UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2019-01657
Patent No. RE47,614

PETITION FOR *INTER PARTES* REVIEW

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I. INTRODUCTION

Petitioner Mylan Pharmaceuticals Inc. ("Mylan") seeks an *inter partes* review ("IPR") of claims 1-18 of U.S. Patent RE47,614 ("Harms"; EX1001), which is assigned to Patent Owner ("Sanofi"). This petition shows a reasonable likelihood that claims 1-18 are unpatentable. 35 U.S.C. 314(a).

Harms claims a configuration for securely holding a cartridge within a drug-delivery device that a person of ordinary skill in the art ("POSA") would have considered obvious. The claimed device includes a cartridge-retaining member, secured to the device's housing, for accepting and retaining a drug cartridge. To ensure the cartridge does not move within the cartridge-retaining member, the device incorporates a spring element—a spring washer—to apply an axially-directed biasing force that presses and holds the cartridge against the cartridge-retaining member. To ensure the necessary biasing force, the spring washer includes at least two fixing elements to hold the washer in place.

As this petition demonstrates, the notion that a spring element, like a spring washer, may be used to secure components against movement within a device was nothing new. And the various means by which this could be accomplished were familiar, well-understood, and readily implemented by those skilled in the art. In sum, the Harms claims are nothing more than a predictable use of well-established

components for the well-understood purpose of securing a component against movement within a drug-delivery device.

II. MANDATORY NOTICES

A. Real Parties-In-Interest

Mylan's real parties-in-interest are Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan GmbH (Mylan N.V. subsidiaries); Biocon Biologics India Limited, Biocon Research Ltd. and Biocon Ltd.; and Becton, Dickinson and Company.

B. Related Matters

Pending U.S. Application No. 16/538,503 is a continuation of the Harms reissue application. IPR2019-01658 also requests IPR of these claims.

C. Identification of Counsel and Service Information

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III. CERTIFICATIONS

Harms is available for IPR. Mylan is not barred or estopped from requesting IPR on these grounds.

IV. IDENTIFICATION OF CHALLENGE; STATEMENT OF PRECISE RELIEF REQUESTED

Mylan seeks cancellation of the challenged claims for the reasons stated below, supported with exhibits, including a declaration from Professor Arthur

Erdman (EX1004). The claims are unpatentable under pre-AIA 35 U.S.C. 103 on this obviousness ground:

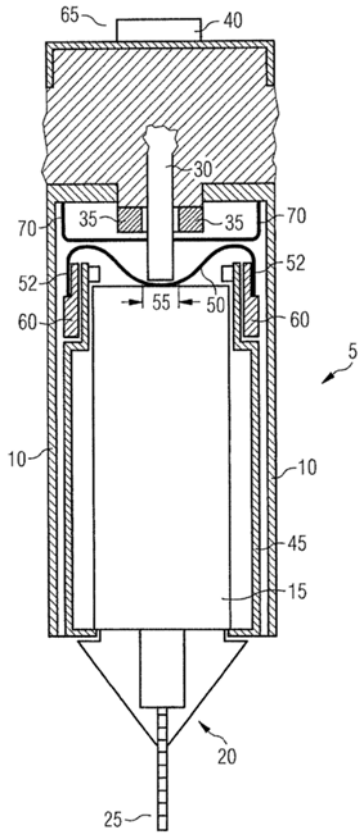
Ground	Claims	Basis
1	1-18	U.S. Patent Application Publication 2007/0021718 ("Burren," EX1006), U.S. Patent 2,882,901 ("Venezia," EX1007), and U.S. Patent 4,144,957 ("De Gennes," EX1008)

V. HARMS

Harms generally relates to a drug-delivery device. EX1001, Abstract, 1:26-29; EX1004, ¶22. The drug-delivery device 5 (FIG. 1 below) includes four primary components: (1) "housing" 10; (2) "cartridge" 15; (3) "cartridge retaining member" 45; and (4) "spring washer" 50.[1]

[1] In this petition, "proximal" indicates the end where a user actuates the device to dispense a dose of medicine, and "distal" indicates the end where medicine is dispensed from the device. *See* EX1004, ¶22 n.2; EX1001, 4:23-24, 5:18-20.

FIG 1

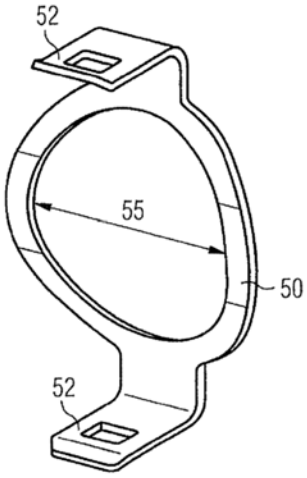


Housing 10 houses cartridge 15, which, at its distal end (bottom in the above figure), includes needle unit 20 through which a drug is dispensed from the cartridge. EX1001, 4:17-27, FIG. 1; EX1004, ¶24. Cartridge 15 is inserted into cartridge-retaining member 45, "which is (releasably) secured to the housing 10." EX1001, 4:30-32; EX1004, ¶25. Once secured, the cartridge's distal end abuts the cartridge-retaining member's distal end and "movement of the cartridge 15 in the distal direction is prevented by the cartridge retaining member 45." EX1001, 5:4-9, FIG. 1; EX1004, ¶25. In the described embodiment, cartridge-retaining member 45 includes a threaded proximal end that threads onto sleeve member 60, which is

fixed to housing 10 using, for example, laser-welding means. *See* EX1001, 5:28, 6:12-14, 7:25-27, FIG. 4; EX1004, ¶25.

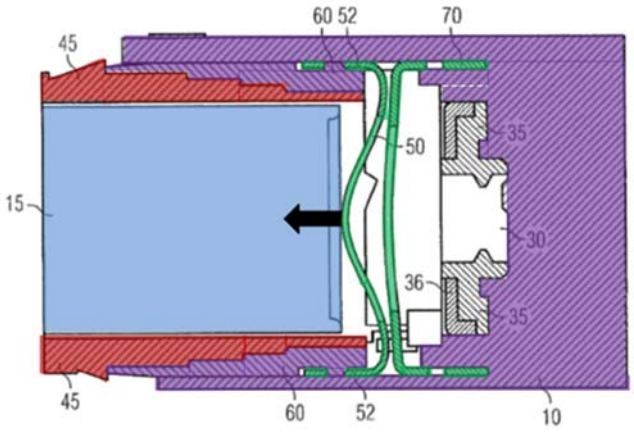
At the cartridge's proximal end, spring washer 50 is arranged within housing 10. EX1001, 5:10-11, FIGS. 1, 4; EX1004, ¶26. "Spring washer 50 exerts a force on the cartridge 15 in the distal direction and secures the cartridge against movement with respect to the cartridge retaining member 45 and against movement with respect to the housing 10." EX1001, 5:11-15; EX1004, ¶26. To exert the force, spring washer 50 is fixed relative to housing 10 using fixing elements 52, which (as shown below in FIG. 5) extend axially from the spring washer and snap-fit onto sleeve member 60, rotationally and axially fixing the washer relative to the housing. EX1001, 5:25-26, 5:29-35; *see also id.*, 5:54-67 (describing alternative form of fixing elements), 6:41-46 (explaining washer may be fixed to other components of the device), 5:44-53 (explaining fixing elements 52 may also serve as "positioning elements," which keep the spring washer "in a determined orientation"), 7:16-20, FIGS. 2, 4; EX1004, ¶26.

FIG 5



In some embodiments, further washer 70, which has a higher spring constant, is arranged on the spring washer's proximal side to "limit[] the movement of the spring washer 50 such that the spring washer 50 is not plastically deformed." EX1001, 6:47-55, 6:57-60, 7:34-44 (explaining further washer 70 may be a disk or spring washer), 6:63-65, 7:5-9, FIGS. 1, 3-4, 6; EX1004, ¶27. A color-coded annotation of FIG. 4 shows this configuration, where cartridge 15 is blue, cartridge-retaining member 45 is red, spring washer 50 and further washer 70 are green, and housing 10 and sleeve member 60 are purple. *See* EX1004, ¶28. As the figure shows, by securing cartridge-retaining member 45 to housing 10, the curved, elastic base of spring washer 50 exerts a distally-directed biasing force on the cartridge (shown by arrow), which presses the cartridge against the cartridge-retaining member's distal end to axially fix the cartridge during use. *Id.*, ¶29; *see also* EX1001, 6:17-30, FIG. 1.

FIG 4



See EX1004, ¶28.

Injection is accomplished by distal movement of a piston rod 30, which pushes a piston (not shown) within the cartridge, dispensing medicine from the device. EX1001, 4:38-45; EX1004, ¶30. To allow the piston rod's movement, both spring washer 50 and further washer 70 contain openings through which the piston rod passes through. EX1001, 5:20-24; EX1004, ¶30.

According to Harms, the spring washer's resilience allows cartridges with different lengths to be installed and manufacturing tolerances to be compensated, while simultaneously reducing or even preventing axial movement of the cartridge in the cartridge-retaining member. EX1001, 2:1-15; *see also id.*, 6:30-36; EX1004, ¶31.

Harms is a reissue of U.S. Patent 9, 132,237 ("the '237 patent"), which claims priority to a European application filed on October 13, 2008. EX1001, cover.

A. Challenged Claims

Harms has 18 claims, including independent claims 1 and 16-18. Claims 1 and 17-18 each recite a drug-delivery device having the four primary components described above. Claim 16 recites a method of manufacturing a drug-delivery device having these four components. Illustrative claim 1 is reproduced below:

> 1. A drug delivery device comprising:
>
> a housing with a proximal end and a distal end,
>
> a cartridge adapted to accommodate a drug,
>
> a cartridge retaining member adapted to retain the cartridge, the cartridge retaining member releasably secured to the housing, and
>
> a spring washer arranged within the housing so as to exert a force on the cartridge and to secure the cartridge against movement with respect to the cartridge retaining member,
>
> wherein the spring washer has at least two fixing elements configured to axially and rotationally fix the spring washer relative to the housing.

Claims 2-15 each depend directly or indirectly from claim 1, and recite additional features of the drug-delivery device, including spring-washer type, fixing-element positioning, a piston rod for dispensing the drug from the cartridge, a threaded sleeve member for fixing the spring washer, and a further washer for limiting movement of the spring washer.

B. Prosecution History

During prosecution of the ’237 patent, the claims were rejected, in part, as anticipated over prior art. *See* EX1003, 371. In response, Sanofi amended the claims to recite that the cartridge-retaining member was “releasably” secured to the housing, *id.*, 393-95, but the Examiner was unpersuaded and upheld the rejection, *id.*, 412-13. Sanofi further amended the claims to recite that the spring washer includes “at least two fixing elements” for axial and rotational fixation of the washer. *Id.*, 429. The Examiner allowed the claims, citing the latter amendments as reasons for allowance. *Id.*, 448.

During the reissue proceedings, Sanofi submitted new independent claims 17-19, leaving original claims 1-16 unamended. EX1002, 16-20. Notably, new claims 17-19 each eliminated the requirement that the cartridge-retaining member be “releasably” secured to the housing, thus broadening the original claims’ scope. *Id.* The Examiner made no prior-art rejections, but did note “surrender-generating limitations” that precluded broadening the claims, including the “releasably” secured limitation. *Id.*, 249-253. The Examiner rejected claim 19 for improper recapture of the surrendered subject matter. *Id.* After canceling claim 19 and addressing other formality objections, the Examiner allowed claims 1-18. *Id.*, 726-28.

VI. LEVEL OF ORDINARY SKILL

A POSA prior to October 13, 2008, would include someone who had, through education or experience, the equivalent of a bachelor's degree in mechanical engineering, or a related field, and an additional two years of work in, or at least an understanding of, the basics of medical-device design and manufacturing techniques. EX1004, ¶¶36-41. The POSA would have been familiar with elements commonly used to bias and secure components within mechanical devices (*e.g.*, spring elements, fastening structures) and the mechanical principles involved in using those elements. *Id.*, ¶38. As demonstrated below in section VIII.A, the POSA would have been familiar with the various spring types (including spring-washer types), the purposes for which they were used, their various design considerations (*e.g.*, load-deflection characteristics), and the materials and manufacturing processes commonly used to make them. *Id.*, ¶39. Professor Erdman explains that, given this general knowledge of spring mechanics and manufacturing, and their widespread use across many industries, a POSA, in developing a spring system for a drug-delivery device, would have considered devices in other fields that exploited the biasing force of springs in a manner analogous to the sought use (*e.g.*, axial securement). *Id.* This understanding of the POSA is confirmed by Harms' specification. *Id.*, ¶40.

VII. CLAIM CONSTRUCTION

The claim terms should be given their ordinary and customary meaning, consistent with the specification, as a POSA would have understood them. 37 C.F.R. §42.100(b); *see* EX1004, ¶42. Some claim terms, however, may warrant means-plus-function construction. In case these terms are construed as means-plus-function limitations, Mylan identifies corresponding structure for the claimed functions. 37 C.F.R. §42.104(b)(3); *see also* EX1004, ¶¶43-47.

1) **"cartridge retaining member"**: The independent claims recite a "cartridge retaining member" that "is adapted to retain" (claims 1 and 16-17) or "configured to accept and retain" (claim 18) the cartridge and is "releasably secured" (claims 1 and 16) or "secured" (claims 17-18) to the housing. The specification identifies cartridge-retaining member 45 as the corresponding structure. *See* EX1001, 4:30-36. FIGS. 1 and 4 (below) illustrate this structure in cross-section, annotated in red:

FIG 1

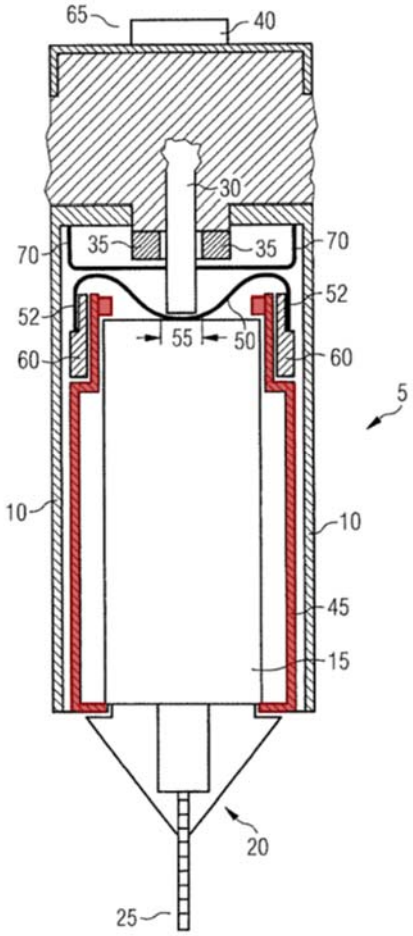
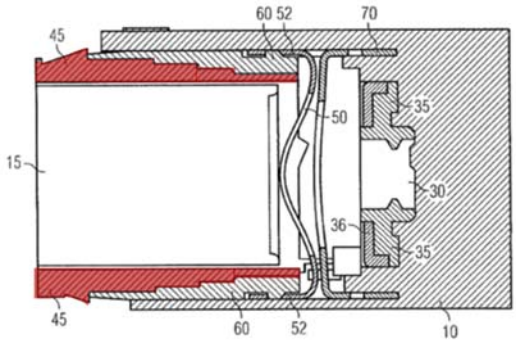


FIG 4



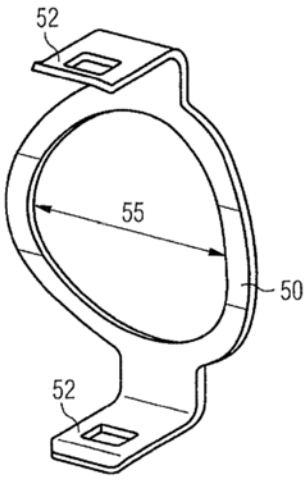
See EX1004, ¶45.

Cartridge-retaining member 45 is shown to have an inner cavity for receiving and holding at least a portion of the cartridge within it. *See, e.g.*, *id.*, 5:4-6. It also includes a proximal end that directly or indirectly secures to housing 10 through a threaded connection. *See id.*, 6:12-14; EX1004, ¶45.

2) **"fixing elements"**: Each of the independent claims recites a spring washer having "fixing elements" that "fix" ("axially and rotationally" in claims 1 and 16-17) the washer relative to the housing. The specification identifies fixing

elements 52 as the corresponding structure, shown below in FIG. 5.

FIG 5



The specification describes fixing elements 52 as "hook-shaped" axial extensions that protrude from the washer's base. *See, e.g.*, EX1001, 5:29-35, 7:16-20, FIGS. 2, 4. These extensions snap-fit directly or indirectly onto the housing. *Id.*; EX1004, ¶46. Alternatively, the specification describes the fixing elements as protrusions that "extend from the outer circumference of the spring washer" and are "arranged and/or axially guided within a respective guide slot" secured to the housing. *Id.*, 5:61-67; EX1004, ¶46.

VIII. PRIOR ART

The following sections provide an overview of the relevant state of the art in October 2008 and a summary of the applied references.

A. Background: drug-delivery devices and spring washers

The components of the claimed drug-delivery devices were well known and widely used before October 13, 2008. As noted above, the claims generally recite

devices including a housing, cartridge, cartridge-retaining member, and spring washer. Drug-delivery devices routinely dispensed medicine from a cartridge within a housing, and such cartridges were commonly retained by another component (*i.e.*, a cartridge-retaining member) secured to the housing. EX1004, ¶¶49-50 (citing EX1006, ¶¶23, 31, FIGS. 1, 4; EX1009, 1:66-2:25, 4:46-49, 5:24-28, FIGS. 1-5; EX1010, 1:58-74, 2:35-71, FIGS. 1-3; EX1007, 2:30-49, 3:2-20, FIGS. 1-4). Depending on how the cartridge is inserted into the device, the cartridge-retaining member could be permanently secured to the housing (*e.g.*, during manufacturing of the device, such as in a single-use injector pen) or releasably secured through known connection methods, which allowed for active removal and insertion of cartridges by a user. *Id.*, ¶50 (citing EX1006, ¶¶23, 29, FIG. 1; EX1009, 4:21-42, 5:24-28, 6:11-20, FIGS. 1-5, 7; EX1010, 2:35-71, FIGS. 1-3; EX1007, 3:2-20, FIGS. 1-4; EX1011, Abstract, 4:34-53, FIGS. 5a, 7-8; EX1012, Abstract, 6:1-35, FIGS. 2-4). Cartridge-retaining members were often designed to operate in conjunction with a spring or spring-like component. *Id.* (citing EX1006, ¶¶2-3, 23, 31-32, FIGS. 1, 4; EX1010, 2:34-71, FIGS. 1-3; EX1007, 2:30-65, 3:2-20, FIGS. 1-4; EX1013, 6 :19-37, 8:11-19, FIGS. 3-4; EX1014, ¶¶41-42, FIG. 11).

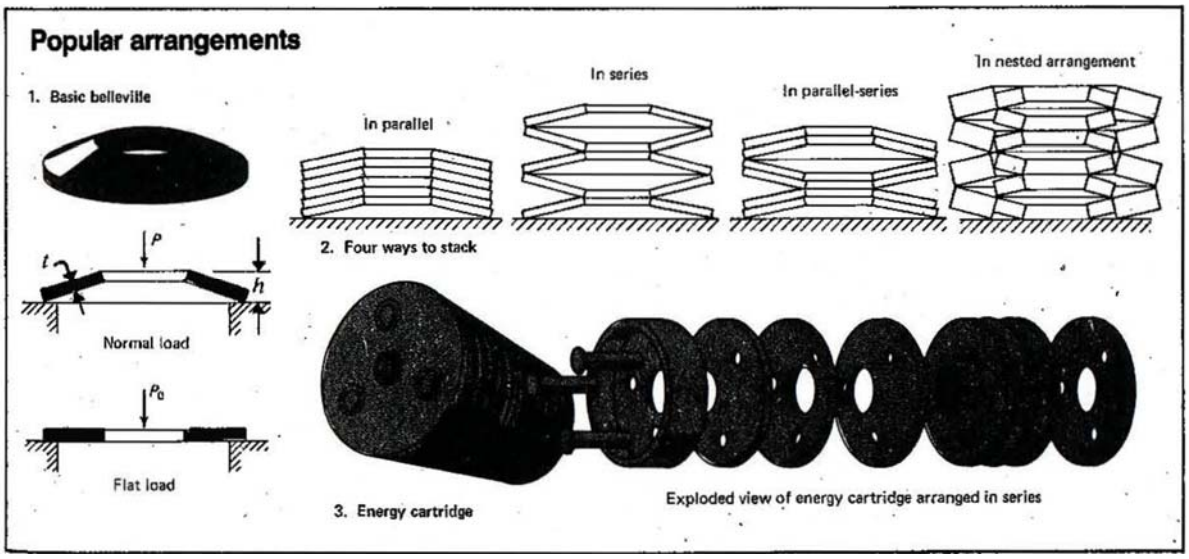
1. Spring Washers

Springs (or spring-like components) often served a variety of functions, including securing adjacent components to one another, and the benefits of such

configurations were well known. EX1004, ¶51 (citing EX1006, ¶¶3, 7; EX1015, ¶¶75-83, 88, 113, 124, 184-203; EX1014, ¶¶41-42; EX1008, 4:1-9, 4:17-23, 5:13-22, FIGS. 1-6). For example, springs were known to provide a straightforward, cost-effective mechanism for securing an inserted component, while providing tolerance for slight manufacturing variations in the component's size. EX1004, ¶52 (citing EX1006, ¶¶2-3; EX1010, 1:75-82; EX1016, 3:17-20, 4:11-13, 4:52-53, FIGS. 2-3; EX1017, ¶49 (stating use of spring is "common in order to equalise length tolerances of the container")). The POSA also understood that spring washers provided the predictable biasing functionality of springs, with additional advantages in certain contexts. EX1004, ¶53 (citing EX1006, ¶¶3, 16-17; EX1015, ¶¶184-203). These included compactness, low-cost manufacturing, and gradual, yet stable, application of biasing force. *Id.* (citing EX1018, ¶70; EX1015, ¶¶200-03, FIGS. 12a-12b; EX1019, ¶55, FIGS. 12A-12B). POSAs understood that these benefits were particularly applicable in drug-delivery devices. *Id.* (citing EX1010, 1:75-82; EX1007, 2:30-65, 3:2-20, FIGS. 1-4; EX1013, 6:19-37, 8:11-19, FIGS. 3-4; EX1014, ¶¶41-42, FIG. 11). The POSA was also familiar with the different types of spring washers commonly used, including curved washers, wave washers, and Belleville washers, and was aware of the various spring characteristics associated with each configuration. EX1004, ¶54 (citing EX1020, 800-02, 854-61,

FIG. 13-2e; EX1021, 501-02; EX1022, 678; EX1023, 221-22; EX1015, ¶¶75, 184-203).

Spring-washer stacking was a common, well-understood technique for fine-tuning the deflection profile of a spring system over a given load range. *Id.*, ¶55. As demonstrated below, the POSA was aware of the various ways in which washers could be stacked (*e.g.*, "in parallel," with curvatures disposed in the same direction, or "in series," with curvatures alternating in direction) and the load-deflection profiles associated with the type of stacking. *Id.* (citing EX1022, 678; EX1021, 501-02).



EX1024, 185 (showing popular arrangements of stacked Belleville-washer systems); *see also* EX1004, ¶56 (noting use of stacked spring-washer systems in other applications, including drug-delivery devices) (citing EX1025, 14:1-45,

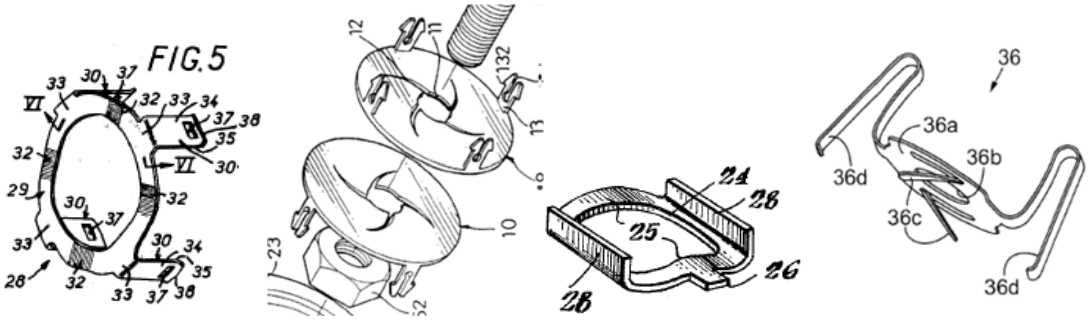
FIGS. 1A, 3A-C, 7A-F; EX1026, 1:5-10, FIGS. 1-6, 8-10, 11A-B; EX1015, Abstract, ¶¶200-03, FIGS. 12a-12b).

The POSA was aware that spring characteristics could be varied by stacking spring washers, and implementation of such systems was considered routine and predictable. EX1004, ¶55.

2. Fixing Elements

Fixing elements were also routinely used to secure washers against axial and rotational movement. EX1004, ¶57 (citing EX1008, FIGS. 5, 15; EX1027, FIG. 1). Those skilled in the art understood that preventing relative movement of a washer and an adjacent component was often desirable, for example, to generate the spring's biasing force and to prevent wear due to frictional contact. *Id*. (citing EX1006, ¶13; EX1028, 1:9-15, 1:23-26; EX1029, 1:11-22, 1:57-67). The structures used to fix a spring element, such as a spring washer, were familiar to those skilled in the art, and their use was appreciated in the context of drug-delivery devices. *Id.* (citing EX1006, ¶¶13-14, 23, 33, FIGS. 1, 4; EX1013, 6 :19-37, 8:11-19, FIGS. 3-4; EX1007, 2:30-65, 3:2-20, FIGS. 1-4; EX1014, ¶¶41-42, FIG. 11; EX1030, 1:17-25, 20:43-45, 20:54-58, FIG. 16). For example, spring washers including laterally or axially-extending arms or protrusions for fixation to a device were commonplace and well known to those in the field. *Id*., ¶58.

Professor Erdman notes several examples of common fixing-element designs used for spring washers in drug-delivery devices and other mechanical fields:



(from left to right) EX1008, FIG. 5; EX1027, FIG. 1 (partial view); EX1007, FIG. 6; EX1013, FIG. 13; *see also* EX1004, ¶58.

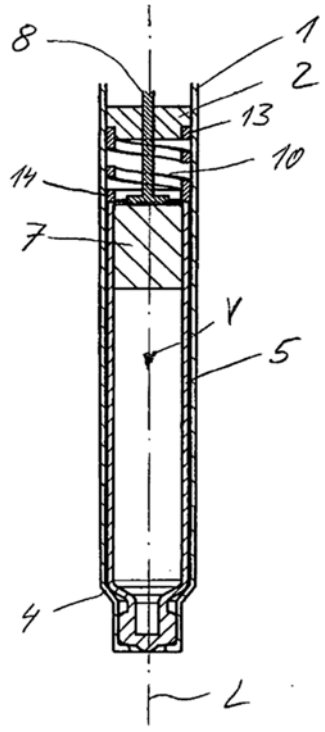
Designing a spring washer with fixing elements that engage a component to fix the spring washer in place was routine for a POSA. *See* EX1004, ¶58 (noting known spring washers with single or multiple fixing elements and their types) (citing EX1007, FIGS. 5-6; EX1013, FIGS. 13, 15; EX1008, FIGS. 1, 3, 5-6, 9, 15-16; EX1008, FIGS. 4-5, 13, 15-16; EX1027, FIG. 1). With typical design objectives in mind, the POSA could predictably implement a successful spring-washer system for securing components, like a cartridge, within a drug-delivery device. EX1004, ¶59.

B. Burren

Burren is a prior-art patent under §102(b). The specification acknowledges Burren as prior art. *See* EX1001, 1:38-42. Burren was also cited in IDSs filed

during the original and reissue prosecutions, but the examiner did not apply Burren substantively.

Burren teaches an injection pen having "[a] spring for use as a compensating, supporting or driving spring...." EX1006, Abstract; *see also id.*, ¶2; EX1004, ¶61. The pen includes a longitudinally-extending, sleeve-type housing 1 containing container 5 filled with a liquid medicament. EX1006, ¶22, FIGS. 1, 4. The container's distal end is supported by stop 4, which may be part of housing 1 or a separate part joined to or carried by the housing. *Id.*, ¶23. Spring 10 at the container's proximal end "biases the container against the stop 4 in the forward drive direction V [*i.e.*, distal direction]." *Id.*; *see also id.*, ¶¶31-34, FIG. 4 (describing alternative spring 20).



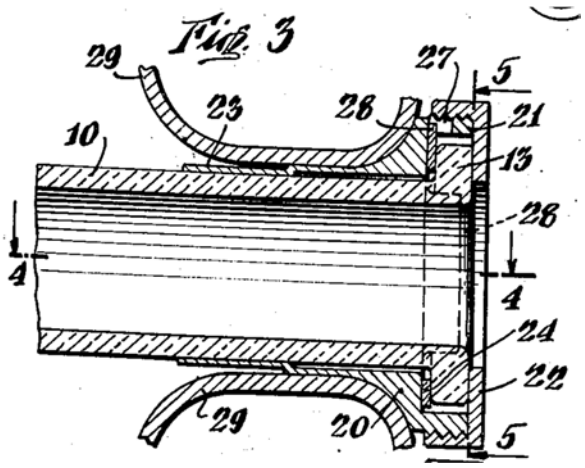
Id., FIG. 1.

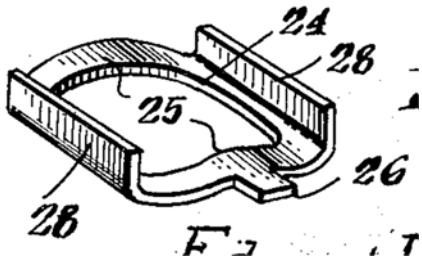
Burren teaches that the spring may take any form, such as "a coil spring, leaf spring, plate spring, a spring with legs, for example, or any suitable configuration." *Id.*, ¶16. In any case, Burren teaches that the spring "serve[s] as a means of compensating longitudinal tolerances for supporting a medicament container in an injection device...." *Id.*, ¶17; EX1004, ¶62.

C. Venezia

Venezia is a prior-art patent under §102(b). Venezia was not before the examiner.

Venezia teaches a hypodermic-syringe assembly having barrel 10 containing medicament, plunger 15 for expelling the medicament, and an attachment for attaching the barrel and the plunger. EX1007, 1:15-19, 1:54-2:5. The attachment includes collar 20 that threadedly engages flanged ring 22. *Id.*, 2:30-37. Between these components is flange 13 of barrel 10. *See id.*, FIGS. 3-4. To prevent undesired axial movement of flange 13, a retainer—washer 24—is positioned between collar 20 and flange 13. *Id.*, 2:50-56, 2:58-60, FIGS. 3-5. The washer includes resilient bulged zones 25, which press against flange 13 when ring 22 is threaded onto collar 20. *Id.*, 2:53-58, 3:11-17. The washer is fixed to the collar via protruding tongue 26, and the washer is fixed to the barrel via two axially-extending extensions 28. *Id.*, 2:63-69, 3:15-22, FIG. 6.





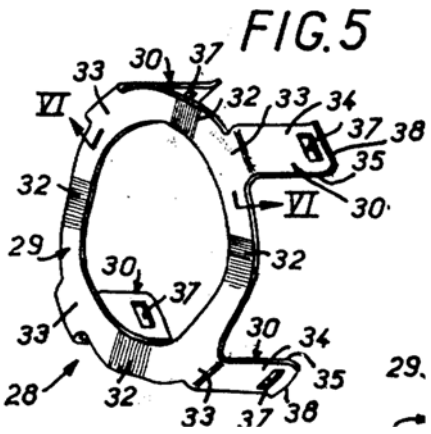
Id., FIGS. 3, 6.

This configuration allows "any one of a series of plungers" to fit "any one of a series of barrels," while also ensuring that the barrel is sufficiently supported so that "predetermined amounts of fluid may be dispensed with accuracy...." *Id.*, 2:6-13, 3:37-42; EX1004, ¶69.

D. De Gennes

De Gennes is a prior-art patent under §102(b). De Gennes was not before the examiner.

De Gennes describes a clutch bearing having resilient cover 28 "suitable for axially fastening together [an] operating element 10 and [a] drive element 11." EX1008, Abstract, 4:1-4; EX1004, ¶71. The cover is a spring washer with alternating resilient support zones 32 that bear on the drive element. *See id.*, 4:21-23, 4:45-54, FIG. 2; *see also id.*, FIG. 5 (below).

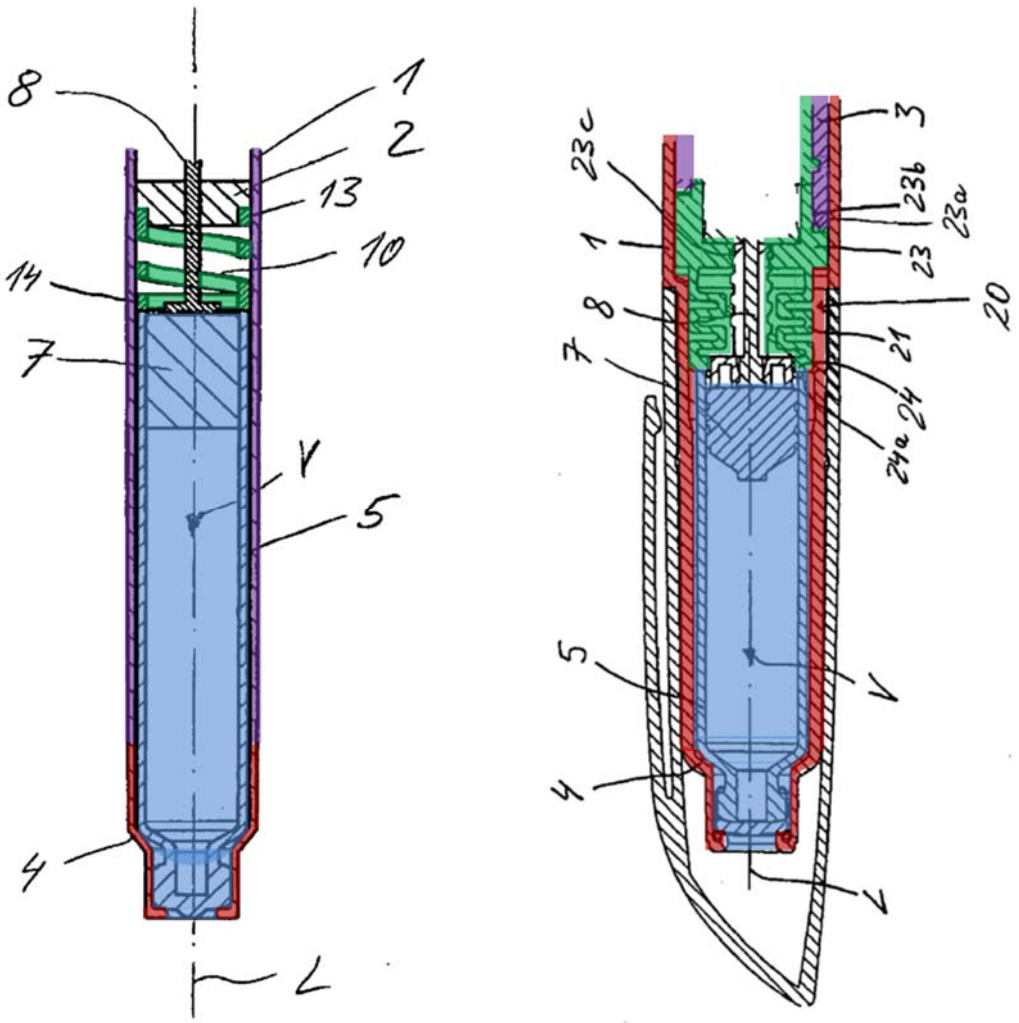


Cover 28 includes axially-extending legs having cutouts 37 that snap-fit onto corresponding claws 20 of reinforcement plate 15, axially and rotationally fixing the components relative to one another. *Id.*, 4:24-28, 4:38-40, 4:59-5:2. De Gennes teaches that this snap-fit engagement grips operating element 10 and drive element 11 together and, due to the washer's resilience, the drive element is fixed axially relative to operating element 10. *Id.*, 1:14-18, 5:14-22; EX1004, ¶72. Professor Erdman explains how De Gennes, while concerned with a clutch bearing, addresses a problem analogous to that addressed in Burren (axially fixation and support of two components relative to one another), and addresses that problem by using a spring washer to exert a biasing force on the components for axial fixation. EX1004, ¶73 (annotating analogous components of De Gennes). As explained above in section VI, given POSAs' familiarity with general spring mechanics and manufacturing and their widespread use for securing components, a POSA would have considered devices like De Gennes, which also incorporates a biasing element, like a spring washer, for a similar function. *Id.*, ¶74.

IX. GROUND 1: CLAIMS 1-18 WERE OBVIOUS OVER BURREN, VENEZIA, AND DE GENNES

Each of claims 1-18, as a whole, would have been obvious from the combined teachings of Burren, Venezia, and De Gennes. As explained above, the independent claims recite a drug-delivery device (or a method of manufacturing such a device) having four main components: (1) a housing for housing internal components of the device; (2) a cartridge containing medicine; (3) a cartridge-retaining member for retaining the cartridge; and (4) a spring washer for biasing the cartridge against the cartridge-retaining member to secure it against movement, where the spring washer includes at least two fixing elements to fix it relative to the housing. *See supra*, §V; EX1004, ¶76.

As shown in the annotated views of FIGS. 1 (left) and 4 (right) below, Burren teaches injection pens also having four similar components that perform the same functions as those claimed by Harms: (1) housing 1 (FIG. 1, purple) or proximal housing portion 2 (FIG. 4, purple) for housing internal components of the device; (2) container 5 (blue) containing medicine; (3) stop 4 (FIG. 1, red) or distal housing portion 1 (FIG. 4, red) for retaining the container; and (4) spring 10 (FIG. 1, green) or spring 20 (FIG. 4, green) for biasing the container against the stop or distal housing portion to secure it against movement, where the springs have positioning devices for fixing the springs relative to the housing. *See, e.g.*, EX1006, ¶¶13, 22-24, 31-33; EX1004, ¶77.



EX1004, ¶77.

The springs shown in Burren's illustrated embodiments are a coil spring and spring bellows, rather than a spring washer. EX1004, ¶¶78-79. Nevertheless, as explained below, Venezia and De Gennes demonstrate the well-known and predictable use of spring washers to perform the same compensating function: biasing a component relative to another to axially fix that component within a device. *See* EX1004, ¶¶80-83; *infra*, §IX.A.5-6. From the references' combined teachings, a

POSA would have recognized that an injection pen like Burren's may be designed and successfully implemented with a spring washer, fixed relative to the housing using at least two fixing elements, to compensate and secure cartridges against axial movement within the device. *See* EX1004, ¶¶84-100; *infra*, §IX.C. Thus, the combination of Burren, Venezia, and De Gennes renders the claims obvious.

An element-by-element analysis for the independent claims appears below, with identical or substantially identical clauses grouped together. A discussion of the dependent claims follows this analysis. The citations listed are illustrative, not exhaustive. An explanation of the rationale to combine the references' teachings is then provided.

A. Claims 1 and 16-18

1. Preambles

Harms	**Burren, Venezia, and De Gennes**
[1.Preamble, 17.Preamble, 18.Preamble] A drug delivery device comprising:	"The present invention relates to devices for dispensing, injecting or delivering substances, and to methods of making and using such devices." EX1006, ¶2; *see also* "Devices for medical and pharmaceutical applications which are predominantly or to a large extent made from plastic components are very commonplace. Typical examples of such devices are injection devices, for example injection pens, for administering medicaments,
[16.Preamble] A method of manufacturing a drug delivery device	

comprising:	usually in liquid form. A typical example of such devices are injection pens such as those used for the treatment of diabetes, administering growth hormones and in the treatment of osteoporosis, for example, and by means of which the respective user self-administers the medicament." *Id.*, ¶10; *see also id.*, ¶¶7, 22-23; EX1007, 1:15-19.

Claims 1, 17, and 18 are each directed to "[a] drug delivery device," while claim 16 is directed to "[a] method of manufacturing" such a device. EX1004, ¶103. Burren teaches drug-delivery devices "for dispensing, injecting or delivering substances" for "medical and pharmaceutical applications" and "methods of making and using such devices." EX1006, ¶¶2, 10; EX1004, ¶104. For example, Burren teaches the use of self-administering "injection pens such as those used for the treatment of diabetes, administering growth hormones and in the treatment of osteoporosis...." *Id.*, ¶10; *see also id.*, ¶¶22-23; EX1007, 1:15-19 (describing hypodermic syringes for drug delivery). Thus, to the extent the preamble is limiting, the combination of Burren, Venezia, and De Gennes teaches the preambles of claims 1 and 16-18. EX1004, ¶105.

2. Elements 1.1, 16.1, 17.1, and 18.1

Harms	**Burren, Venezia, and De Gennes**
[1.1, 17.1, 18.1] a	"FIG. 1 illustrates a distal portion (or front end portion of an

housing with a proximal end and a distal end,	injection device, which in the embodiment illustrated as an example is an injection pen, wherein the device has a central longitudinal axis L. The injection device has a longitudinally extending, sleeve-type housing 1 comprising one or more parts." EX1006, ¶22; *see also id.*, ¶31, FIG. 4.
[16.1] providing a housing with a proximal end and a distal end,	

Each of the claims recites a housing (or providing a housing) having two ends, a "proximal end" and a "distal end." EX1004, ¶106. Burren describes an injection pen having a "sleeve-type housing 1" that extends along central longitudinal axis L. *Id.*, ¶22, FIG. 1; *see also id.*, ¶31, FIG. 4 (illustrating second embodiment having proximal housing portion 3); EX1004, ¶107. A POSA would have understood housing 1 to have both a "distal end" at the device's dispensing end (bottom of FIG. 1, shown below), and a "proximal end" at the device's actuating end (top of FIG. 1). EX1004, ¶107.

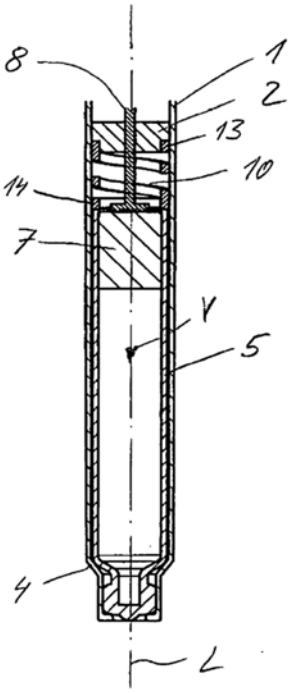


Fig. 1

Thus, the combination teaches the claimed "housing." EX1004, ¶108.

3. Elements 1.2, 16.2, 17.2, and 18.2

Harms	**Burren, Venezia, and De Gennes**
[1.2, 17.2, 18.2] a cartridge adapted to accommodate a drug,	"Accommodated in a distal portion of the housing 1 is a container 5, for example a glass ampoule, which is filled with a liquid medicament, for example insulin." EX1006, ¶22, FIG. 1; *see also id.*, ¶31, FIG. 4 (illustrating second embodiment with container 5).
[16.2] providing a cartridge adapted to accommodate a drug;	

Each of the claims recites a cartridge (or providing a cartridge) "adapted to accommodate a drug." EX1004, ¶109. Burren teaches the injection pen includes

container 5 (*i.e.*, a "cartridge") that is "filled with a liquid medicament," EX1006, ¶22, meaning the container is "adapted to accommodate a drug." EX1004, ¶110. The combination thus teaches the claimed "cartridge."

4. Elements 1.3, 16.3, 17.3, and 18.3

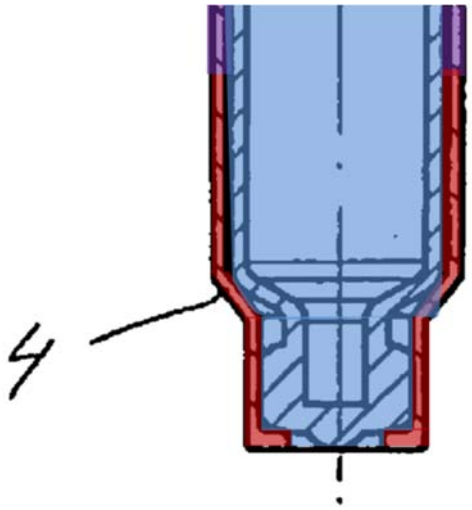
Harms	**Burren, Venezia, and De Gennes**
[1.3] a cartridge retaining member adapted to retain the cartridge, the cartridge retaining member releasably secured to the housing, and	"In the forward drive direction V parallel with the longitudinal axis L of the driving element 7, the container 5 is supported by means of an abutment contact on the housing 1. In the embodiment illustrated as an example, the housing 1 itself directly forms a stop 4 for the container 5. In principle, however, a stop 4 may be provided in the form of a part joined to or carried by or in the housing 1 so that it [cannot] move axially." EX1006, ¶23; *see also id.*, ¶¶22, 29, FIG. 1. "FIG. 4 illustrates another exemplary embodiment of the present invention, in this case, a distal portion of an injection device which, in the embodiment illustrated as an example, is again an injection pen.... The housing of the embodiment illustrated as a second example has a distal housing portion 1 accommodating the container 5 and a proximal portion 3 which is connected to the housing portion 1 so that it [cannot] be moved axially and which is preferably also prevented from rotating." *Id.*, ¶31, FIG. 4.
[16.3] providing a cartridge retaining member adapted to retain the cartridge and be releasably secured to the housing,	
[17.3] a cartridge retaining member adapted to retain the cartridge, the cartridge retaining member is secured to the housing, and	

[18.3] a cartridge retaining member configured to accept and retain the cartridge, the cartridge retaining member is secured to the housing, and	

Each of the claims recites a "cartridge retaining member" or providing such a component, but with two notable differences. EX1004, ¶111. First, elements 1.3, 16.3, and 17.3 recite that the cartridge-retaining member is "adapted to retain" the cartridge, while element 18.3 recites that the component is "configured to accept and retain" the cartridge. Second, elements 1.3 and 16.3 recite the cartridge-retaining member is "releasably secured to the housing," while elements 17.3 and 18.3 recite that it is "secured" to the housing. As explained below, the combination teaches a "cartridge retaining member" having each of the features recited in each of the elements. *Id.*

Burren teaches container 5 is "[a]ccommodated in a distal portion of the housing 1," and "is supported by means of an abutment contact," which, in the illustrated embodiment, is a stop 4, integrally formed with housing 1. *Id.*, ¶¶22-23, FIG. 1; EX1004, ¶112. As shown below in a partial, annotated view of FIG. 1, stop 4 (red) forms a distal-end portion of housing 1 (purple) and includes an inner

cavity with a bowl-like distal end for receiving and supporting a distal portion of the container. EX1004, ¶113. A POSA would have understood this structure to be "adapted to retain" and "configured to accept and retain" container 5. *Id.* Moreover, as an integrated part of housing 1, a POSA would have understood stop 4 as being "secured" to the housing. *Id.*

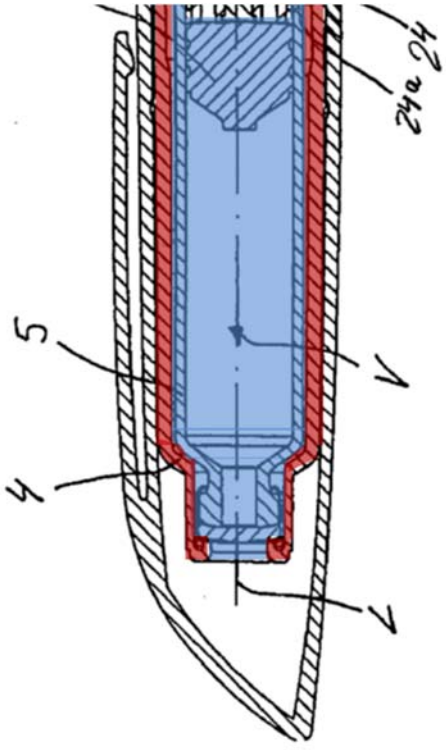


Id.

Accordingly, Burren teaches a "cartridge retaining member" in the form of stop 4, which, as illustrated in FIG. 1, is "secured to the housing" and "adapted to retain" (element 17.3) or "configured to accept and retain" (element 18.3) the cartridge. *Id.*

A POSA also would have understood Burren as suggesting a "cartridge retaining member" that is "releasably secured" to the housing, as recited in elements 1.3 and 16.3. EX1004, ¶¶114-17. Burren teaches that stop 4 may be provided as a separate part that is "joined to or carried by or in the housing 1 so

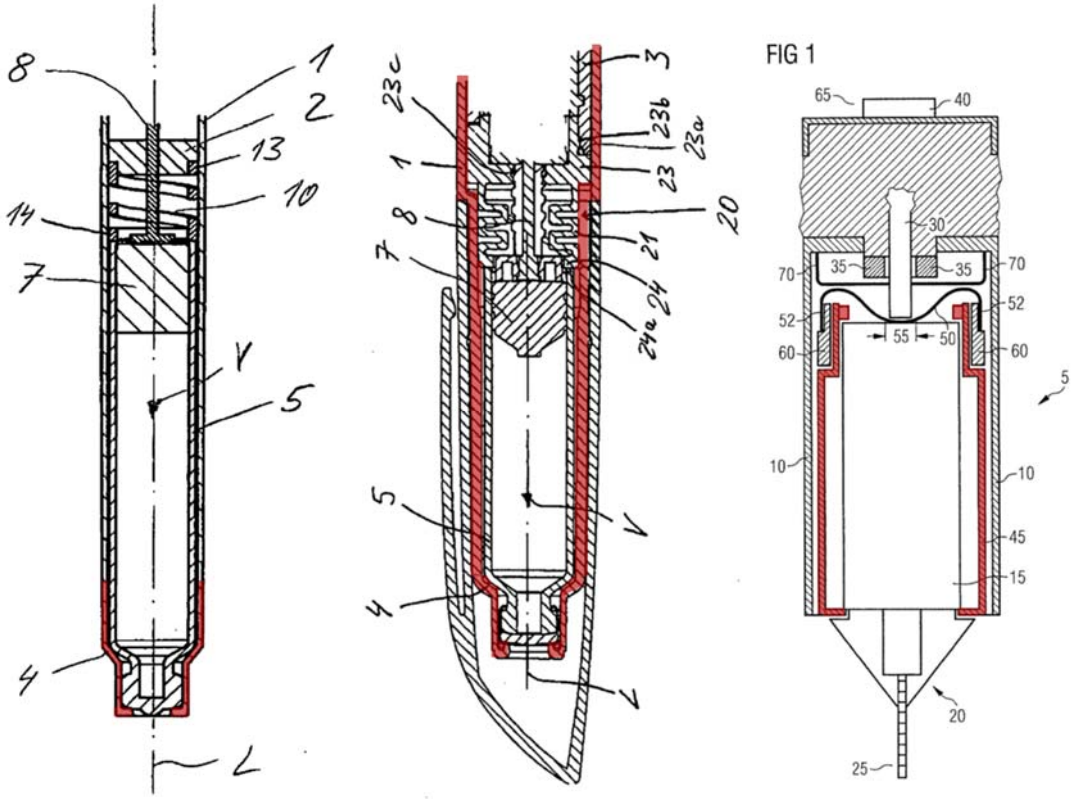
that it [cannot] move axially." EX1006, ¶23; *see also id.*, ¶22 (stating housing 1 may "compris[e] one or more parts"); EX1004, ¶114. Moreover, in a second embodiment, Burren describes a substantially identical injection pen where the housing includes two parts: distal housing portion 1 and proximal housing portion 3. EX1006, ¶31, FIG. 4. Distal housing portion 1 includes stop 4 and "accommodat[es] the container 5." *Id.* Burren explains distal housing portion 1 is secured to proximal housing portion 3 (*i.e.*, a "housing" with proximal and distal ends). *Id.* As shown in a partial, annotated view of FIG. 4, distal housing portion 1 (red) includes an inner cavity that fully accepts container 5 and retains the container by abutting the container's distal end against the distal end of stop 4. EX1004, ¶114.



Thus, a POSA would have understood Burren as suggesting a "cartridge retaining member" that is a part separate from the housing (*e.g.*, a separate stop 4 or distal housing portion 1) for accommodating a portion of, or the entire, drug cartridge. EX1004, ¶115.

In addition, the POSA would have understood that the separate stop or distal housing portion may be "releasably secured" to the housing. EX1004, ¶116. Burren teaches an injection pen that "can be repeatedly re-used," where the container may be replaced after use. EX1006, ¶29. To facilitate cartridge replacement, a POSA would have found it apparent that stop 4 or distal housing portion 1 should be releasably secured to the housing. EX1004, ¶116. The use of separable structures for holding a cartridge within a delivery device was well-known, and those structures often included releasable connections, such as threaded or similar connections to allow replacement of the cartridge. EX1004, ¶116 (citing as examples EX1009, EX1011, EX1012); *see also supra*, §§VI, VIII.A; EX1004, ¶50. The POSA would have considered these types of connections to be well understood and would have predictably implemented a releasably-secured stop or distal housing portion to the device's housing to facilitate re-use of the device. EX1004, ¶116. Accordingly, the combination further teaches a "cartridge retaining member" that is "releasably secured" (and for the same reasons, also "secured") to the housing. EX1004, ¶117.

If a means-plus-function interpretation applies, Burren suggests a "cartridge retaining member" that performs the function of claims 1 and 16-18 using a structure equivalent to the corresponding structure for the same reasons explained above and as illustrated by the comparison to Harms below. *See* EX1004, ¶118; *supra*, §VII. Specifically, Burren suggests connecting a separate part (*e.g.*, stop 4/distal housing portion 1), which accepts and retains at least a portion of a cartridge within its inner cavity, to a housing. EX1004, ¶118. And, to facilitate removal of an empty cartridge, the POSA would have understood the connection should be releasable, such as, for example, a threaded connection. *Id.*



EX1006, FIG. 1 (left, stop 4 annotated red), FIG. 4 (center, distal housing portion 1 annotated red); EX1001, FIG. 1 (right, cartridge retaining member 45 annotated red).

Thus, the combination teaches the claimed "cartridge retaining member."

5. Elements 1.4, 16.4, 17.4, and 18.5[2]

Harms	Burren, Venezia, and De Gennes
[1.4, 17.4] a spring washer arranged within the housing so as to exert a force on the cartridge and to secure the cartridge against movement with respect to the cartridge retaining member,	"In the direction opposite the forward drive direction V, the container 5 is supported on the housing 1 by means of a spring 10 and the insert 2. The spring 10 is provided in the form of a coil spring and operates as a compression spring. The longitudinal axis L of the device also constitutes the spring axis. The spring 10 bridges a space left free between the container 5 and the insert 2 and biases the container 5 against the stop 4 in the forward drive direction V." EX1006, ¶23, FIG. 1.
[16.4] arranging a spring washer within the housing and releasably securing the cartridge retaining member to the housing, thereby loading the spring washer so as to exert a	"A spring in accordance with the present invention may be a tension spring, flexion spring or torsion

[2] Element 18.5 is addressed here due to its similarities with elements 1.4, 16.4, and 17.4. Element 18.4 is addressed below in section IX.A.6.

force on the cartridge and to secure the cartridge against displacement with respect to the cartridge retaining member,	spring and, in some preferred embodiments, a compression spring. Its shape may be that of a coil spring, leaf spring, plate spring, a spring with legs, for example, or any suitable configuration." *Id.*, ¶16; *see also id.*, ¶¶3, 16-17, 24, 31-34, FIGS. 2-4.
[18.5] a spring washer...positioned axially within the housing so as to exert a force on the cartridge to secure the cartridge against movement with respect to the cartridge retaining member,	***** "[I]t is contemplated to employ a retainer as part of the collar assembly; such retainer preferably involving the detailed construction illustrated in Fig. 6. In that view, it will be noted that the retainer is in the form of a washer 24 which may embrace a circular body and include upwardly bulged zones 25, which yieldingly resist deformation into the body zone of the spring retaining member. This washer should be inserted into the cup-shaped rear portion of the extension as defined by flange 21 in the manner shown in Figs. 3, 4 and 5." EX1007, 2:45-65, FIGS. 3-4, 6. "Under continued tightening, the bulged portions 25 will bear with increasing resistance against the end face of flange 13." *Id.*, 3:11-17; *see also id.*, 1:15-17, 1:34-38, 1:56-2:5, 2:30-37, 2:45-60, FIGS. 1-2. ***** "[A] cover or connecting member 28 is provided

	which is suitable for axially fastening together the operating element 10 and the drive element 11; this cover 28 comprises a transverse wall 29 whose overall shape is such as to enable it to form by itself an axially acting resilient means suitable for urging the drive element 11 in the direction of the flange 13....” EX1008, 4:1-8; *see also id.*, 4:17-23, 4:45-51. “Whatever the method of engagement, the cover 28 and the reinforcement plate 15 together grip the drive element 11 and the operating element 10; due to the undulations with which it is formed, the transverse wall 29 of the cover 28 elastically presses the outer race 24 of the ball bearing constituting the drive element 11 against the transverse flange 13 of the operating element 10, while by its axial legs 34 the cover 28 secures the reinforcement plate 15, which lines its rear face, to the flange 13.” *Id.*, 5:13-22, FIGS. 5, 15.

Elements 1.4, 16.4, and 17.4 recite a “spring washer” (or providing a “spring washer”) that is “arranged within the housing.” Element 18.5 similarly recites a “spring washer” that is “positioned axially within the housing.” Each of the claims recites the spring washer is arranged or positioned “so as to exert a force on the

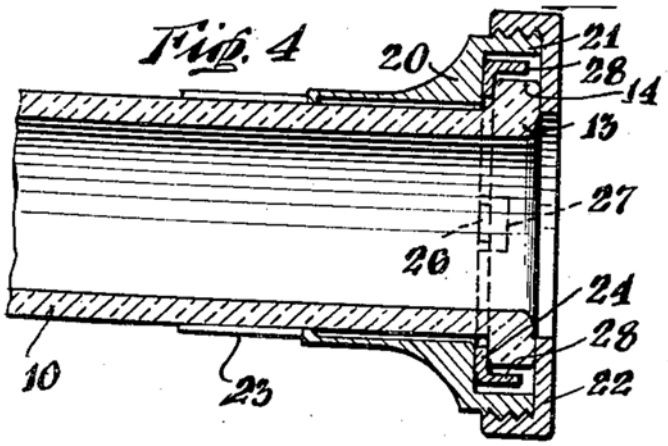
cartridge." For element 16.4, this occurs by securing the cartridge-retaining member to the housing, "thereby loading the spring washer." Finally, elements 1.4, 17.4, and 18.5 recite that the spring washer "secure[s] the cartridge against movement with respect to the cartridge retaining member," while element 16.4 recites that the spring washer is secured against "displacement." As explained below, the combination teaches a "spring washer" as recited in the claims. EX1004, ¶120.

Burren teaches two embodiments of an injection pen having a spring element for securing container 5 against axial movement. EX1004, ¶121. In the first, Burren explains that spring 10, formed as a coil spring, is positioned between the container's proximal end and an insert 2 within housing 1, and "bridges a space left free between the container 5 and the insert 2 and biases the container 5 against the stop 4" in the distal direction. EX1006, ¶¶23-24, FIGS. 1-3. By biasing container 5 against stop 4, Burren teaches manufacturing tolerances associated with the parts are compensated. *Id.*, ¶¶3, 17; EX1004, ¶121. In a second embodiment, Burren again teaches an injection pen having spring 20, in the form of a spring bellows, which serves the same compensating function as spring 10: it biases container 5 against stop 4 in the distal direction. *See id.*, ¶¶31-34, FIG. 4; EX1004, ¶122. In both embodiments, the springs are "arranged within the housing," and, because the springs apply a biasing force in the longitudinal

direction, they are also "positioned axially within the housing." EX1004, ¶123. Moreover, based on the springs' compensating function, a POSA would have understood that the biasing force applied by the springs would "secure" the container against longitudinal movement and displacement relative to stop 4 or distal housing portion 1. *Id.*, ¶124. And, as recited in element 16.4, a POSA would have understood that, once the stop or distal housing portion was releasably secured to the housing, the container would push against the spring's distal end, causing the spring to compress. *Id.* A POSA would have understood this action to "load" the spring, which would, in turn, cause the spring to exert its biasing force. *Id.* Accordingly, Burren teaches a spring that is "load[ed]" by "releasably securing the cartridge retaining member to the housing" so as to "exert a force on the cartridge" to "secure the cartridge against movement [or displacement] with respect to the cartridge retaining member."

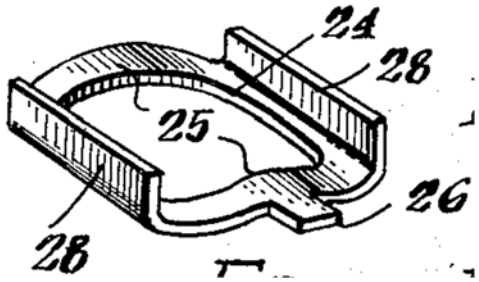
Although the compensating springs illustrated in Burren are a coil spring and a spring bellows, rather than a "spring washer," Burren expressly teaches that other spring types may be used, including a "leaf spring, ***plate spring, a spring with legs***, for example, or any suitable configuration." EX1006, ¶16 (emphasis added); EX1004, ¶125. Notably, a POSA would have understood a spring washer to be a type of plate spring. *Id.*

Venezia specifically describes use of a spring washer within a drug-delivery device to secure a component against axial movement. EX1004, ¶126. Venezia teaches a hypodermic syringe with an attachment for joining barrel 10 (analogous to a "cartridge") to plunger 15. EX1007, 1:15-17, 1:34-38, 1:56-2:5, FIGS. 1-2. As shown in FIG. 4, reproduced below, the attachment includes collar 20 (analogous to a "housing") having threaded flange 21 onto which flanged ring 22 (analogous to a "cartridge retaining member") is releasably mounted. *Id.*, 2:30-36, FIGS. 3-4. Flanged ring 22 receives flange 13 of the barrel and, when the flanged ring is threaded onto threaded flange 21, flange 13 is housed within collar 20. *Id.*, 2:33-37; EX1004, ¶126; *see also* EX1004, ¶80 (showing annotated FIG. 4).

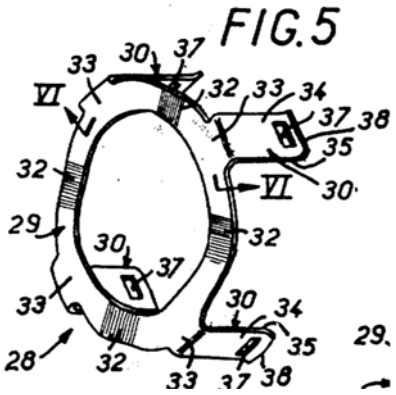


To prevent movement of barrel 10 within collar 20, a spring washer 24 is disposed between flange 13 and collar 20. *See id.*, 2:45-60, FIGS. 3-4, 6; EX1004, ¶127. As shown in FIG. 6 below, the washer has a circular body with "upwardly bulged zones 25, which yieldingly resist deformation...." *Id.*, 2:53-58. When ring

22 is threaded onto flange 21, flange 13 presses against bulged zones 25, "loading" the spring washer. *Id.*, 3:11-17; EX1004, ¶127. Zones 25, in turn, exert a biasing force on flange 13, which a POSA would have understood "secures" barrel 10 from moving or displacing with respect to ring 22. EX1004, ¶127.



In addition, De Gennes illustrates the common, predictable use of a spring washer to solve a similar problem: biasing components for axial fixation. EX1004, ¶128. In De Gennes' device (a clutch bearing), cover or connecting member 28 (shown below in FIG. 5) is formed as a spring washer having resilient, undulating support zones 32 that apply a biasing force against outer race 24 of drive element 11 to axially fasten (or "secure") operating element 10 with the drive element. EX1008, 4:1-8, 4:17-23, 4:45-51, 5:13-22, FIGS. 5, 15; EX1004, ¶128.



As explained in detail in section IX.C, a POSA would have found it obvious to replace the springs illustrated in Burren with a spring washer, like those taught by Venezia and De Gennes, to provide the same compensating function for securing a cartridge against movement within an injection pen. EX1004, ¶129. Accordingly, the combination teaches the recited "spring washer" of elements 1.4, 16.4, 17.4, and 18.5.

6. Elements 1.5, 16.5, 17.5, and 18.4

Harms	**Burren, Venezia, and De Gennes**
[1.5, 16.5, 17.5] wherein the spring washer has at least two fixing elements configured to axially and rotationally fix the spring washer relative to the housing.	"For supporting the spring 10 the insert 2 forms a shoulder surface pointing in the direction opposite the forward drive direction V, from which a flat base surrounded by the spring 10 projects in the forward drive direction V. The spring 10 can be connected to the insert 2, in particular in a friction contact, by means of the base and retained on the insert 2 thereby. Other suitable connection methods or structures may be used." EX1006, ¶23; *see also id.*, ¶24, FIGS. 1-3. "Not only does the positioning device 23 serve as an axial support, namely by means of its support surface 23a pointing in the distal direction, it also assumes the function of a retaining mechanism 23b by means of which the spring 20 is held in a latched or snap-fit connection with the proximal housing portion 3.... As a
[18.4] a spring washer comprising at least two fixing elements configured to fix the spring washer from movement with respect to the housing,	

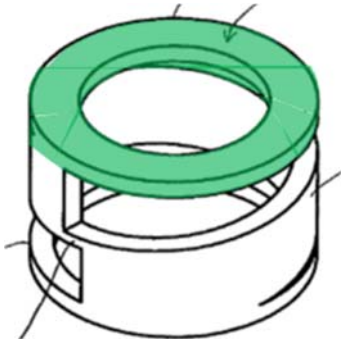
	result, the spring 20 is retained on the housing portion 3 on the one hand and is disposed so that it [cannot] rotate relative to the housing portion 3, on the other hand, i.e. is retained so that it is prevented from rotating." *Id.*, ¶33, FIG. 4. ***** "[Washer] Body 24 is also preferably provided with a tongue 26. The latter projects into an opening 27 formed in flange 21." EX1007, 2:63-65, FIGS. 3, 5-6. "The tongue of [body 24] extends through opening 27 to thus provide a spline and recess structure.... Under continued tightening, the bulged portions 25 will bear with increasing resistance against the end face of flange 13.... Body 24 may not turn because of tongue 26 preventing this. With finger-accommodating rings 29 projecting from opposite sides of collar 20, it is apparent that a complete attachment is furnished." *Id.*, 3:8-20. ***** "In the example illustrated, and as can best be seen in FIG. 5, the peripheral skirt 30 of the cover 28 is reduced to at least two legs or tabs 34 which extend axially from the transverse wall of the cover and which alternative circumferentially with gaps 35." EX1008, 4:25-29. "In the example illustrated in FIGS. 1 to 6, these legs are

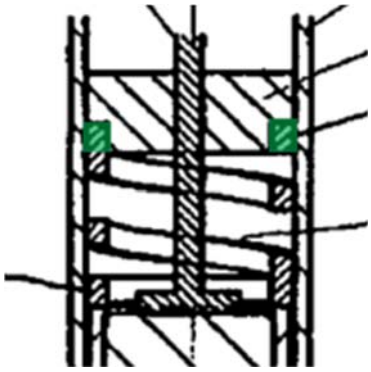
	four in number and are regularly distributed peripherally...so as to co-operate...with the corresponding fastening claw 20 formed by the free end of the corresponding radial extension of the rear reinforcement plate 15 associated with the flange 13. For this purpose each leg 34 of the cover 28 is provided near its free end with a cutout 37 adapted to engage over the corresponding fastening claw 20." *Id.*, 4:30-40; *see also id.*, 4:1-16, 4:55-5:12, 7:26-39, FIGS. 2, 4-5, 15.

Each of the claims recites that the spring washer includes "at least two fixing elements" for fixing the washer relative to the housing. For elements 1.5, 16.5, and 17.5, the fixing elements "axially and rotationally fix the spring washer," while for element 18.4, the fixing elements "fix the spring washer from movement." The combination of Burren, Venezia, and De Gennes teaches the fixing elements recited in the claims. EX1004, ¶131.

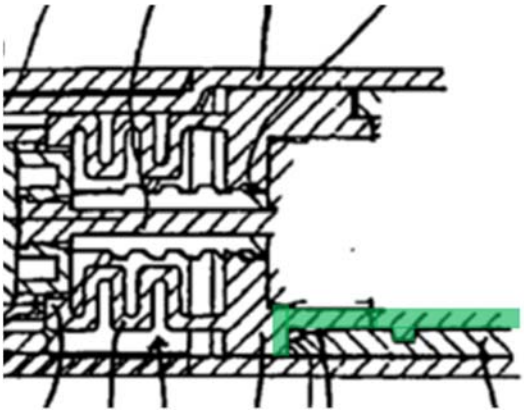
Burren generally teaches using fixing elements to axially and rotationally fix a spring element directly or indirectly to the housing. EX1004, ¶132. For example, spring 10 is indirectly fixed to the housing through insert 2, which includes an axially-extending "shoulder surface" at its distal end. EX1006, ¶23, FIG. 1. Positioning device 13, formed as a ring at the spring's proximal end, fictions-fits around the insert's shoulder surface, thereby retaining the spring on the insert. *Id.*,

¶¶23-24, FIGS. 2-3. This connection is illustrated in FIGS. 1 (right) and 3 (left) below, where positioning device 13 is annotated in green. EX1004, ¶132. Due to this retaining function, a POSA would have understood positioning device 13 to be a "fixing element" that fastens spring 10 indirectly to the housing, rotationally and axially fixing the spring relative to the housing. EX1004, ¶133.





Burren teaches another form of "fixing element" that rotationally and axially fixes a spring element directly to the housing. *See* EX1004, ¶134. In the second embodiment, spring 20 includes a positioning device 23 having retaining mechanism 23b, which holds the spring via "a latched or snap-fit connection with" proximal housing portion 3. EX1006, ¶33, FIG. 4; EX1004, ¶134 (explaining retaining mechanism 23b is "an outwardly projecting cam" that engages with "a recess in an internal face of the housing portion 3" to axially and rotationally fix the spring). This connection is illustrated in the partial view of FIG. 4 below, where positioning device 23 is annotated in green. EX1004, ¶134.

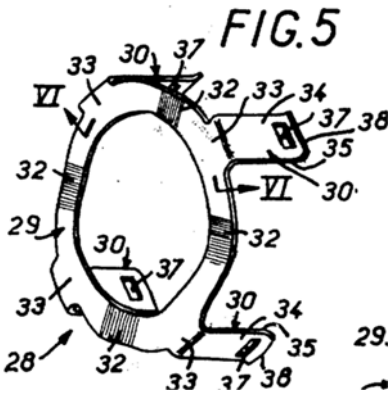


Although Burren illustrates springs having only one positioning device, or "fixing element," Burren expressly teaches that "[o]ther suitable connection methods or structures may be used." EX1006, ¶23. A POSA would have readily recognized that other connection methods or structures would include a spring washer having two or more fixing elements, such as those taught by Venezia and De Gennes, for fixing the washer directly or indirectly to the housing. EX1004, ¶135.

For example, Venezia teaches a "fixing element" in the form of radially-extending tongue 26, which projects into an opening formed in flange 21 of collar 20 and forms a "spline and recess structure" to fix, at least rotationally, washer 24 to collar 20. EX1007, 2:63-65, 3:8-10, 3:19-20, FIGS. 3, 5-6; EX1004, ¶136. As explained in more detail in section IX.C, a POSA would have understood this tongue to be a form of "fixing element" that would aid in installing a spring washer in Burren's device as a compensating spring. EX1004, ¶137. The POSA would have readily appreciated that this would be accomplished through, for example, a

slot-fit connection with the housing, resulting in both axial and rotational fixation of the spring washer relative to the housing. *Id.* Moreover, the POSA would have recognized the value of providing at least two tongues to prevent tilting of the spring washer during use. *Id.*; *infra*, §IX.C.

De Gennes is another example of known fixing elements a POSA would have recognized as beneficial for axially and rotationally fixing a spring washer in a Burren-type device. *See* EX1004, ¶138; *infra*, §IX.C. As shown in FIG. 5 below, in De Gennes's device, the spring washer includes at least two axially-extending legs 34, which snap-fit over corresponding fastening claws 20 provided on reinforcement plate 15. *See* EX1008, 4:11-16, 4:30-40, 4:55-5:12, FIGS. 2, 4; *see also id.*, 7:26-39, FIG. 15 (showing alternative bayonet-type fixing connection). As also explained more in section IX.C, a POSA would have understood the legs taught by De Gennes was another form of "fixing elements" that would successfully fix the spring washer to the housing in order to exert its biasing force on the cartridge. EX1004, ¶139. Professor Erdman explains that the POSA would have understood that the snap-fit connection illustrated in De Gennes was commonly used to fix components to one another and would have readily understood its applicability in fixing a similar spring washer within a drug-delivery device. *Id.* (citing EX1031).



For a possible means-plus-function interpretation, both Venezia and De Gennes teach the two structures identified by specification that perform the claimed fixing function of claims 1 and 16-18. EX1004, ¶¶140-41; *see also supra*, §VII. For the first structure—axially-extending legs that snap-fit onto corresponding protrusions secured to the housing—De Gennes teaches such a structure. FIG. 5 (above); EX1004, ¶141. The POSA would have understood that such a connection would axially and rotationally fix the spring washer to the housing in an injection pen like that of Burren's. *Id.*; *infra*, §IX.C. For the second structure—extensions that fit into a slot or opening secured to the housing—Venezia teaches the structure. EX1004, ¶141. The POSA also would have understood that this connection would axially and rotationally secure the spring washer to the housing of a Burren-type device. *Id.*; *infra*, §IX.C. Thus, to the extent the term "fixing elements" is construed under a means-plus-function interpretation, the combination teaches both corresponding structures identified in Harms that perform the same function claimed in the claims.

Accordingly, the combination teaches the claimed "at least two fixing elements."

7. Element 18.6

Element 18.6 recites that the fixing elements "allow axial loading of the spring washer when the cartridge retaining member is secured to the housing," which is language similar to that of element 16.4 ("releasably securing the cartridge retaining member to the housing, thereby loading the spring washer"). As explained above, by securing the cartridge-retaining member to the housing, the cartridge "loads" the spring washer, which, in turn, exerts the axial biasing force needed to secure the cartridge. *See supra*, §IX.A.5; EX1004, ¶144. Moreover, for the cartridge to load the spring washer, the POSA would have recognized that the spring washer must be fixed relative to the housing, which fixing elements like those of Venezia and De Gennes would accomplish. EX1004, ¶144; *see also infra*, §IX.C. Due to this fixation, the POSA would have understood that "the fixing elements allow axial loading of the spring washer when the spring washer is secured to the housing." EX1004, ¶144. The combination thus teaches element 18.6.

B. Claims 2-15

Each of the dependent claims depends, directly or indirectly, from claim 1. The references teach the limitations recited by the claims and render the claims obvious.

1. Claim 2

Claim 2 recites "the spring washer is biased so as to exert the force on the cartridge in the distal direction." The compensating springs of Burren bias (or exert a force on) the cartridge in the distal direction. EX1006, ¶¶17, 23, 30, FIGS. 1, 4; EX1004, ¶146. A POSA would have understood that a spring washer installed as a compensating spring in Burren's device should likewise exert a biasing force in the same direction to secure the cartridge against movement. EX1004, ¶146. Thus, the combination teaches claim 2.

2. Claim 3

Claim 3 recites "the spring washer is secured against axial movement with respect to the housing." As explained in sections IX.A.6 and IX.C, a POSA would have readily appreciated the need to use fixing elements to axially and rotationally fix the spring washer relative to the housing of Burren's device so that it could perform its compensating function. EX1004, ¶147. The POSA would have understood that this would "secure[] [the spring washer] against axial movement with respect to the housing." *Id.* Thus, the combination teaches claim 3.

3. Claim 4

Claim 4 recites that the drug-delivery device also includes "a piston rod for dispensing a dose of the drug from the device when the piston rod is driven in the distal direction." The spring washer also "comprises an opening" that is "arranged so as to allow the piston rod to run through the opening."

Burren further teaches the injection pen includes a driving mechanism having a driving member 8, formed by a plunger rod (a "piston rod"), that pushes a driving element 7, formed by a plunger, accommodated within container 5 in the distal direction, which dispenses medicine from the container. EX1006, ¶22, FIGS. 1, 4; EX1004, ¶148. Burren's springs include openings to allow for the plunger rod's axial movement during dose-dispensing. *See id.*, ¶26, FIGS. 2-3; EX1004, ¶149. The spring washers of Venezia and De Gennes have similar openings for accommodating components, *see, e.g.*, EX1007, 2:60-63, FIGS. 2, 5-6, EX1008, FIGS. 5, 15, and a POSA would have immediately recognized that these openings should be retained when incorporating similar spring washers into Burren's device to maintain the plunger rod's ability to distally displace the plunger during dose-dispensing. EX1004, ¶149. Thus, the combination teaches claim 4.

4. Claim 5

Claim 5 recites "the spring washer is curved in an axial direction." The spring washers of Venezia and De Gennes include curvatures that extend in an

axial direction, which a POSA would have understood that, when deflected, apply the spring washer's biasing force. *See, e.g.*, EX1007, 2:53-58, 3:15-17, FIG. 6; EX1008, 4:17-23, 4:45-51, 5 :35-36, FIGS. 5-6, EX1004, ¶151. The POSA also would have understood that the curvatures should be retained in a spring washer installed in Burren's device as these curvatures would be necessary for the spring washer to perform its compensating function. EX1004, ¶151. Thus, the combination teaches claim 5.

5. Claim 6

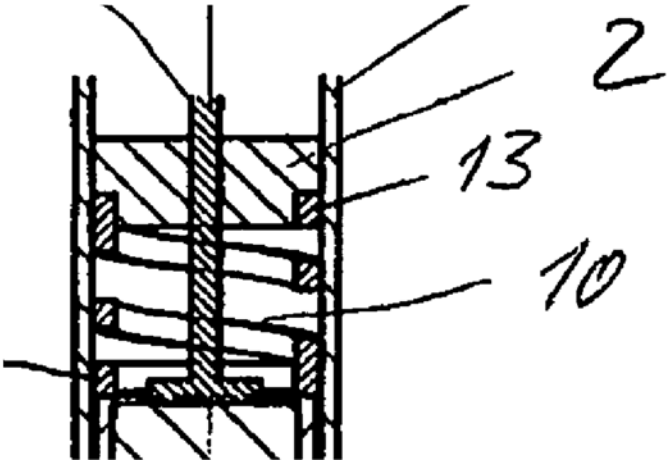
Claim 6 recites "the spring washer is a Belleville type washer." The POSA was well-aware of spring washers and their various types, including the commonly-used Belleville washer. *See* EX1020, 801-02, 854 (showing Belleville as exemplary spring washer, known in the art since 1867); *supra*, §§VI, VIII.A; EX1004, ¶152. Already familiar with the advantages and tradeoffs of using such a washer to axially secure components, the POSA would have viewed a Belleville washer as an appropriate spring washer that would successfully bias a cartridge within an injection pen and would have considered its use as a compensating spring to be predictable and well-known. *See, e.g.*, EX1020, 854-61 (describing Belleville washers as "extremely compact" and "capable of large push forces," making them ideal "where high loads over small deflections are needed in compact spaces"; further detailing design equations and force-deflection profiles); EX1023,

221-22 (Belleville design considerations and equations); EX1004, ¶¶152-53 (further noting Harms' reliance on POSA's common knowledge of Belleville-washer design and applications). Moreover, a POSA would have also sought to fix a Belleville washer using fixing elements like those taught by Venezia and De Gennes and would have predictably implemented such a design for the reasons discussed above. *See supra*, §§IX.A, IX.C; EX1004, ¶153. Accordingly, the combination suggests claim 6.

6. Claims 7-8

Each of claims 7-8 recites that the drug-delivery device also includes "a threaded sleeve member of the housing" to which the spring washer is fixed. Claim 8 recites that the threaded sleeve member is "fixed to the housing."

Burren teaches the pen includes an insert 2, which is fixed to housing 1 and axially guides plunger rod 8 during dose-dispensing. EX1006, ¶22, FIGS. 1, 4. As shown in the partial view of FIG. 1 below, insert 2 is a sleeve-like structure, which a POSA would have understood to be a "sleeve member." EX1004, ¶155.



Burren also teaches compensating springs that include "positioning devices" for fixing the spring relative to the housing. *See supra*, §IX.A.6; EX1004, ¶156. In the embodiment shown above, positioning device 13 friction-fits to insert 2 and retains spring 10 on the insert, which, in turn, indirectly fixes the spring to the housing. EX1006, ¶23, FIG. 1; EX1004, ¶156. Thus, Burren generally teaches a spring element that is "fixed to a...sleeve member of the housing," which is also "fixed to the housing." EX1004, ¶156.

Burren also contemplates "other suitable methods or structures" for connecting the spring element to the housing. *See* EX1006, ¶¶14, 23, 33, FIG. 4. The POSA would have readily understood that connection methods like those taught by Venezia and De Gennes could similarly fix a spring washer to the insert to act as a compensating spring. EX1004, ¶156. The POSA would have viewed those methods as predictable and readily-implemented mechanisms for attaching the washer. *See* EX1004, ¶156; *supra*, §§VIII.A, IX.A.6; *infra*, §IX.C.

Burren does not explicitly state whether insert 2 is "threaded," *see* EX1006, ¶22, but explains that plunger rod 8 may be driven during dose-dispensing using a threaded engagement with a component fixed relative to the housing, *id.*, ¶15; EX1004, ¶157. Although, in a specific example, that threaded component is compensating spring 20, *see id.*, ¶34, FIG. 4 (linking element 23c), the POSA would have appreciated Burren as at least suggesting that insert 2 may be the threaded component (a "threaded sleeve member") for guiding a threaded plunger rod during dose-dispensing. EX1004, ¶157. Indeed, Professor Erdman notes that such threaded "insert" structures were known and predictably implemented by those in the art at the relevant time. *Id.* (citing EX1032, 5:55-61, 7:30-35, 11:11-15, FIGS. 2, 7, 15-16). Accordingly, the combination teaches claims 7-8.

7. Claim 9

Claim 9 recites the fixing elements "comprise two oppositely disposed fixing elements which extend in the axial direction." De Gennes teaches a spring washer having at least two legs that axially extend from the washer's base. EX1008, 4:25-29, 5:3-4, FIGS. 5, 15. In the illustrated embodiments, the washer includes four legs evenly distributed so that a given leg is oppositely disposed from another. *Id.*, 5:30-32, FIG. 5. A POSA would have understood that this configuration—that is, at least a pair of axially-extending, oppositely-disposed legs—should be retained when fixing a spring washer in Burren's device because

doing so would stably support the spring washer within the housing. EX1004, ¶159; *see also supra*, §IX.C. Accordingly, the combination teaches claim 9.

8. Claim 10

Claim 10 recites the fixing elements "are further configured as positioning elements, which keep the spring washer in a determined orientation." A POSA would have understood that fixing elements like those taught by Venezia and Gennes would axially and rotationally fix a spring washer when installed within a Burren-type injection pen for compensating purposes. EX1004, ¶160; *see also supra*, §IX.A.6; *infra*, §IX.C. The POSA would have understood that this would also render the fixing elements "positioning elements" that "keep the spring washer in a determined orientation" within the housing. EX1004, ¶160; *cf.* EX1001, 5:44-53 (stating "fixing elements 52 may serve as positioning elements"). The combination thus teaches claim 10.

9. Claim 11

Claim 11 recites the drug-delivery device also includes "a further washer" that is "arranged on the proximal side of the spring washer." Each of the references discusses the use of only one spring element or washer to secure components within a device. Nevertheless, Burren expressly contemplates the use of "several spring elements or components" in a single drug-delivery device, EX1006, ¶16, and, as explained above, the practice of stacking two or more spring washers to

fine-tune the spring characteristics of a spring system was well-understood and predictably implemented by those in the art. EX1004, ¶161; *supra*, §VIII.A. Professor Erdman notes that spring 10 of Burren is similar to a stacked-washer system having a split washer (spring element 11) positioned between two disc washers (positioning devices 13, 14). EX1004, ¶161.

Given this knowledge, the POSA would have readily appreciated the beneficial use of, and would have known how to successfully implement, a "further washer" arranged on the proximal side of a spring washer fixed to Burren's device for securing a cartridge in order to, for example, establish a desired deflection profile of the spring washer over a given load range. EX1004, ¶162. For example, as explained in section VIII.A above, spring washers stacked in parallel were known to permit a greater load over a given deflection. *Id.* The POSA would have understood that this would be desirable for compensating purposes over small distances in order to axially hold the cartridge. *Id.* As also explained in section VIII.A above, the POSA would have known how to predictably implement a stacked spring system in a drug-delivery device. *Id.*

10. Claims 12-14

Claims 12-14 each depend from claim 11. Claim 12 recites the further washer "is a disk washer or a further spring washer having a higher strength as compared to the spring washer." Claims 13-14 recite the further washer is arranged

to "limit the loading distance of the spring washer" or "limit deformation of the spring washer to elastic deformation," respectively.

In fine-tuning the spring characteristics of a stacked system, those skilled in the art commonly included spring washers containing different strengths. *See supra*, §VIII.A; EX1004, ¶163. For a stacked system that compensates for length variances among cartridges used in an injection pen, the POSA would have recognized that a "further washer" arranged on the spring washer's proximal side would desirably have a higher strength than the spring washer because such an arrangement would provide a limit as to the amount of deformation the spring washer would undergo at higher loads, thus preserving the washer's elasticity during use and preventing washer failure due to the application of unnecessarily large loads. EX1004, ¶163. As a result, the POSA would have understood that the higher-strength "further washer" would be arranged to "limit the loading distance of the spring washer" to act as a "backstop" against failure. *Id.*, ¶164. Moreover, because the POSA would have been aware that any deformation of the spring washer should remain within its elastic range, or else washer failure would occur, the "further washer" would also be arranged to "limit deformation of the spring washer to elastic deformation." *Id.* Accordingly, the combination teaches claims 12-14.

11. Claim 15

Claim 15, which depends from claim 11, recites the further washer "is curved in an axial direction so as to correspond to a curvature of the spring washer." The POSA was aware of the common practice of stacking spring washers in series where the curvatures of each of the washers ran in the same direction or alternated in direction. EX1004, ¶165; *supra*, §VIII.A. Based on the spring characteristics desired, the POSA would have considered and predictably implemented a stacked system where the washers' curvatures corresponded to one another (*i.e.*, extended in the same direction). EX1004, ¶165. A POSA would have understood that this would correspond to a system stacked in parallel, which, as explained above, would have been understood to allow for greater loads over a smaller deflection, a characteristic that would have been viewed as desirable for compensating purposes in a drug-delivery device. *Id.* Thus, the combination teaches claim 15.

C. Rationale to combine

As explained above, Burren teaches each of the four primary components claimed by Harms, except a "spring washer" having "at least two fixing elements" for axially and rotationally fixing the washer relative to the housing. *See supra*, §§IX.A.5-6. Nevertheless, a POSA would have had reason to use (1) a spring washer as a compensating spring for securing a cartridge against axial movement

within a drug-delivery device like Burren's, and (2) at least two fixing elements to axially and rotationally fix the spring washer within the device. *Id.*, ¶¶77-94.

Regarding the first point, both Venezia and De Gennes demonstrate the well-understood and common use of a spring washer to accomplish a "compensating" function similar to that of Burren's device. *See id.*, ¶¶80-83. In Venezia's case, like Burren's device, the syringe includes four components analogous to those claimed by Harms: (1) collar 20 for internally housing proximal-end flange 13 of barrel 10; (2) barrel 10 for dispensing medicine from the syringe; (3) flanged ring 22 for retaining the barrel's flange within the collar; and (4) spring washer 24, fixed relative to the collar using radially-extending tongue 26, for biasing the flange against the ring to secure the barrel against movement. *See id.*, ¶¶80-82 (showing annotated FIG. 4 of Venezia) (citing EX1007, 1:15-17, 1:34-38, 2:30-65, 3:2-20, 3:37-42). Similarly, De Gennes further illustrates the ubiquitous and predictable use of spring washers to bias and fix components in mechanical systems. *Id.*, ¶83; *see also supra*, §VIII.A. Like Burren and Venezia, De Gennes seeks to address a similar problem—axially securing two components, a drive element and an operating element, relative to one another to prevent movement—and does so through the use of a spring washer to bias the drive element into abutting contact with the operating element. *Id.*, ¶83; *see also id.*, ¶73 (annotating analogous components shown in FIG. 2 of EX1008, in which spring

washer28 is highlighted green, drive element 11 is highlighted blue, and operating element 10 and reinforcement plate 15 are highlighted red). Thus, both Venezia and De Gennes demonstrate that a spring washer was a known biasing element capable of securing components within a device.

Moreover, while Burren illustrates a coil spring and a spring bellows as two examples of compensating springs, Burren expressly suggests that other spring types may be easily adapted to perform the same function, including a "plate spring," of which a spring washer was a known type. *See* EX1006, ¶16; EX1004, ¶85. And, as Professor Erdman explains, Burren suggests several design features that a POSA would have considered when designing a spring element for compensating purposes in an injection pen, including (1) short spring-path compactness, (2) even spring-force distribution, and (3) minimal sliding surfaces. EX1004, ¶85. Each of these considerations would have led a POSA to use a spring washer as a compensating spring in a Burren-type injection pen. *Id.*

For example, Burren teaches that only a short spring-path is needed when using a biasing element to compensate for length tolerances among cartridges. EX1006, ¶17 (stating only "1 to 3 mm is needed" and envisioning deflection of "at most 5 mm," or preferably, "at most 3 mm"); EX1004, ¶86. A POSA would have recognized that a spring washer was a known spring-type that could easily accommodate deflections of this length. EX1004, ¶86. And, in addition to

accommodating small variances, the POSA would have readily appreciated a follow-on benefit conferred by the spring washer: its compactness, which is an important and desirable feature in the manufacturing of injection pens like Burren's. *See* EX1004, ¶86; *supra*, §VIII.A.

Moreover, Burren identifies a desire that the spring element exerts a substantially uniform biasing force on the cartridge, and illustrates one means of accomplishing this by forming an end of the spring element as a "base disc." *See* EX1006, ¶¶30, 33, FIGS. 1-4; EX1004, ¶87. The POSA would have viewed this structure as analogous to the disc-like structure of a spring washer, *see, e.g.*, EX1007, FIG. 6, EX1008, FIGS. 5, 15, *supra*, §VIII.A, and would have understood that a spring washer would perform a similar, substantially-uniform biasing function. EX1004, ¶87.

Finally, Burren teaches a need to maintain minimal sliding contact between the spring element and other components within the device. *See* EX1006, ¶30 (explaining external surface of spring 10 "has a narrow sliding contact with the internal surface of the housing 1"); EX1004, ¶88. A POSA would have readily understood that, because of its compact size and overall shape, a spring washer would be suitable for minimizing undesirable friction-contact as the washer deflects. *See* EX1004, ¶88.

Accordingly, for at least the reasons identified above, a POSA would have had reason to use a spring washer as a compensating spring in a Burren-type device because the spring washer would, for example, be capable of deflecting the small distances needed to axially secure a drug cartridge while also maintain compactness of the device, apply a sufficiently uniform biasing force, and minimize sliding contact with other components. *Id.*, ¶89.

In addition, regarding the use of fixing elements, Burren similarly identifies several functions that would have suggested to the POSA to use fixing elements like those of Venezia and De Gennes to axially and rotationally fix the washer. EX1004, ¶90. These functions include: (1) to anchor the washer; (2) to prevent tilting; and (3) to minimize wear. *Id.*

Regarding anchoring, Burren explains the need to axially fix the spring element so that the spring's resilient force is generated when the cartridge is inserted into the device. *See* EX1006, ¶¶13-14, 23 (describing positioning device 13, which is prevented from axially moving by abutting against insert 2), 33 (describing positioning device 33, which includes snap-fit retaining mechanism 23b that anchors the spring); EX1004, ¶91. A POSA would have understood why this was the case: to exert its opposing biasing force against the cartridge, the spring must be prevented from moving axially away when the cartridge is pushed against it. EX1004, ¶91 (citing EX1006, ¶13, which teaches that the positioning

devices allow "a resilient force to be generated by the spring"); *see also supra*, §VIII.A.2. The POSA would have readily appreciated that the slot-fit feature of Venezia and the snap-fit connection of De Gennes would have accomplished this needed axial fixing in Burren's device. *Id.*

Burren also suggests fixing the spring element to "prevent any tilting forces." EX1006, ¶30. A POSA would have appreciated that any tilting of the spring washer would undesirably result in an uneven application of force on the cartridge. EX1004, ¶92. Thus, to prevent tilting, the POSA would have appreciated that the washer should be fixed evenly along its circumference such that any load applied would be evenly distributed. *Id.* Professor Erdman explains that, in Venezia's case, the POSA would have viewed its slot-fit configuration as providing sufficient support for the washer, but also would have recognized that at least a second tongue, equally spaced from the first tongue, should be provided to prevent tilting. *Id.* Moreover, with De Gennes, the POSA would have viewed its evenly-spaced, axially-extending legs as providing sufficient load-distribution support to mitigate any tilting. *Id.*

And, as noted above, Burren suggests minimizing moving contact between the spring and other components. *See* EX1006, ¶30; EX1004, ¶93. Those skilled in the art commonly viewed this consideration as an important feature to a device. EX1004, ¶93. By minimizing friction contact between components, the potential

for wear and subsequent failure of a component would be reduced. *Id.* A POSA would have recognized this was equally applicable to a spring washer installed in a Burren-type injection pen. *Id.* As a result, the POSA would have sought to not only prevent axial movement of the spring washer, but also rotational movement so that unnecessary frictional movement between the washer and the component to which it connects is prevented. *Id.* The POSA would have understood the slot-fit and snap-fit configurations of Venezia and De Gennes would achieve this type of axial and rotational fixation of the spring washer when incorporated into Burren's injection pen. *Id.* Accordingly, for at least these reasons, a POSA would have had reason to use at least two fixing elements like those of Venezia and De Gennes to axially and rotationally fix the spring washer relative to the housing of Burren's device. *Id.*, ¶94.

Finally, a POSA would have had a reasonable expectation of success in using spring washers having fixing elements like those of Venezia and De Gennes. *Id.*, ¶95.

The use of springs and their various functions in mechanical systems was well-understood by those in the art, and indeed, Burren confirms this understanding by describing the varied, known, and predictable use of springs in drug-delivery devices. *See* EX1006, ¶3 (describing use of springs as "driving," "returning," "compensating," or "supporting" springs); EX1004, ¶96. Although

Burren illustrates two specific examples of compensating springs and fixing features, Burren recognizes the skilled artisan's knowledge and ability to readily design and adapt spring elements and any fixing features to a given system according to desired characteristics to achieve the desired purpose (*e.g.*, axial securement). *See* EX1006, ¶¶16, 23 (envisioning "any suitable configuration" of spring and fixing features); EX1004, ¶96; *see also supra*, §§VI, VIII.A; *cf. In re Fox*, 471 F.2d 1405, 1407 (CCPA 1973) (appellant's specification "assumes anyone desiring to carry out the process would know of the equipment and techniques to be used, none being specifically described"). In view of the POSA's underlying skill, Professor Erdman explains that while Venezia and De Gennes show design features specific to their particular use of the spring washer, the POSA, with his own objectives related to using a compensating spring in a Burren-type device, would have readily appreciated the features that would need to be adapted or eliminated to successfully implement a spring-washer design in Burren's device. EX1004, ¶97 (addressing specific examples, such as Venezia's axially extending legs 28 or location of protruding tongue 26, or De Gennes' radial clearance J between legs 34 and drive element 11). Making such adaptions to device-specific washers was considered a routine task by those skilled in the art. *Id.*; *see also supra*, §§VI, VIII.A.

Similarly, while Burren suggests certain preferences for its injection pen, the POSA would not have been deterred from incorporating a spring washer into such a pen. *See* EX1004, ¶¶98-99. For example, while Burren suggests a benefit to using injection-molded plastic springs, the POSA would have recognized that the spring washer's material was simply one of finite options based on routine considerations, such as manufacturing capabilities and production needs. *See* EX1004, ¶98 (explaining benefits and trade-offs between injection-molded pieces and off-the-shelf components). Whatever material was chosen, the POSA would have known how to implement a successful spring-washer design, with the reasonable expectation that the washer would perform its known and predictable function: biasing the cartridge distally to secure it in place. *Id*; *see also supra*, §VI.

The same reasoning also applies to Burren's preference that the spring is replaced along with the cartridge after use. *See* EX1006, ¶29; EX1004, ¶99. That is, in addition to viewing spring replacement as an optional and routine consideration during the design process, the POSA would have known how to successfully implement a permanent or replaceable spring washer using fixing elements like those of Venezia and De Gennes, again expecting the washer would still perform its intended biasing function. *See* EX1004, ¶99 (providing design examples for permanent and replaceable spring washers in a Burren-type injection device); *see also supra*, §VI. Thus, given the above reasons, the POSA would have

had a reasonable expectation of success in using a spring washer having at least two fixing elements as a compensating spring in an injection pen like Burren's. *Id.*, ¶100.

The references thus render the claims obvious.

X. CONCLUSION

The challenged claims are unpatentable. Mylan respectfully requests that IPR be instituted.

Dated: 7 October 2019

/Richard Torczon/
Richard Torczon, Reg. No. 34,448
Counsel for Mylan

CERTIFICATION UNDER 37 C.F.R. §42.24(d)

I certify that the word count for this petition totals 13,165 words.

Dated: 7 October 2019

/Richard Torczon/
Richard Torczon, Reg. No. 34,448

PAYMENT OF FEES UNDER 37 C.F.R. §§42.15(a) AND 42.103

The required fees have been paid. If any additional fees are due at any time during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 23-2415.

LIST OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. RE47,614 - Michael Harms et al. (Issued 09/24/2019)
1002	File History of U.S. Patent RE47,614 (USSN 14/934,406)
1003	File History of USSN 13/123,530 (parent of 14/934,406)
1004	Expert Declaration of Arthur G. Erdman, Ph.D. in Support of Petition for *Inter Partes* Review of U.S. No. Patent RE47,614
1005	*Curriculum Vitae* of Arthur G. Erdman, Ph.D.
1006	U.S. Patent Application Publication No. 2007/0021718, "Plastic Spring" (Burren)
1007	U.S. Patent No. 2,882,901, "Control Syringe Assembly and Attachment" (Venezia)
1008	U.S. Patent No. 4,144,957, "Self-Centering Clutch Bearings" (De Gennes)
1009	U.S. Patent No. 6,648,859, "Disposable, Pre-Filled Drug Cartridge" (Bitdinger)
1010	GB Patent No. 743,839, "Improvements in Or Relating to Devices for Dispensing or Delivering Predetermined Quantities of Liquid from Cartridges or The Like Containers" (Schofield)
1011	U.S. Patent No. 5,279,585, "Medication Delivery Pen Having Improved Dose Delivery Features" (Balkwill)
1012	U.S. Patent No. 5,688,251, "Cartridge Loading and Priming Mechanism for a Pen Injector" (Chanoch)
1013	U.S. Patent No. 6,585,685, "Jet Injector Apparatus and Method" (Staylor)
1014	U.S. Patent Application Publication No. 2004/0035491, "Method and Apparatus for Needle-Less Injection with a Degassed Fluid (Castellano)

1015	U.S. Patent Publication No. 2002/0055734, "Ingestible Device" (Houzego)
1016	U.S. Patent No. 5,891,106, "Syringe" (Butuzov)
1017	U.S. Patent Publication No. 2005/0137571, "Administering Apparatus with a Resettable Activating Block" (Hommann)
1018	U.S. Patent Publication No. 2002/0052595, "Curved Clamp Arm Tissue Pad Attachment for Use with Ultrasonic Surgical Instruments" (Witt)
1019	U.S. Patent Publication No. 2008/0082082, "Surgical Fluid Transfer Apparatus" (Carlyon)
1020	Norton, Robert L. "Machine Design – An Integrated Approach", copyright 2000 Prentice-Hall, 2000 (16 pgs.)
1021	Juvinall, Robert C., et al. "Fundamentals of Machine Component Design", 4th Ed., copyright 2006 John Wiley & Sons, Inc., p.501-502
1022	Shigley-Mischke, "Mechanical Engineering Design", 6th Ed., copyright 2001 McGraw-Hill Ed., p. 678
1023	Spotts, M.F., "Design of Machine Elements", 5th Ed, copyright 1978 Prentice-Hall (6 pgs.)
1024	Chironis, Nicholas P., "Mechanisms & Mechanical Devices Sourcebook" copyright 1991 McGraw-Hill (3 pgs.)
1025	U.S. Patent No. 4,2376,947, "Roller Belleville Spring Damper" (Hebel)
1026	U.S. Patent No. 5,720,683, "Mechanical Chain Tensioner with Belleville Springs" (Patton)
1027	CN2317349Y (Translation), "Bolt Spring Washer with Mortise Cap" (Chen)
1028	U.S. Patent No. 3,233,497, "Spring Finger Retaining Rings" (McCormick)
1029	U.S. Patent No. 6,783,314, "Fastener Device" (Gattone)

1030	U.S Patent No. 8,348,905, “Device for Injecting Apportioned Doses of Liquid Drug” (Radmer)
1031	Snap-Fit Design Manual -Copyright 2007 BASF Corporation (p.24 pgs.)
1032	U.S. Patent No. 6,235,004, “Injection Syringe” (Steenfeldt-Jensen)

CERTIFICATE OF SERVICE

I certify that today this petition and Exhibits EX1001-EX1032 were served by *Priority Mail Express Delivery* on the Patent Owner's correspondence address of record for this patent as follows:

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Respectfully submitted,

Dated: 7 October 2019

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