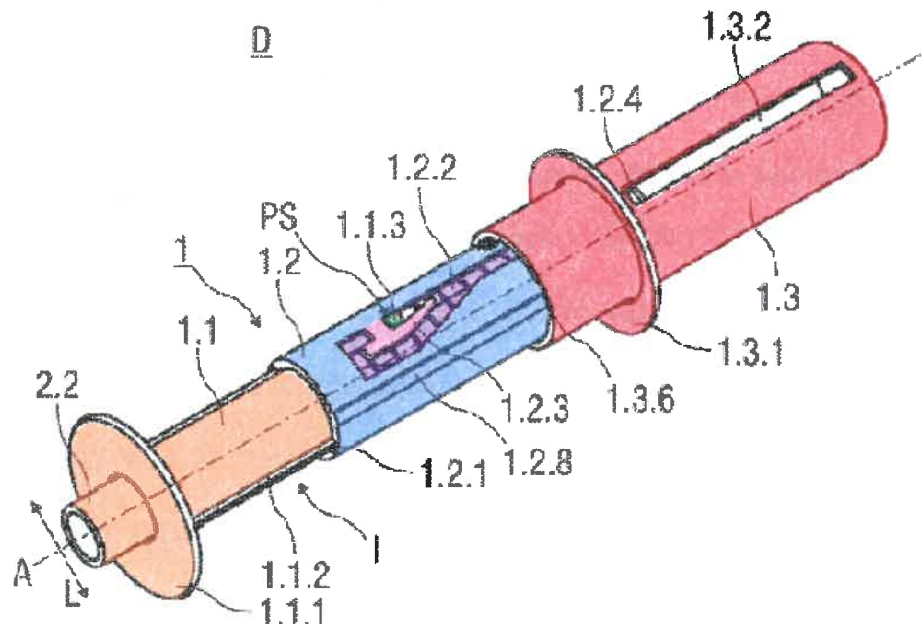


FIG 1

Id., FIG. 1 (annotated).

43. The hollow needle shield is element 1.1 (shaded in orange). The hollow support body that holds the needle is element 1.2 (shaded in blue). The guiding mechanism comprises the claimed guide track (element 1.2.2, shaded in purple), disposed on the hollow support body 1.2, a “deflectable flexible arm [1.1.4] with a guide pin [1.1.3] radially extending therefrom.” *Id.*, 14:13-16. The guide pin (shaded in green) on the deflectable flexible arm (shaded in yellow) follows the guide track as the needle shield 1.1 moves relative to the support body 1.2. Figures 2 and 3 are illustrative.

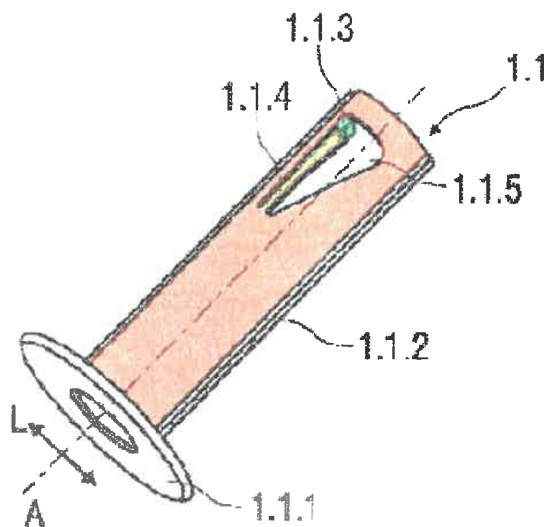


FIG 2

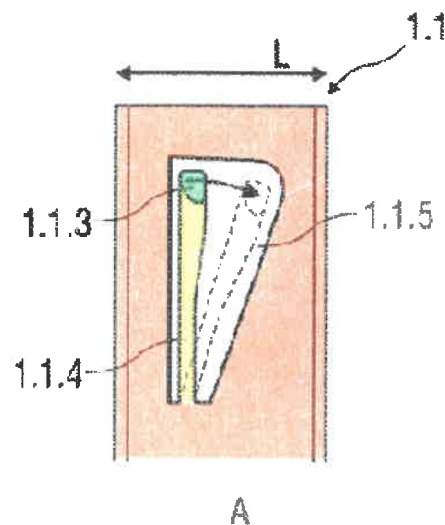


FIG 3

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

44. The claimed invention transitions between three positions. Initially, in a start or storage position, the needle shield is extended over the needle, as illustrated in Figure 4. At an intermediate position, the device is pressed against an object (i.e., a patient's skin), the needle shield 1.1 is retracted, relative to the support body 1.2 and allows the needle to be exposed for injection, as illustrated in Figure 6. At the advanced or end position, the needle shield 1.1 is again extended over needle 2.1, as depicted in Figure 7.

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

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

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

48. Claim 1 of the '011 Patent is illustrative:

A safety device for a pre-filled syringe, comprising:
an outer body;

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

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

a guiding mechanism to guide the movement of the needle shield relative to the support body, the guiding mechanism comprising a deflectable flexible arm with a guide pin radially extending therefrom, the flexible arm extending essentially parallel to a central axis of the safety device, and

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

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

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

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

VI. Overview of the Prior Art

A. Carrel

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

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

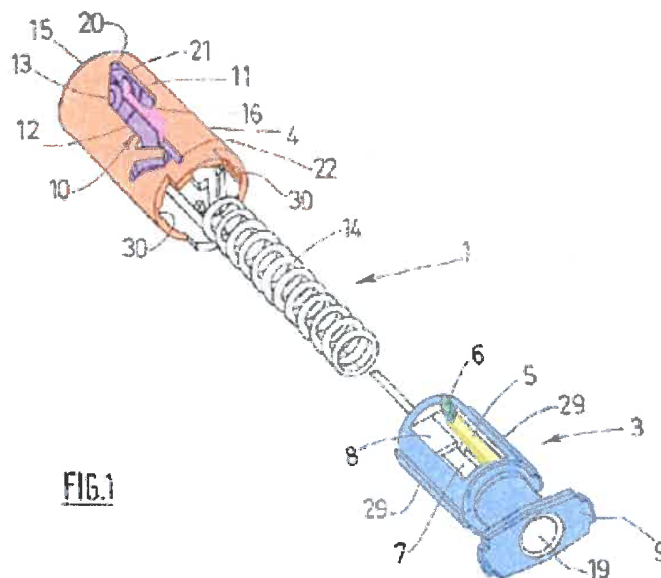


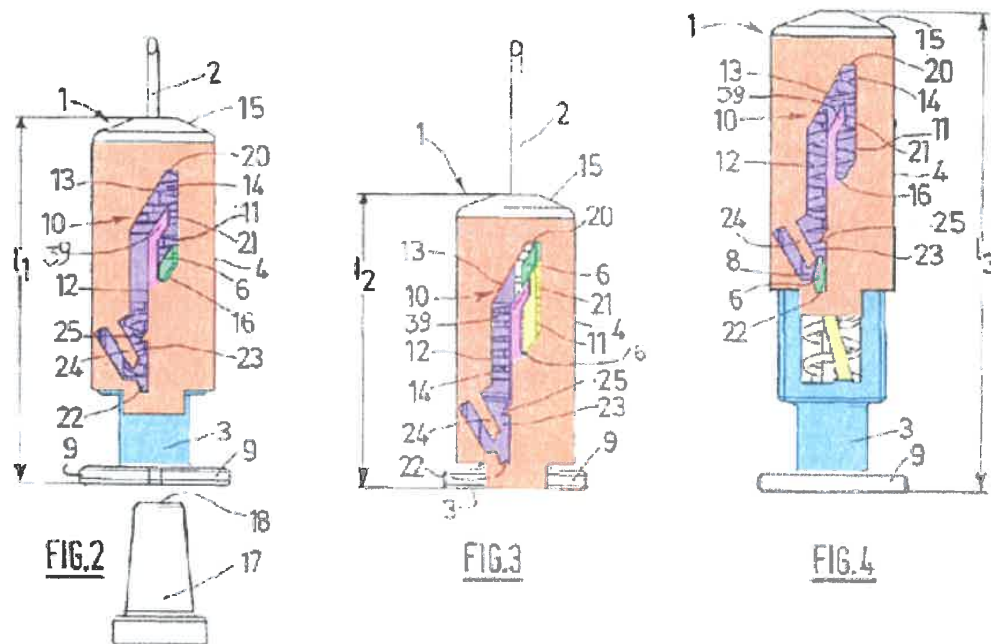
FIG.1

Id., FIG. 1 (annotated).

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

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

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



Id., FIGS. 2-4 (annotated).

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

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

injection stroke and as the needle is extracted, sleeve 4 slides over the needle and the guide pin travels back down the guide track (passageway 10) where the guide pin (peg 6) is deflected away from the starting position, and towards the ultimate ending position (protection position).

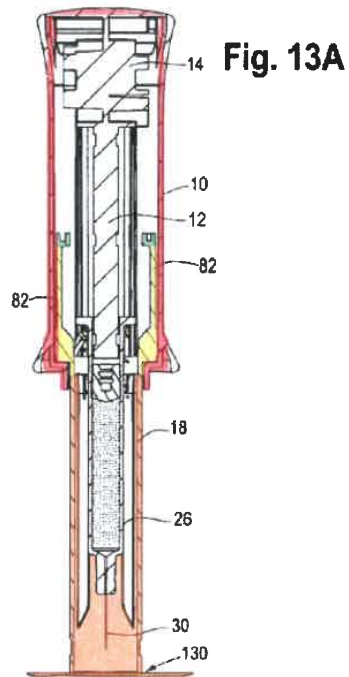
55. Carrel's protection device teaches simple mechanical techniques "for shielding a needle so as to protect the patient and/or the user from the risk of needlestick injury." *Id.*, [0001]. In my experience, Carrel teaches one of a variety of common mechanical approaches, for automatically shielding a needle as it is withdrawn after an injection, that were known in the art at the time of the purported invention in the '011 Patent. As Carrel demonstrates, it was commonplace to employ nested hollow bodies to protect and shield the needle of an auto-injection or self-injection device. It was also commonplace to use a variety of simple mechanical techniques including tracks in conjunction with a deflectable, flexible arms to guide the injection and retraction strokes of a pre-filled syringe having a hypodermic needle supported by the nested hollow bodies. Indeed, a POSA could have easily designed any number of variations on this theme depending on the specific needs of the device.

56. I now turn to the David-Hegerich reference, which is yet another variation on the design themes expressed in Carrel.

B. David-Hegerich

57. 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.*

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



Id., FIG. 13A (annotated).

59. 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.

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

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

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

Id.

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

[I]t provides an ergonomic, easy-to-use device that is particularly suitable for self administration of injections by patients with dexterity limitations, including the elderly and persons suffering from arthritis in the hands or fingers. The handle 10 is preferably designed without sharp edges or

surfaces that would generate pressure points during use. No squeezing is required. The wide tubular structure of the handle allows for ease of grip by the user, in a variety of different hand positions. The injector handle 10 is designed to provide a stable hand grip.

Id., [0050] and [0020].

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

63. David-Hegerich is additional evidence of the general state of the art at the time of the purported invention. Like Carrel, David-Hegerich employs nested hollow bodies to support the pre-filled syringe. And like Carrel, David-Hegerich uses a slightly different guide track and deflectable, flexible arm mechanism to guide the injection and retraction strokes of the needle, while at the same time protecting and shielding the needle. It is my opinion, again, that a POSA at the time of the purported invention could have designed any number of variations on this theme.

VII. Claim Construction

64. The application of the Carrel and David-Hegerich to the purported invention of the '011 Patent is clear and straightforward. I do not see any terms in the '011 Patent that a POSA would not understand after reviewing the '011 Patent

specification. I also do not see any terms that are susceptible to different meanings such that it would impact my analysis below. So in my view, the terms and phrases in the '011 Patent should be accorded their broadest reasonable construction, in view of the '011 Patent specification, and as understood by a POSA.

VIII. The Combination of Carrel and David-Hegerich Renders Obvious Claims 1-13, 18, and 20 of the '011 Patent

65. As I explained above, claims 1 and 20 are the only independent claims recited in the '011 Patent. Each of claims 2-13, 18, and 20 depends, directly or indirectly, on independent claim 1. Each of these claims would have been obvious to a POSA in view of Carrel and David-Hegerich. In the next sections I address each claim individually.

A. A POSA Would Have Been Motivated to Combine Carrel and David-Hegerich

66. Carrel and David-Hegerich are sufficiently similar to each other, and to the subject matter of the challenged claims, such that a POSA interested in the art of needle-based, self-injection, drug delivery devices having prefilled syringes—and the always-present usability and safety concerns that accompany such devices—would have known of and been motivated to combine both prior-art references. Further motivation to combine these references would be in the instance of utilizing the David-Hegerich design specifically for standard pre-filled syringes having their own standard plungers that don't have custom tracks

provided. In that instance the guide and track of Carrel would be highly desired and easily integrated to manipulate the needle shield. Both are directed to needle safety devices for pre-filled syringes. And both similarly solve the problem of protecting the needle of a pre-filled to needle sticks, as I explained in Sections VI.A-B above.

67. Moreover, a POSA specifically would have been motivated to modify Carrel with the slidable handle disclosed in David-Hegerich because David-Hegerich teaches that its handle makes needle safety systems easier to use. A POSA would further have been motivated to incorporate the slidability taught by David-Hegerich onto the hollow support body a Carrel because this person would have sought to reduce the overall length of the device to reduce the size and facilitate a smoother injection. The resulting combination is little more than use of a known mechanical configuration or technique to improve the injection stroke—e.g., using a hollow support body for the pre-filled syringe and needle that is received in an outer body that functions as an easy-to-hold handle, and where the handle and is slidably arranged relative to the hollow support body to perform an injection stroke. A POSA thus would have improved injection devices, like Carrel's, in the same way that David-Hegerich suggests. And after the combination, each feature would continue to function as intended.

68. A POSA would have recognized (since at least from 1990) the advantages of David-Hegerich's "handle" for improving handling for users with low dexterity and other important reasons. Ex.1006, [0050]. 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...." *Id.* 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.* Additionally, as I explained in Section IV regarding auto-injectors, ease of use is an important feature for critical emergency self-injection, particularly for those who are injection averse. Thus, it would have been obvious to enhance Carrel with David-Hegerich's "handle" approach, and the handle approach employed in similar devices since the 90's, to improve handling.

69. A POSA would have recognized the advantages of advancing David-Hegerich's handle down (and over) the needle guard, gradually bringing their proximal ends into closer proximity for an improved injection stroke by transmitting the force on the handle through the plunger. *Id.*, [0061]. The larger handle being formed for better more secure and stable gripping facilitates an easy,

smooth injection less likely to experience any interruption of injection due to finger slippage.

70. David-Hegerich thus expressly teaches numerous benefits of employing an outer, slidable handle on a needle safety device for a pre-filled syringe. I agree with those expressed benefits. The benefits of employing an outer handle like David-Hegerich's handle would have thus been predictable to a POSA.

71. To be more specific with respect to the combination I propose here, Carrel's needle safety device would have benefited from David-Hegerich's outer handle in much the same way as David-Hegerich itself describes. For example, Carrel's device appears to be a relatively small device, and as described, Carrel's sleeve 4 is configured to retain a pre-filled syringe therein. Ex. 1005, FIG. 5, [0002] and [0061].

72. The self-user must grip the small device in a traditional sense with thumb, middle, and fore fingers. This grip orientation is less than optimal for self-injections as pointed out earlier. Further, the added forward weight imbalance, needle shield and spring feature, and partial needle exposure may additionally disadvantage the injection process.

73. Accordingly, a POSA would have understood that Carrel's device would be difficult to use. For example, because Carrel's device is small, it would be difficult for an elderly person or a person with limited dexterity to use the

device. Thus, Carrel would benefit from a larger easy-to-use handle with a stable hand grip, as taught in David-Hegerich. Ex. 1006, [0050].

74. Further, as I explained above, Carrel's sleeve 4 is configured to retain a pre-filled syringe therein. Ex. 1005, FIG. 5, [0002] and [0061]. Carrel's Figures 1-4 illustrate a method for attaching a pre-filled syringe within sleeve 4 that would require a patient (or caregiver) to apply force to the syringe's plunger relatively far away from the injection site. 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.

75. For example, applying a force to the proximal end of the syringe plunger becomes more difficult the further it is from the injection site, thereby increasing the force required to deliver the injection and the likelihood that the plunger will bind during injection.

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

injection stroke by transmitting the force on the handle through the plunger and closer to the injection site. *See* Ex. 1006, [0061].

77. A POSA would also have had a reasonable expectation of success in implementing David-Hegerich's slidable handle onto Carrel's device because such a modification would have been a routine matter for a POSA. As one example, a POSA would have considered to elongate and modify Carrel's support 3 along with adding David-Hegerich's handle to enclose and support the prefilled syringe up to its own syringe barrel flange. This is a basic plastic injection molded part and implementing additional features to support part 3 is easily conceptualized and implemented with a new tool. This elongated support 3 section would include the interface features required to slidably mount the handle, as described in David-Hegerich, and to function with a standard injection plunger. Carrel already possesses the "Running Passageway" 10, and "Flexible Tab" 5, and "Peg" 6 which function to operate the needle shield safely operation during and after injection. The shield, passageway, and tab parts of Carrel can easily be elongated to completely hide the needle same as the David-Hegerich. The "handle" 10 of David-Hegerich would be plastic injection molded with a closed off end which would interface to apply the force to the proximal syringe plunger for injection. This is only one of the at least two or more obvious design approaches to combine Carrel and David-Hegerich to function per the claims in the '011 Patent.

78. For at least the reasons I explained above, a POSA would have found it obvious to modify Carrel to include a David-Hegerich-style slidable handle and to arrive at the safety device for a pre-filled syringe set forth in the '011 Patent.

B. Claim 1

79. I now turn to the prior-art references and provide a detailed mapping of features disclosed in the Carrel and David-Hegerich references onto the challenged claims. For ease of reference, and to eliminate any confusion, my mapping of the prior art to the elements of the challenged claims is aligned substantively and stylistically with the IPR petition on the '011 Patent that this declaration supports.

80. The combination of Carrel and David-Hegerich renders claim 1 obvious. I have reproduced claim 1 again, below. I have labeled the claim limitations for ease of discussion.

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

[1.1] an outer body;

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

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

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

comprising a deflectable flexible arm with a guide pin radially extending therefrom, the flexible arm extending essentially parallel to a central axis of the safety device, and
[1.5] a guide track configured to guide the guide pin within and along the guide track so that the guide pin follows the guide track when the needle shield is slid relative to the support body,
[1.6] wherein the flexible arm is configured to be laterally deflected as the guide pin follows the guide track, and
[1.7] wherein the flexible arm is connected to or is integrally formed to the needle shield or the support body, and the guide track is formed into the other of the needle shield or the support body.

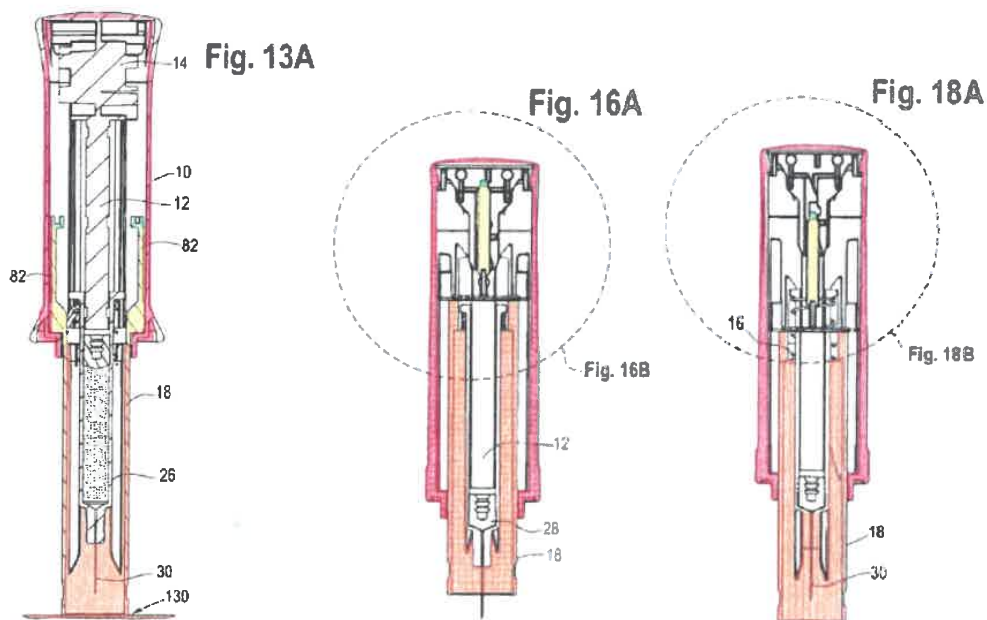
1. [1.P]: “[a] safety device for a pre-filled syringe”

81. Carrel is directed to a *protection device 1* (i.e., safety device) to at least partially cover the needle of a safety device. Ex. 1005, Abstract. Carrel further 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.” *Id.*, [0061]. Thus, Carrel teaches a safety device for a pre-filled syringe.

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

2. [1.1]: “an outer body”

83. Carrel teaches a handle (fixing means 9). David-Hegerich teaches a handle (i.e., outer body) that is slidable. For example, as illustrated in Figures 14 and 15, the David-Hegerich device discloses “a *hollow tubular handle 10* which is grasped by the user to make an injection.” *Id.*, [0046], *see also* [0137] (“a hollow tubular handle 10 having an interior region receiving the needle guard 18 and syringe 26”).



Id., FIGS. 13A, 16A, and 18A (annotated). A POSA would have understood that the David-Hegerich hollow tubular handle 10 is an outer body, as claimed.

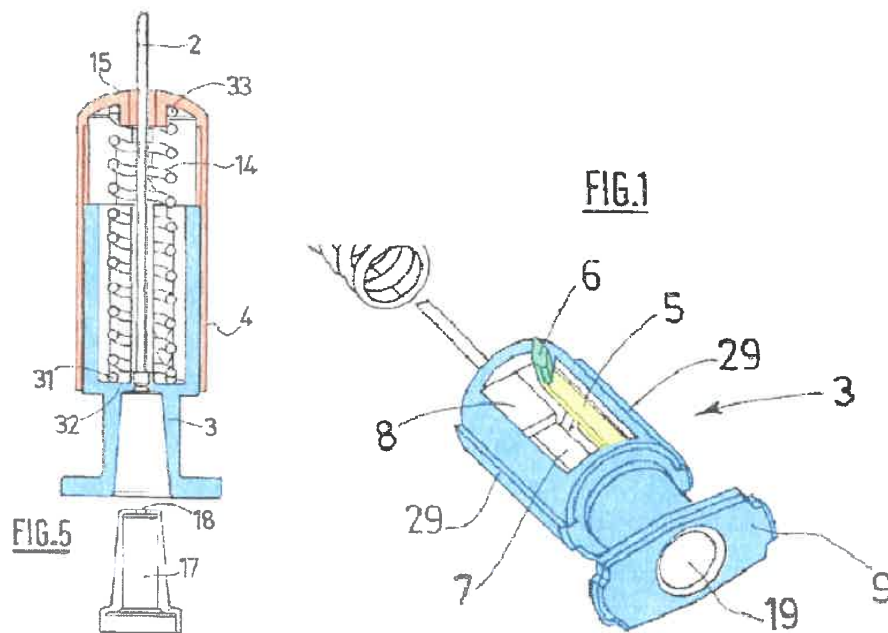
84. Further, Carrel would benefit from a larger easy-to-use handle with a stable hand grip, as taught in David-Hegerich. *See id.*, [0050]. For this reason, and

the reasons that I provided in Section VIII.A above, a POSA would have been motivated to enhance Carrel's needle safety device with David-Hegerich's handle. Thus, a POSA would have understood that the combination of Carrel and David-Hegerich thus teaches an outer body.

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

85. Carrel teaches a hollow support (support 3) to retain the pre-filled syringe (syringe body prefilled with the medicinal product) therein. Ex. 1005, [0061]. More specifically, Carrel explains that the end of a syringe body “may be provided with a syringe tip to which a needle support bearing the needle can be fixed. This syringe tip is, for example, of the ‘luer’ or ‘luer lock’ type.” *Id.*, [0002]. A POSA would have understood that both the “luer” and “luer lock” syringes provide a leak proof connection. The luer lock syringe includes a screw lock mechanism that securely holds the syringe in place.

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



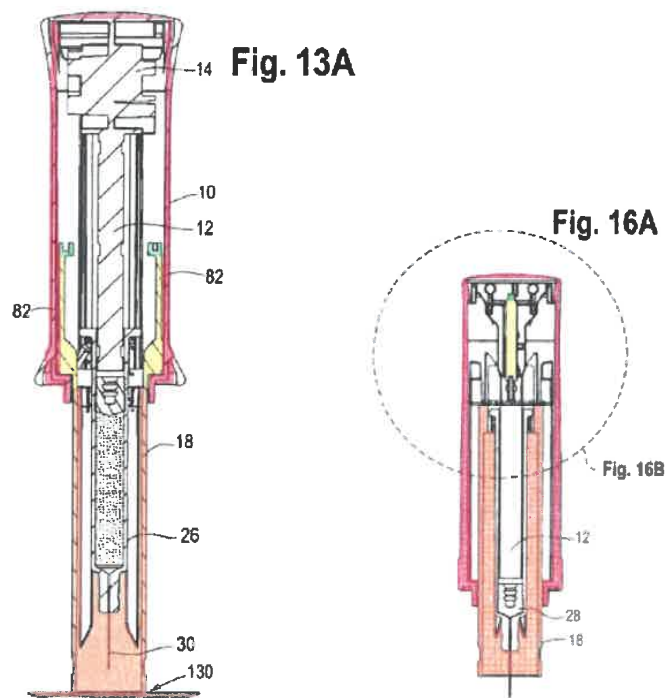
Id., FIGS. 1 and 5 (annotated).

87. As shown, “the *syringe body 17*, partially depicted in FIG. 2 [and FIG. 5], *prefilled with the medicinal product* to be injected into the injection site.” *Id.*, [0061]. Carrel further teaches that its “*syringe body 17* comprises a standard distal tip 18 that can be *fitted to the proximal base 19* (see FIG. 1) of the support 3... The user thus *connects the syringe body 17 to the protection device 1* of the invention.” *Id.*

88. A POSA would have understood that the syringe body’s standard distal tip would include a luer or luer locking mechanism, as I described above. Thus, Carrel teaches a hollow support to retain the pre-filled syringe therein.

89. David-Hegerich teaches a hollow support body that is received into an outer body handle that is slidably arranged relative to the outer body to perform an injection stroke feature, and a POSA would have found it obvious to modify Carrel to incorporate David-Hegerich's outer handle into Carrel's device, and a POSA would have found it obvious to modify Carrel to incorporate David-Hegerich's handle onto Carrel's device at least for the reasons that I provided in Section VIII.A above.

90. As I explained in Section VIII.B.1 above with respect to limitation [1.1], and as illustrated in Figures 13A and 16A, David-Hegerich teaches a "*hollow tubular handle 10* which is grasped by the user *to make an injection.*" Ex. 1006, [0046].



Id., FIGS. 13A and 16A (annotated). Figure 13A depicts an injection device ready for use, with the plunger located at the proximal end of the syringe, and the pre-filled syringe still full of the medication. *See id.*, [0033]. Figure 16A depicts the same injection device “with the handle at its lowest position relative to the needle guard and plunger, at the point where the expelling of the medicament in the syringe is complete.” *Id.*, [0036].

91. David-Hegerich further teaches that its “plunger 12 includes a top portion 14 which is attached to the open proximal end of the generally cylindrically-shaped handle 10.” *Id.*, [0049]. David-Hegerich continues:

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

Id. Based at least on the foregoing, a POSA would have understood that the hollow support body is received in the outer body and slidably arranged relative to the outer body to perform an injection stroke.

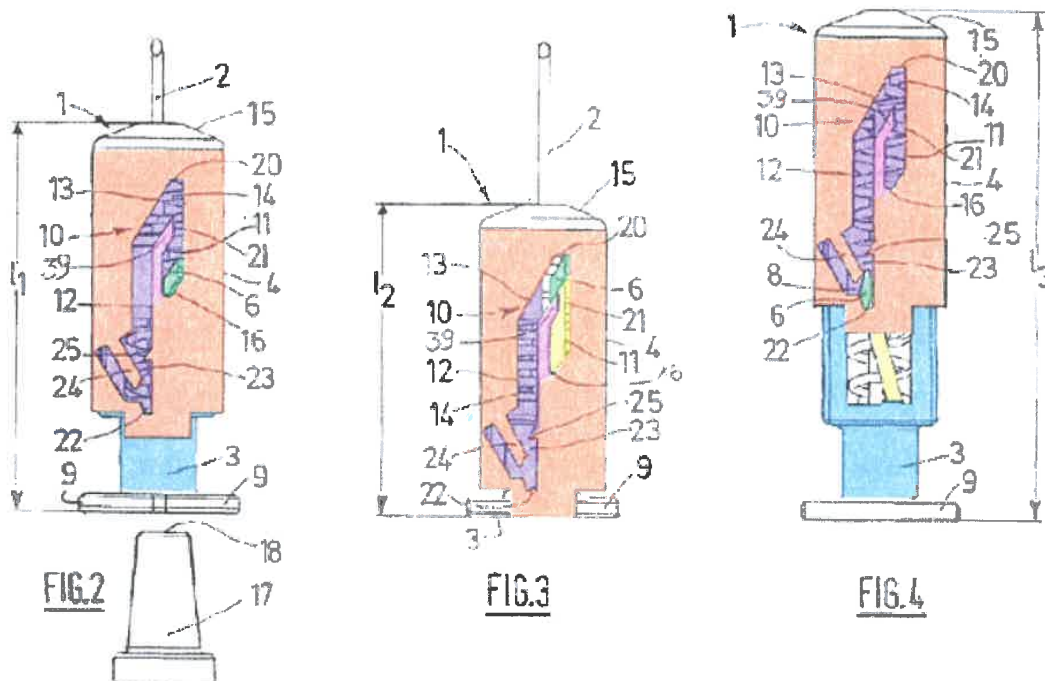
92. As I explained in Section VIII.A above with respect to the motivation to combine Carrel and David-Hegerich, because the Carrel device is small, it would be difficult for an elderly person or a person with limited dexterity to use Carrel's device. Thus, Carrel would benefit from the addition of a large, easy-to-use, outer handle with a stable hand grip, as taught in David-Hegerich. *Id.*, [0050]. A POSA would have been motivated to enhance Carrel's device with the addition of a David-Hegerich-like handle 10, at least for the reasons that I provided in Section VIII.A, above.

93. A POSA would have thus modified Carrel in view of David-Hegerich, as I explained in Section VIII.A, 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.

4. [1.3]: “a hollow needle shield slidable relative to the support body”

94. 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).

These features are set forth in Figures 2-4, included below:



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

95. Carrel “depicts a protection device 1 for protecting an injection needle 2.” *Id.*, [0051]. Carrel additionally 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:

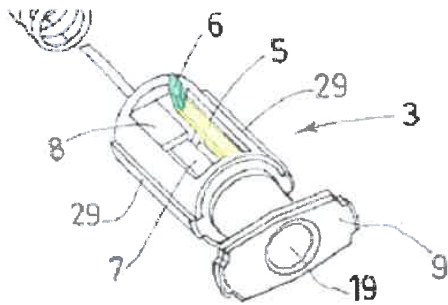
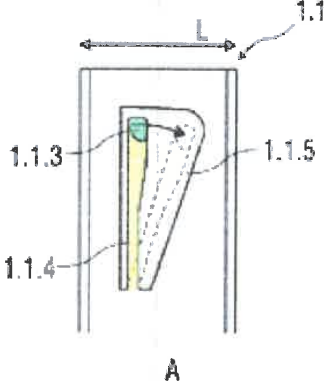
This protection device 1 comprises a support 3 for a needle 2 and a sleeve 4 arranged in such a way as to accept the support 3. *This sleeve 4 can be moved in translation with respect to the support 3, from a storage position depicted in FIG. 2 towards a second position, the injection position, depicted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

Id. Based on the foregoing, 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. Thus, Carrel teaches a hollow needle shield slidable relative to the support body.

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

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

97. Carrel discloses the guide mechanism of the challenged claims. Carrel teaches that “support 3 comprises a flexible tab 5 which runs longitudinally from the proximal part of the support 3 in the distal direction. This flexible tab 5 at its distal end comprises a peg 6.” Ex. 1005, [0053]. Carrel’s “flexible tab 5 is able to deflect laterally between a normal position and at least one stressed deflected position.” *Id.*

Carrel	The flexible arm and guide pin of the '011 Patent
 <p>Ex. 1005, FIG. 1 (annotated).</p>	 <p>FIG 3</p> <p>Ex. 1001, FIG. 3 (annotated).</p>

98. Like the challenged '011 Patent claims, Carrel teaches that its flexible tab 5 and peg 6 together form a guiding mechanism. For example, Carrel teaches:

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

Ex. 1005, [0067].

99. In view of the foregoing, namely that Carrel's peg 6 follows passageway 10, a POSA would have understood that Carrel's flexible tab 5 and peg 6 together teach the pin and essentially parallel flexible arm of the guiding mechanism of the challenged claims to guide the movement of the needle shield relative to the support body, as claimed. Thus, Carrel teaches a guiding mechanism to guide the movement of the needle shield relative to the support body, the guiding mechanism comprising a deflectable flexible arm with a guide pin radially extending therefrom, the flexible arm extending essentially parallel to a central axis of the safety device.

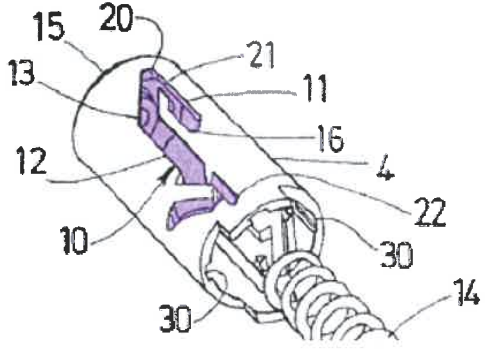
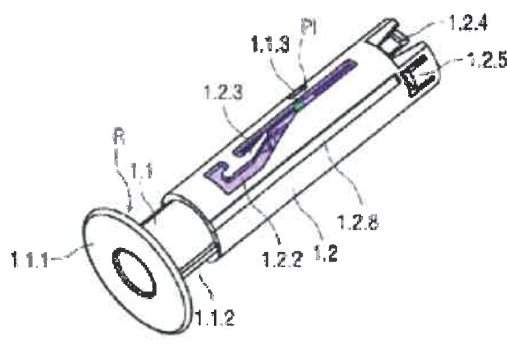
100. David-Hegerich also discloses a similar guide mechanism having an essentially parallel flexible arm and pin attached thereto for guiding the movement of a needle shield to a support body. For example, its track followers 82 act as a deflectable flexible arm with a guide pin (hooked end) that guides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

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

101. Carrel teaches a guide track (running passageway 10) configured to guide the guide pin (peg 6) within and along the guide track so that the guide pin follows the guide track when the needle shield (sleeve 4) is slid relative to the support body (support 3).

102. 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 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].

103. The structural similarity between the Carrel’s guide track and that of the challenged ’011 Patent claims are illustrated in the following table:

Carrel	The guide track of the '011 Patent
 <p data-bbox="284 724 665 756">Ex. 1005, FIG. 1 (annotated).</p>	 <p data-bbox="933 714 998 745">FIG 5</p> <p data-bbox="828 787 1209 819">Ex. 1001, FIG. 5 (annotated).</p>

104. Based on the foregoing, Carrel teaches a running passageway 10 configured to guide peg 6 within and along passageway 10 so that peg 6 follows passageway 10 when sleeve 4 is slid relative to support 3. Thus, a POSA would have understood that Carrel teaches a guide track configured to guide the guide pin within and along the guide track so that the guide pin follows the guide track when the needle shield is slid relative to the support body.

105. It should be noted, that while the images are very similar, the two main differences between the figures include the shape of the guide tracks and the location of the guide track – neither of which is an element of the challenged claims.

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

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

107. As I explained in Section VIII.B.5 above with respect to limitation [1.4], Carrel teaches that its flexible tab 5 is configured to be laterally deflected as peg 6 follows running passageway 10.

108. 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.*

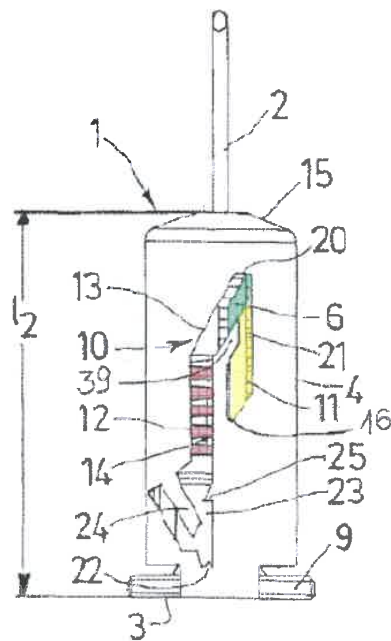


FIG. 3

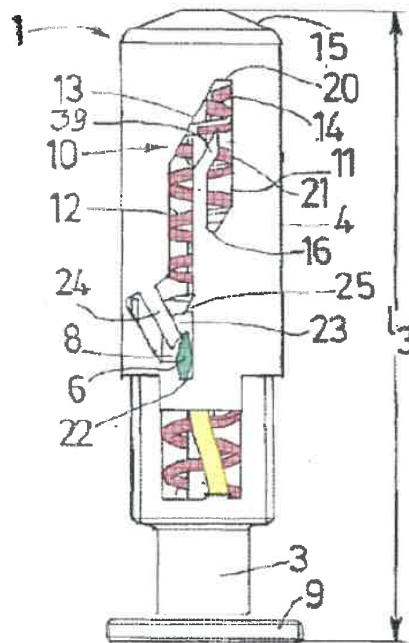


FIG. 4

Id., FIGS. 3-4 (annotated). As illustrated in the figures, 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 (purple), flexible tab (yellow) is deflected laterally. *See id.*, FIGS. 2-4.

109. 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." *Id.*, [0053]. More specifically, Carrel teaches that its flexible tab 5 is configured to be laterally deflected as peg 6 follows running passageway 10. Thus, based at least on

the foregoing excerpts, a POSA would have understood that Carrel teaches a flexible arm that is configured to be laterally deflected as the guide pin follows the guide track.

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

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

111. Carrel discloses a flexible arm integrally formed in the needle shield and the guide track in Carrel is in the support body. As I explained in Section VIII.B.3 with respect to limitation [1.2], Carrel's support 3 teaches a support body, as claimed. *See* Ex. 1005, FIG. 1. Carrel's “*support 3 comprises a flexible tab 5 which runs longitudinally from the proximal part of the support 3 in the distal direction.*” *Id.*, [0053]. Thus, a POSA would have understood that Carrel's flexible tab 5 (in yellow) is connected to or is integrally formed to the support body, support 3.

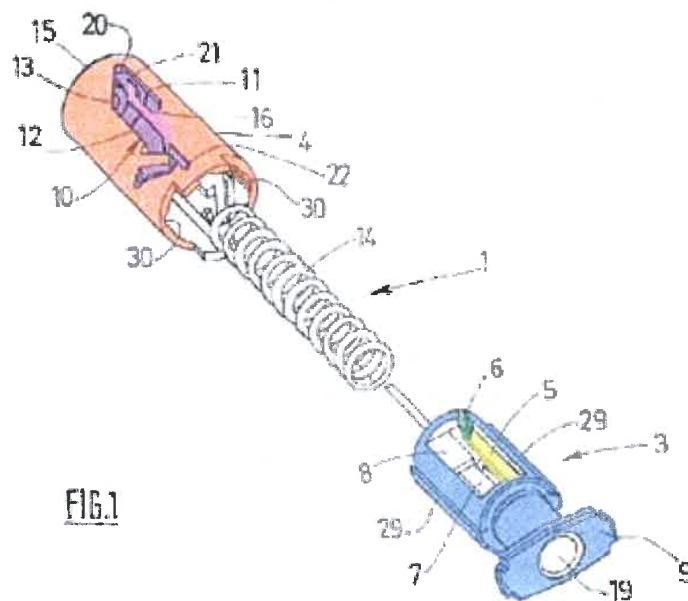
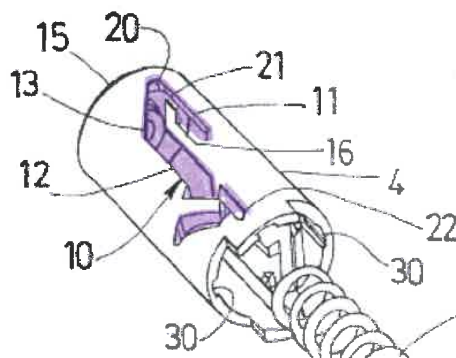


FIG.1

Id., FIG. 1 (annotated).

112. Further, as I explained in Section VIII.B.6 with respect to limitation [1.5], Carrel's running passageway 10 teaches a guide track that is formed into the needle shield. *See id.*



Id. (annotated). As illustrated, Carrel's "sleeve 4 comprises a running passageway 10 forming a U, made in the wall of the sleeve 4 and arranged in such a way as to

collaborate with the peg 6 over the entire travel of the sleeve, as will be apparent from FIGS. 2-4.” *Id.*, [0055]. For at least these reasons, a POSA would have understood that Carrel teaches a flexible arm that is connected to or is integrally formed to the support body, and the guide track is formed into the needle shield.

C. Claim 2

113. The combination of Carrel and David-Hegerich renders claim 2 obvious. Claim 2 is reproduced below.

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

114. Carrel teaches an axial guidance means (29, 30) for preventing the sleeve 4 from pivoting with respect to support 3 teaches this limitation. *Id.*,

Abstract. More specifically, Carrel teaches:

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].

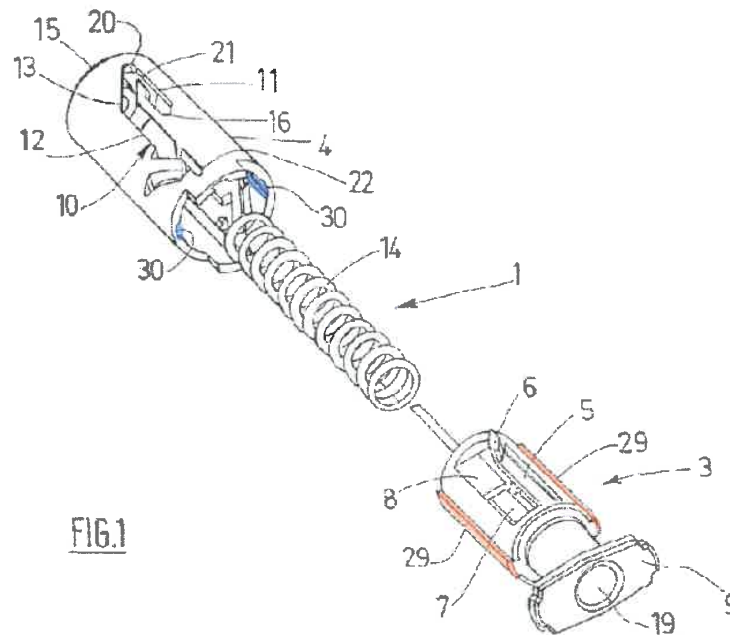


FIG.1

Id., FIG. 1 (annotated). A POSA would have understood that, Carrel's longitudinal bulges 29 (shaded in orange) teach the longitudinal tongue and Carrel's slideways 30 (shaded in blue) teach the longitudinal groove, as claimed.

115. A POSA would have further understood that, Carrel's 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. *Id.*, Abstract.

116. Thus, based on the foregoing excerpts and explanations, the combination of Carrel and David-Hegerich teaches wherein the guiding mechanism further comprises a longitudinal tongue configured to be received in a longitudinal groove to inhibit relative rotation of the needle shield and the support body when the needle shield is moved with respect to the support body in a distal direction.

D. Claim 3

117. The combination of Carrel and David-Hegerich renders claim 3 obvious. Claim 3 is reproduced below.

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

118. As I explained in Section VIII.B.5-8 with respect to limitations [1.4]-[1.7], and as illustrated in Figure 1, Carrel's preferred embodiment has its flexible arm (flexible tab 5) connected to or integrally formed in the support body (support 3), while Carrel's guide track (passageway 10) is formed into the needle shield (sleeve 4). But Carrel also teaches an alternate embodiment with the opposite configuration. Specifically, Carrel teaches that in an "undepicted embodiment of the invention, the *flexible tab 5 is arranged on the sleeve 4* and the *running passageway 10 is formed within the wall of the support 3*" *Id.*, [0073].

119. Based on the foregoing, a POSA would have understood that the combination of Carrel and David-Hegerich teaches wherein the flexible arm is connected to or is integrally formed to the needle shield and the guide track is formed into the support body.

E. Claim 4

120. The combination of Carrel and David-Hegerich renders claim 4 obvious. Claim 4 is reproduced below.

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

121. This is Carrel's preferred embodiment, as I explained in Section VIII.B.5-8 with respect to limitations [1.4]-[1.7], and illustrated in Figure 1. Specifically, 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].

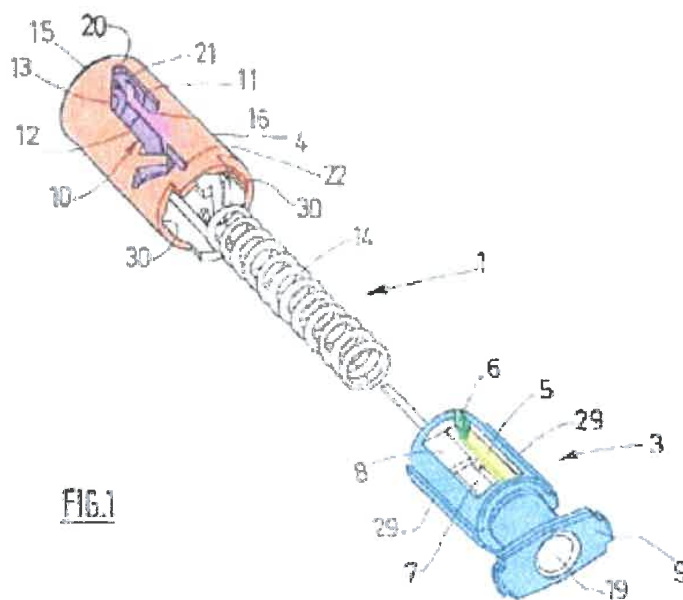


FIG. 1

Id., FIG. 1 (annotated).

122. At least for the reasons that I provided above, Carrel teaches a flexible arm that is connected to or is integrally formed to the support body. 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." *Id.*, FIG. 1, [0055]. Based on the foregoing, Carrel expressly teaches a guide track formed into the needle shield. Thus, a POSA would have understood that combination of Carrel and David-Hegerich teaches wherein the flexible arm is connected to or is integrally formed to the support body and the guide track is formed into the needle shield.

F. Claim 5

123. The combination of Carrel and David-Hegerich renders claim 5 obvious. Claim 5 is reproduced below.

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

124. Carrel's protection device comprises a helical spring 14 located between internal flange 32 of the proximal part of the support 3 and the internal face of the radial distal wall 15 of sleeve 4. *See id.*, [0057].

125. In a storage position, Carrel's "*flexible tab 5* (partly concealed by the sleeve 4 in FIG. 2) *is in the normal position* and the peg 6 is kept in abutment against the proximal end 16 of the first longitudinal section 11 of the running passageway 10 *by the action of the spring 14* which is partially compressed between the sleeve 4 and the support 3, as can be seen in FIG. 5." *Id.*, [0060]. These features are further set forth in Figures 3-4, below.

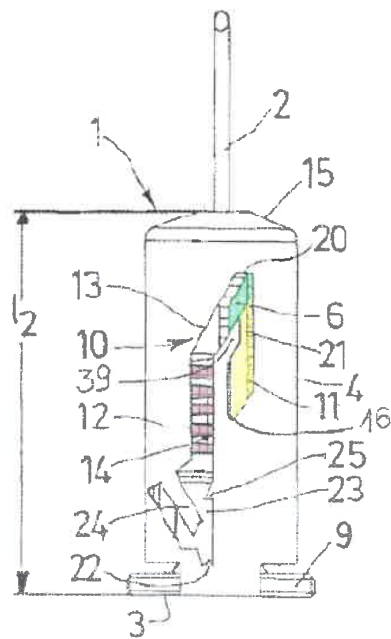


FIG. 3

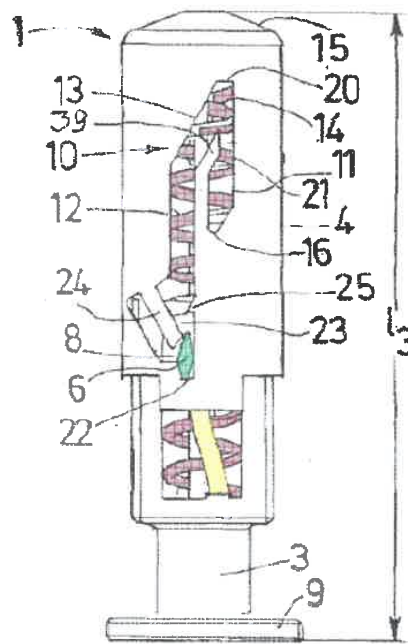


FIG. 4

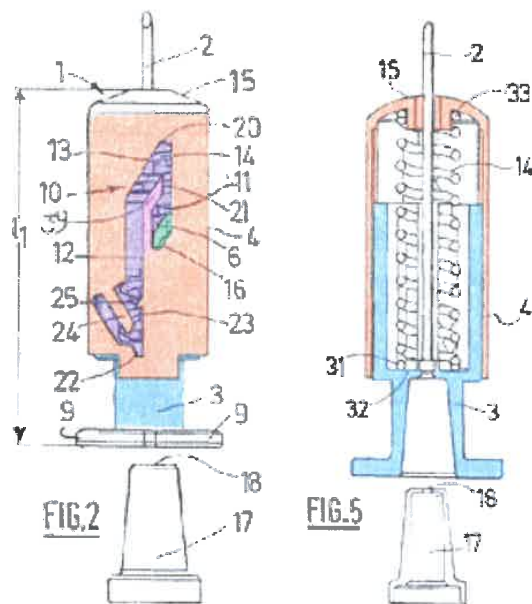
Id., FIGS. 3-4 (annotated). The relaxing spring is shaded in brown. These images are significant because they illustrate a coiled spring 14 in Figure 3 and the subsequent deflection of the flexible tab and the transfer of energy from the spring to the flexible tab (shaded in yellow). In view of the foregoing, a POSA would have understood that Carrel's flexible tab is deflectable and energizable by the action of spring 14. Thus, the combination of Carrel and David-Hegerich teaches wherein the flexible arm is deflectable and energizable by the action of a relaxing spring.

G. Claim 6

126. The combination of Carrel and David-Hegerich renders claim 6 obvious. Claim 6 is reproduced below.

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

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



Id., FIGS. 2 and 5 (annotated). The foregoing excerpts and Figures are significant because they teach that Carrel's spring is in a partially energized (partially compressed state) and the needle shield (sleeve 4) protrudes from the support body (support 3) when Carrel's device is in the initial position (storage position). Thus, a POSA would have understood that the combination of Carrel and David-Hegerich teaches wherein: the needle shield is arranged to protrude from the support body in an initial position, and the spring is configured to be in a partially energized state when the needle shield is in the initial position.

H. Claim 7

128. The combination of Carrel and David-Hegerich renders claim 7 obvious. Claim 7 is reproduced below.

7. The safety device according to claim 1, wherein:

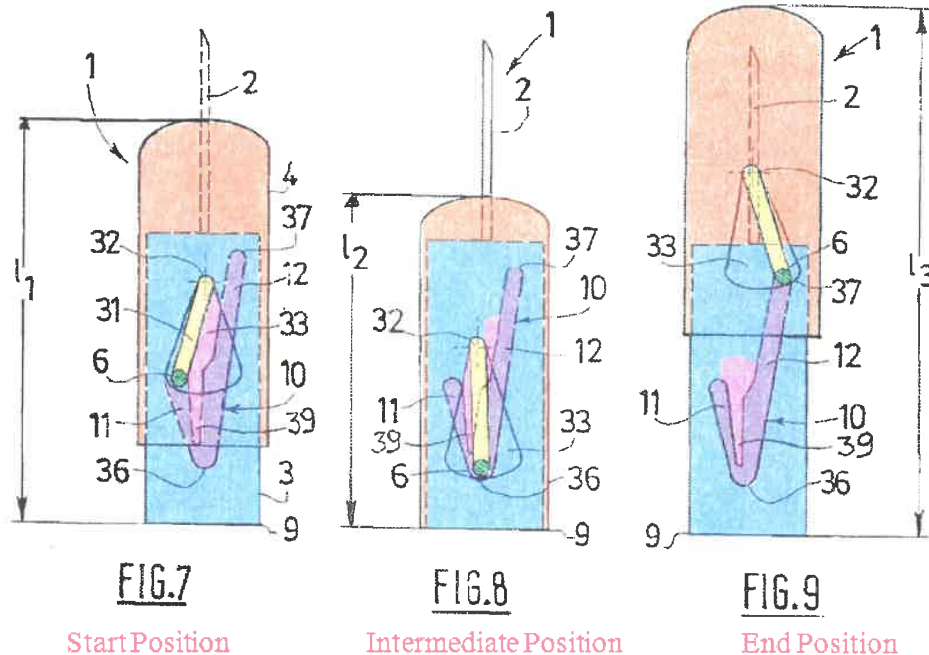
[7.1] the guide pin is arranged to be located in an intermediate position in proximity of a proximal end of the guide track when the needle shield is in a retracted position, [7.2] the guide pin arranged to be located in an end position in proximity of a distal end of the guide track when the needle shield is in an advanced position, and [7.3] the needle shield is arranged to be substantially received in the support body in the retracted position and to protrude from the distal end of the support body in the advanced position.

1. Limitation [7.1]

129. Carrel teaches that its guide pin (peg 6) is arranged to be located in an intermediate position in proximity of the proximal end of the guide track (the vertex 36 of the U) when the needle shield is in a retracted position. *Id.*, FIG. 8 and [0077].

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

pivoting tab 31 has pivoted and the peg 6 is blocked in the vertex 36 of the U that forms the running passageway 10.” *Id.* These features configurations are set forth in Figures 7-9, below.



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

131. Figures 7-9 illustrate a running passageway 10 that has a different shape than that of the running passageway 10 depicted in Figures 2-4. More specifically, Figures 7-9 depict “a second alternative form of embodiment of the protection device according to the invention in the storage position, the injection position and the protection position respectively.” *Id.*, [0048]. Though the shape of passageway 10 differs between the embodiments, it would not affect the way the device would be used by a patient or caregiver and it would still implement the

safety features described with respect to the embodiment of Figures 2-4. A POSA would have understood that there were no advantages for using the passageway 10 illustrated in Figures 2-4 over that depicted in Figures 7-9 and that implemented one disclosed embodiment or the other disclosed embodiment would have been merely a design choice.

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

2. Limitation [7.2]

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

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

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

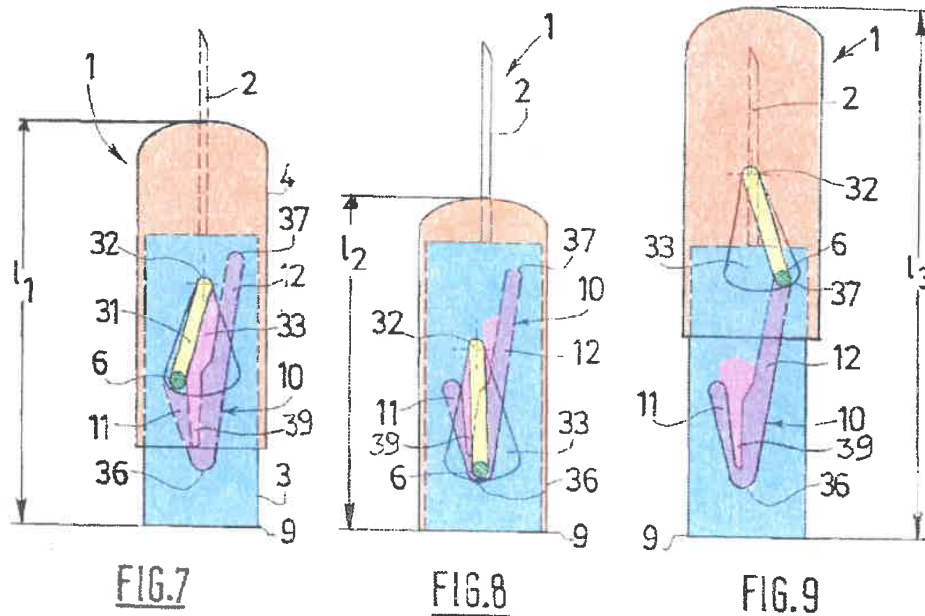


FIG. 7

Start Position

FIG. 8

Intermediate Position

FIG. 9

End Position

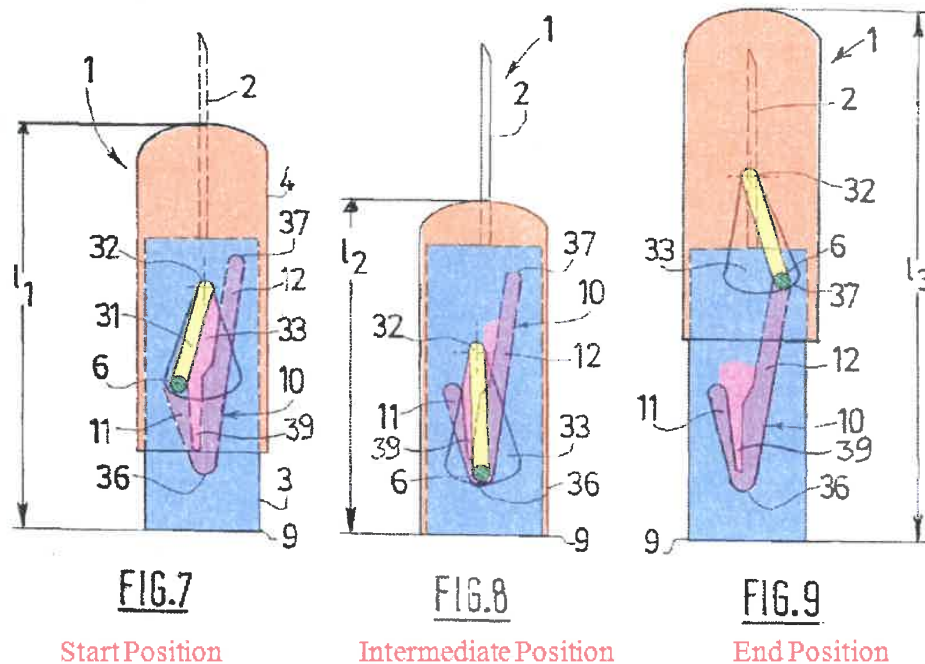
Id., FIGS. 7-9 (annotated).

136. Based on the foregoing, a POSA would have understood that the combination of Carrel and David-Hegerich teaches this limitation.

3. Limitation [7.3]

137. As I explained in the preceding two sections (Sections VIII.H.1-2) and illustrated in the embodiment of Figures 8 and 9, Carrel's needle shield (sleeve 4) is arranged to be substantially received in the support body (support 3) in the retracted position (injection position) and to protrude from the distal end of the support body in the advanced position (protection position).

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



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

139. Based on the foregoing, a POSA would have understood that the combination of Carrel and David-Hegerich teaches this limitation.

140. In view of foregoing Sections, namely Sections VIII.H.1-2, a POSA would have understood that the combination of Carrel and David-Hegerich teaches wherein: the guide pin is arranged to be located in an intermediate position in proximity of a proximal end of the guide track when the needle shield is in a retracted position, the guide pin arranged to be located in an end position in proximity of a distal end of the guide track when the needle shield is an advanced position, and the needle shield is arranged to be substantially received in the

support body in the retracted position and to protrude from the distal end of the support body in the advanced position, as recited in claim 7.

I. Claim 8

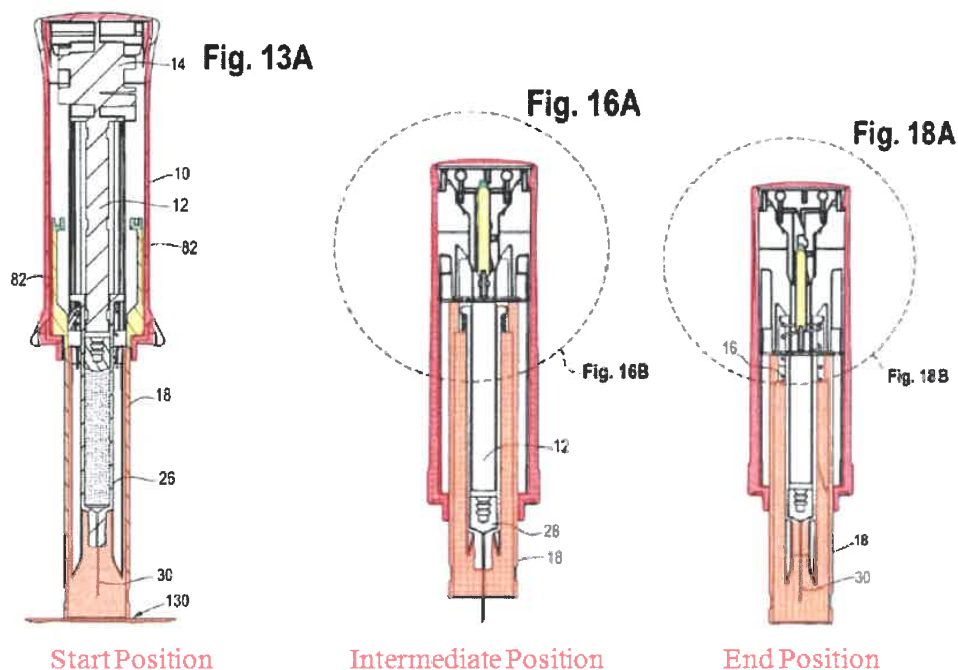
141. The combination of Carrel and David-Hegerich renders claim 8 obvious. Claim 8 is reproduced below.

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

142. In the embodiment described above with respect to dependent claim 7, Carrel's deflectable, flexible arm appears to be non-biased only in the intermediate, injection position. Dependent claim 8 of the '011 Patent, however, requires that the deflectable, flexible arm and guide pin are non-biased in all three of the start position, end position, and intermediate position. Carrel does not describe such an embodiment. But devising an alternate guide track so that the deflectable, flexible arm and guide pin meets these requirements would nonetheless have been obvious to a POSA. Indeed, David-Hegerich discloses just such an alternative configuration for its deflectable, flexible arm and guide pin.

143. More 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).

144. The David-Hegerich track follower 82 thus 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:

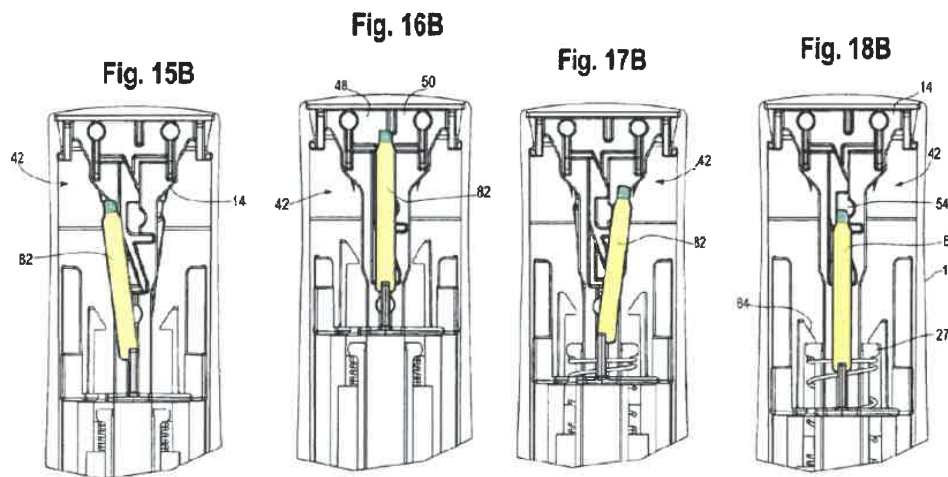
As the injection process proceeds, the track follower 82 will engage with the ramp 44 and be deflected to the left. After engagement, as the needle guard 18 and handle 10

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].

145. This excerpt is significant because it teaches that track follower 82 has an “original relaxed position” that is non-biased in a lateral direction perpendicular to the central axis. The excerpt is additionally important because, as is further set forth in Figure 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. Finally, 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., FIGS. 15B, 16B, 17B, and 18B (annotated).

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

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

J. Claim 9

148. The combination of Carrel and David-Hegerich renders claim 9 obvious. Claim 9 is reproduced below.

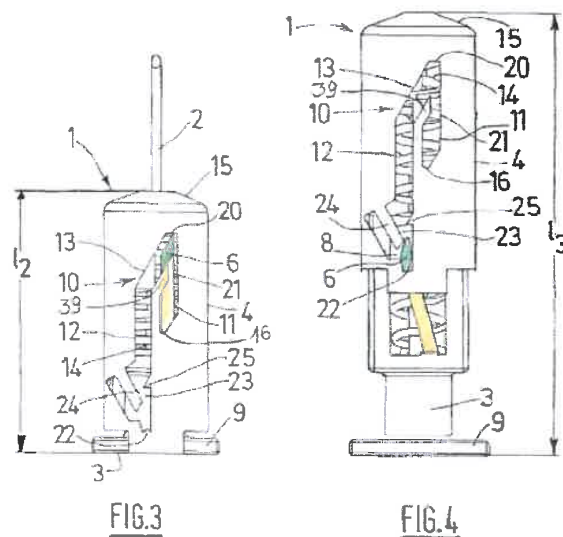
9. The safety device according to claim 1, wherein the flexible arm is deflectable to bias the guide pin in the lateral direction when the guide pin moves along the guide track from the intermediate position towards the end position.

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

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

Ex. 1005, [0065].

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



Id., FIGS. 3-4.

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

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

153. Thus, a POSA would have understood that the combination of Carrel and David-Hegerich teaches wherein the flexible arm is deflectable to bias the guide pin in the lateral direction when the guide pin moves along the guide track from the intermediate position towards the end position.

K. Claim 10

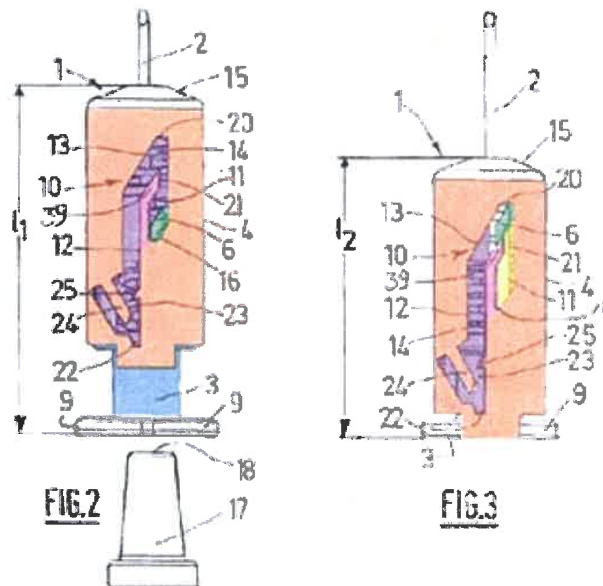
154. The combination of Carrel and David-Hegerich renders claim 10 obvious. Claim 10 is reproduced below.

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

155. 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.” *Id.*, [0066].

Carrel further discloses that the flexible tongue 39 is “elastically deformable” and is configured to prevent “peg 6 from returning from the said second section 12 to the said first section 11.” *Id.* During an injection sequence, between the storage position and the injection position, Carrel’s “peg 6 is displaced along the first longitudinal section 11 where it presses against the flexible tongue 39 and bends it to reach the vertex 36 of the U.” *Id.*, [0077].



Id., FIGS. 2-3.

156. Based on the shape and physical characteristics of flexible tongue 39, namely, that flexible tongue 39 is angled to define a narrowing 21 for peg 6 to pass through and that flexible tongue 39 is elastically deformable, a POSA would have

understood that flexible tongue 39 would retain the needle shield (sleeve 4) in an initial position and retain the guide pin (peg 6) in a start position between a distal end and a proximal end of the guide track (passageway 10). *Id.*, FIGS. 2-4, [0066].

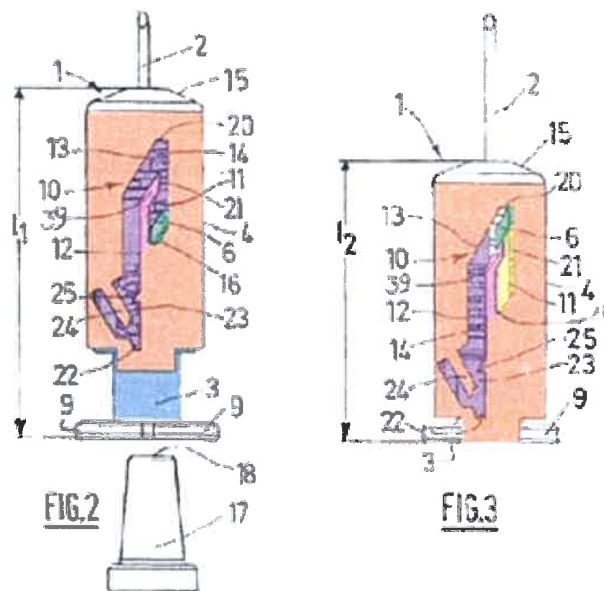
157. Thus, the combination of Carrel and David-Hegerich teaches wherein the needle shield is retainable in an initial position by a flexing gate element configured to retain the guide pin in a start position between a distal end and a proximal end of the guide track.

L. Claim 11

158. The combination of Carrel and David-Hegerich renders claim 11 obvious. Claim 11 is reproduced below.

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

159. 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.*" *Id.*, [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.

160. 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).

161. Thus, the combination of Carrel and David-Hegerich teaches wherein the flexing gate element is configured to guide the movement of the guide pin within the guide track.

M. Claim 12

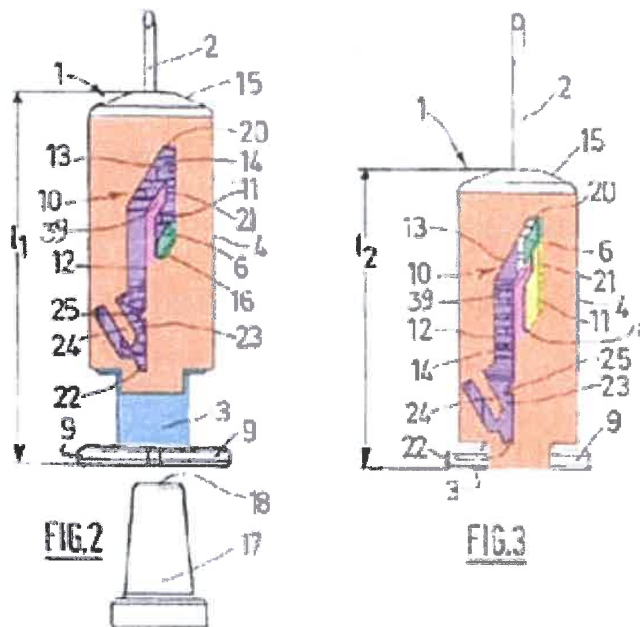
162. The combination of Carrel and David-Hegerich renders claim 12 obvious. Claim 12 is reproduced below.

12. The safety device according to claim 10, wherein the flexing gate element is deflectable in a lateral direction as to

allow the guide pin to move from the start position towards the intermediate position.

163. As I explained in Sections VIII.K-L with respect to claims 10-11, 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." *Id.*, [0066].

164. 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.

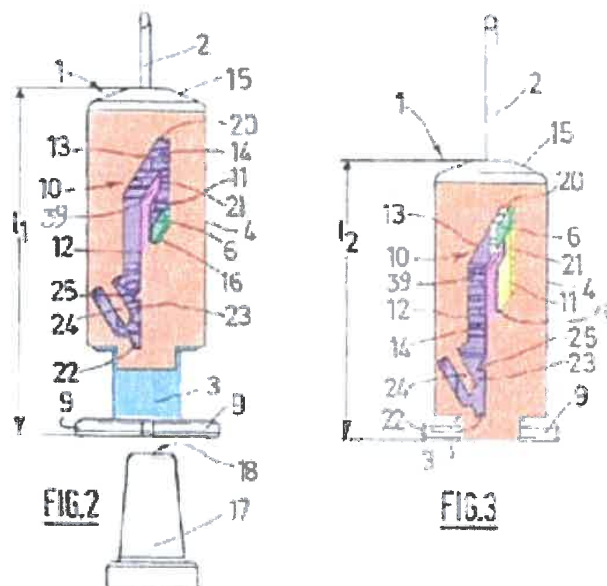
165. As described and illustrated, a POSA would have understood that Carrel's flexing tab 39 is deflectable in a lateral direction as to allow peg 6 to move from the storage position towards the injection position. Thus, the combination of Carrel and David-Hegerich teaches wherein the flexing gate element is deflectable in a lateral direction as to allow the guide pin to move from the start position towards the intermediate position.

N. Claim 13

166. The combination of Carrel and David-Hegerich renders claim 13 obvious. Claim 13 is reproduced below.

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

167. As explained in Sections VIII.K-M with respect to claims 10-12, Carrel's Figures 2-4 depict a "flexible tongue 39 which allows the peg 6 to pass in the distal direction and prevents the said peg 6 from returning in the proximal direction." *Id.*, [0066]. Carrel further discloses that "flexible tongue 39 forms at least in part the first safety means, elastically deformable, *preventing the peg 6 from returning from the said second section 12 to the said first section 11.*" *Id.* These features are set forth in Figures 2-3, included below.



Id., FIGS. 2-3.

168. As illustrated, flexing tab 39 comprises a sloped section that defines narrowing 21. A POSA would have understood that the sloped section of flexing tab 39 is configured to guide the movement of the guide pin along a section of the guide track and inhibit the guide pin from re-entering the start position. Thus, the combination of Carrel and David-Hegerich teaches wherein a sloped section of the flexing gate element is configured to guide the movement of the guide pin along a section of the guide track and inhibit the guide pin from re-entering the start position.

O. Claim 18

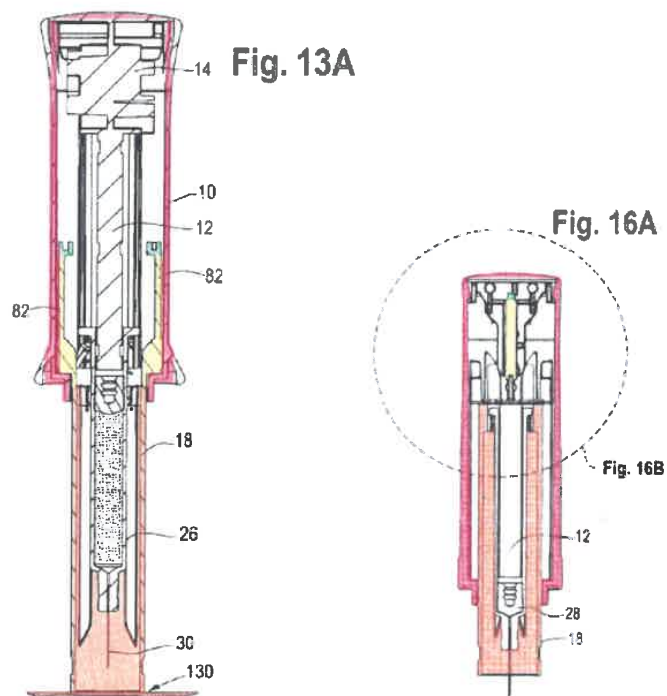
169. The combination of Carrel and David-Hegerich renders claim 18 obvious. Claim 18 is reproduced below.

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

170. Carrel is directed to “an injection device comprising at least one injection needle and a reservoir of product that is to be injected.” *Id.*, [0040]. Carrel further teaches that “syringe body 17, partially depicted in FIG. 2, [is] prefilled with the medicinal product to be injected into the injection site.” *Id.*,

[0061]. Carrel does not teach or suggest an outer body, however, this limitation is taught by David-Hegerich.

171. As I explained in Sections VIII.B.2-3 with respect to limitations [1.1]-[1.2], David-Hegerich's handle 10 is an outer body and the combination of Carrel and David-Hegerich teaches the outer body is capable of receiving a hollow support body that is slidably arranged relative to the outer body to perform an injection stroke. This feature is set forth in Figures 13A and 16A, included below.



Ex. 1006, FIGS. 13A and 16A (annotated). David-Hegerich further teaches that its “plunger 12 includes a top portion 14 which is attached to the open proximal end

of the generally cylindrically-shaped handle 10.” *Id.*, [0049]. David-Hegerich continues:

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

Id.

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

173. Carrel would benefit from a larger easy-to-use handle with a stable hand grip, as taught in David-Hegerich. *See id.*, [0050]. Thus, a POSA would have been motivated to enhance Carrel with David-Hegerich’s handle.

P. Claim 20

174. The combination of Carrel and David-Hegerich renders claim 20 obvious. I have reproduced claim 20, below. As I did with claim 1, I have labeled the claim limitations for ease of discussion.

[20.P] An injection device comprising:

[20.1] a pre-filled syringe; and

[20.2] a safety device comprising an outer body,

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

[20.4] a hollow needle shield slidable relative to the support body, and

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

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

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

[20.8] wherein the flexible arm is connected to or is integrally formed to the needle shield or the support body, and the guide

track is formed into the other of the needle shield or the support body, and

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

1. [20.1]: “a pre-filled syringe”

175. This claim element is substantially similar to element that I labeled [1.P] herein. For at least the reasons that I described in Section VIII.B.1 above, Carrel teaches this limitation.

2. [20.2]: “a safety device comprising an outer body”

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

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

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

4. [20.4]: “a hollow needle shield slidable relative to the support body”

178. This claim element is substantially similar to element that I labeled [1.3] herein. For at least the reasons that I described in Section VIII.B.4 above, Carrel teaches this limitation.

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

179. This claim element is substantially similar to element that I labeled [1.4] herein. For at least the reasons that I described in Section VIII.B.5 above, Carrel teaches this limitation.

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

180. This claim element is substantially similar to element that I labeled [1.5] herein. For at least the reasons that I described in Section VIII.B.6 above, Carrel teaches this limitation.

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

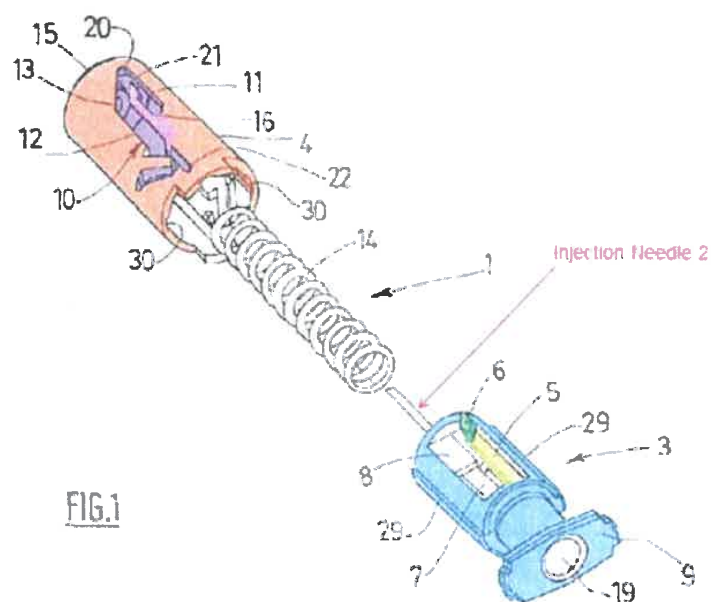
181. This claim element is substantially similar to element that I labeled [1.6] herein. For at least the reasons that I described in Section VIII.B.7 above, Carrel teaches this limitation.

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

182. This claim element is substantially similar to element that I labeled [1.7] herein. For at least the reasons that I described in Section VIII.B.8 above, Carrel teaches this limitation.

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

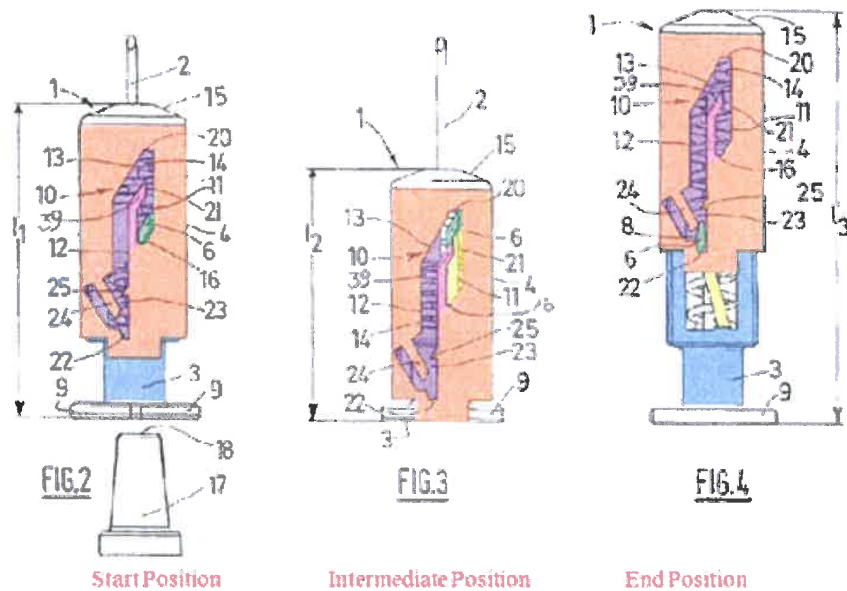
183. As explained in Section VIII.B.3 with respect to limitation [1.2], Carrel teaches wherein the pre-filled syringe is retained within the support body of the safety device. Carrel also teaches a hypodermic needle that protrudes the distal end of the support body. For example, Carrel’s Figure 1 illustrates “a protection device 1 for protecting an injection needle 2.” Ex. 1005, [0051].



Id., FIG. 1 (annotated).

184. As illustrated, Carrel's injection needle 2 protrudes the distal end of the support body (support 3). A POSA would have understood that Carrel's injection needle 2 is a hypodermic needle, as claimed.

185. As I explained in Sections VIII.H.1-3 with respect to claim 7, Carrel also teaches a configuration where the hypodermic needle is surrounded by the needle shield in the advanced position (protection position) and the hypodermic needle is exposed when the needle shield is in the retracted position (injection position).

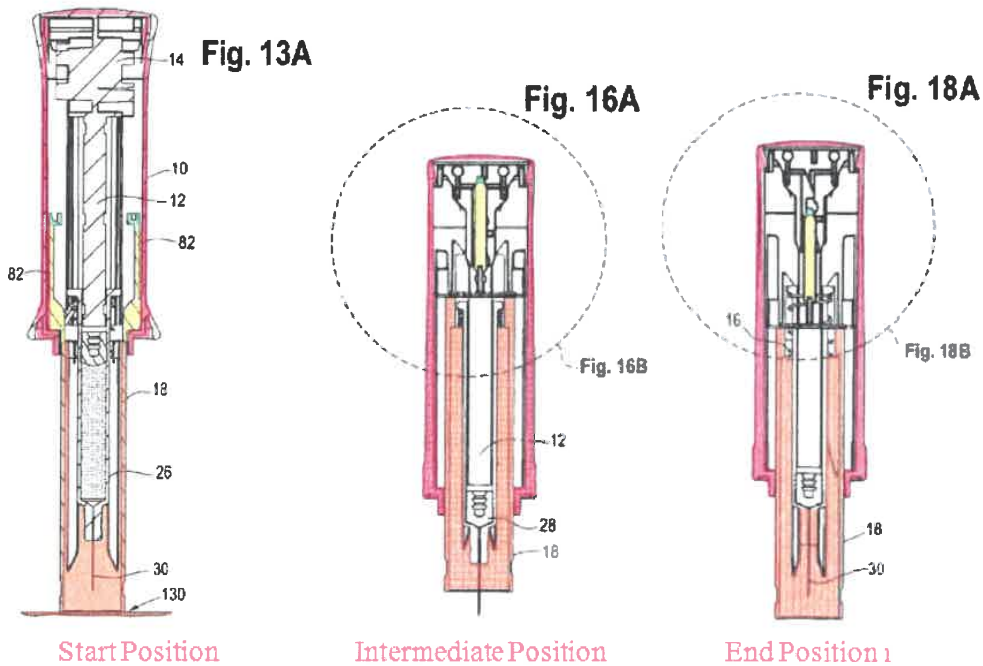


Id., FIGS. 2-4 (annotated).

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

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

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



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

188. Thus, Carrel's device, when modified in view of David-Hegerich, also teaches the "and" embodiment of this claim.

IX. Conclusion

189. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place

within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed this 9th day of May, 2018.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "C. E. Clemens", is written over a horizontal line.

Charles E. Clemens